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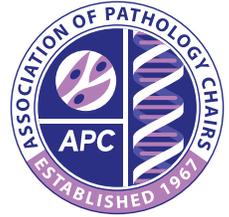
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Academic Pathology – Journal Scope and Purpose:

Extracted from the opening editorial, published in November 2014 - DOI: 10.1177/2374289514561001.

The decision to launch a new journal was borne out of the desire to give voice to the innovations in leadership and management of academic departments of pathology (in their entirety, including anatomic pathology, laboratory medicine, experimental pathology, etc). Although the field of medicine has been evolving continuously since its modern origins in the 19th century, the pace of change has accelerated in an extraordinary fashion. The modern structure of academic departments of pathology was established in the mid-20th century, coinciding with the growth of robust extramural funding for basic and clinical research and the convergence of anatomic pathology and laboratory medicine as specialty areas in academic pathology. Although the criteria for success of academic departments of pathology maintain continuity with those of the 20th century, the 21st-century models for health care delivery—and funding—require an almost completely new approach to establishing the sustaining value of academic pathology. In turn, academic departments of pathology have unprecedented opportunity to provide leadership in the transformation of our specialty in the 21st century. We seek these voices of leadership and change.

There is a strong call for leadership development and performance in medicine. To date, the discipline of academic pathology has been underrepresented in this discussion, although the need for such leadership is recognized. Articles relevant to the performance of the 3 missions of academic pathology are published both in pathology journals and elsewhere. Until now, however, a journal has not existed that specifically solicits articles addressing the operational and leadership challenges faced by academic departments of pathology. In creating this journal, we seek to cultivate scholarship in this arena and help disseminate innovation and best practices.

This is an open-access journal, and the intended audience for this journal reaches beyond academic pathology. It is precisely the innovative practices developed and assessed in academic departments of pathology that can help improve the performance of pathology and laboratory medicine throughout the industry. Moreover, pathology practice, education, and research have impact on the delivery of health care writ large. Hence, we hope that articles published in this journal will reach a national and international audience both within the field of pathology and beyond. In the latter case, health care providers, educators, researchers, and policy makers alike may benefit from articles published in Academic Pathology. We also consider that this journal should both welcome an international authorship and give consideration to articles of value to the worldwide practice of academic pathology.

This journal will publish original articles, reviews, case studies, and commentaries that address the core missions of academic departments of pathology. Contributions should reflect the best practices of pathology as a dynamic 21st-century discipline. All articles will be rigorously peer reviewed for relevance and quality. Priority will be given to articles that address any of the following:

1. methods or infrastructure that advance pathology and clinical laboratory practice quality and improve patient care including clinical informatics, genomic testing and data management, laboratory automation, electronic health record integration, and annotated biorepositories;
2. best practices in cost-effective multidisciplinary and/or interprofessional clinical partnerships that add demonstrated value to patient care;
3. new and effective pedagogical approaches to undergraduate and graduate medical education in pathology including curricula and practice settings designed to enhance resident and fellowship training;
4. evaluative methods for reaching objective teaching goals, such as competencies, milestones, and core entrustable professional activities;
5. models for training and sustaining academic pathologists, including clinician scientists in pathology;
6. methods for enhancing extramural support for basic, translational, and/or clinical outcomes research in pathology;
7. administrative and organizational models that best promote academic pathology's clinical, educational, and research missions;
8. business practices that advance the ability of academic pathology to serve its 3 missions, including access to regional or national markets, effective service to home institutions, and best practices in business and operational performance; and
9. leadership development in academic pathology, including the leadership role of academic pathology in academic medical centers and health systems.

Pathology is unique in bridging basic science with the practice of clinical medicine, across the totality of the human condition. Realizing our potential through innovation and execution of original ideas creates a potentially vast body of original scholarship. We challenge all leaders and participants in academic pathology to examine and rigorously report opportunities that could enhance our discipline. We invite you to submit such studies to Academic Pathology and help build the scholarly evidence base that will ensure the future success of both journal and discipline.

James M. Crawford, MD, PhD
Editor-in-Chief

TABLE OF CONTENTS



The Association of Departmental Quality Infrastructure and Positive Change: A Pathology Department Illustration	1
Evaluating Nonclinical Performance of the Academic Pathologist: A Comprehensive, Scalable, and Flexible System for Leadership Use.	8
A “Pathology Explanation Clinic (PEC)” for Patient-Centered Laboratory Medicine Test Results	15
The Continuing Fellowship Conundrum Trends in Pathology Graduate Medical Education Programs and Positions, 2001 to 2017	22
Trends in Pathology Graduate Medical Education Programs and Positions, 2001 to 2017	25
Outsourcing of Academic Clinical Laboratories: Experiences and Lessons From the Association of Pathology Chairs Laboratory Outsourcing Survey	31
Dealing With Deans and Academic Medical Center Leadership: Advice From Leaders	36
A Next-Generation Sequencing Primer—How Does It Work and What Can It Do?	43
The Pathology Workforce and Clinical Licensure: The Role of the PhD Clinical Laboratorian in the United States	54
The Evolution of Earned, Transparent, and Quantifiable Faculty Salary Compensation: The Johns Hopkins Pathology Experience	62
Development of Professionalism in Graduate Medical Education: A Case-Based Educational Approach From the College of American Pathologists’ Graduate Medical Education Committee	74
Quantification of the Effectiveness of a Residency Program Using the Resident In-Service Examination.	86
Impact of Daylight Saving Time on the Clinical Laboratory	91
When Pathology and Laboratory Medicine Becomes a Commodity and Health Care Becomes Both Its Customer and Owner	98
Evidence-Based Alignment of Pathology Residency With Practice: Methodology and General Consideration of Results	104
Report and Recommendations of the Association of Pathology Chairs’ Autopsy Working Group	115
A New Era in Pathology Consultation: The MyPathologist Electronic Consultation Tool	125



Activation and Utilization of an Electronic Health Record Patient Portal at an Academic Medical Center—Impact of Patient Demographics and Geographic Location	132
Benchmarking Subspecialty Practice in Academic Anatomic Pathology: The 2017 Association of Pathology Chairs Survey	141
A Professionalism and Mentoring Curriculum for Pathology Residents in Training	150
What Advice Current Pathology Chairs Seek From Former Chairs	157
The Legal Aspects of Diversity in Academic Pathology	161
Due Process in Medical Education: Legal Considerations	168
The Johns Hopkins Department of Pathology Novel Organizational Model: A 25-Year-Old Ongoing Experiment.	189
A Difficult Challenge for the Clinical Laboratory: Accessing and Interpreting Manufacturer Cross-Reactivity Data for Immunoassays Used in Urine Drug Testing	203
Impact of Daily Electronic Laboratory Alerting on Early Detection and Clinical Documentation of Acute Kidney Injury in Hospital Settings	213
Association of Pathology Chairs: Abstracts of the 2018 Annual Meeting: Educating Stakeholders on the Roles of Pathologists, July 15 to 19, 2018, Hotel del Coronado, San Diego, CA	223



The Association of Departmental Quality Infrastructure and Positive Change: A Pathology Department Illustration

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Abstract

A vertically and horizontally well-integrated quality improvement team is essential for effective quality data collection and implementation of improvement measures. We outline the quality structure of a large academic pathology department and describe successful projects across multiple divisions made possible by this tightly integrated structure. The physician vice chair for quality organizes departmental quality efforts and provides representation at the hospital level. The department has an independent continuous quality improvement unit and each laboratory of the department has a staff quality improvement representative. Faculty and staff experts have interacted to produce improvements such as accurate container labeling, efficient triage of specimens, and reduction of unnecessary testing. Specialized task forces such as the Courier Task Force are producing concrete recommendations for process improvement. All phases of pathology patient care are represented by faculty and staff who are trained in quality improvement, and each position touches and communicates actively with levels above and below itself. The key to the department's approach has been the daily attention to quality efforts in all of its activities and the close association of faculty and staff to accomplish the goals of greater efficiency, safety, and cost savings.

Keywords

infrastructure, laboratory, patient safety, quality assurance, quality improvement

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Introduction

The recent Institute of Medicine report “Improving Diagnosis in Health Care” points out the importance of pathology and the pathologist in fostering teamwork in the diagnostic process and in providing feedback on the quality of health care. The importance of benchmarks, dashboards, and improvement planning has long been well recognized by pathologists because of the regulatory requirements of the work and the service orientation of the discipline. For example, in the area of transfusion medicine, pathology has developed successful model systems of quality and safety. Though much of pathology does not involve direct contact with the patient, a model of a “physician client,” whose goals of care and satisfaction may be regarded as similar to those identified in direct care of a patient, has been highly useful in developing a robust quality environment.

Infrastructure is key to the implementation of quality improvement. In particular, a quality improvement team comprising of faculty and staff is essential to effective quality data collection and to the development and implementation of improvement measures. In addition, members of the pathology quality structure must learn from and interact with each other, other departmental quality programs, and report to

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Figure 1. Health system-wide quality improvement structure.

hospital-level quality leadership. Yet in many health systems, this quality structure is underdeveloped. In a previous paper, we have described the quality structure for Johns Hopkins Medicine (JHM), a large academic health system.¹ Here we outline the quality structure of a large academic pathology department at Johns Hopkins Hospital (JHH), detailing the parallel physician and staff involvement and interaction in making the structure successful. We then describe *key projects* which this integrated structure has made possible. Though in many hospitals the quality structure may not be as expansive or intricate as at JHH, the successful templates and methodologies described here may be utilized in many different structures and settings, in part or as a whole.

Hospital Quality Structure

In the quality improvement structure presented here, the hospital-wide quality improvement committee reports to the hospital medical board and the board of trustees and is currently chaired by a member of the department of medicine (Figure 1). This committee meets monthly and governs policy pertaining to clinical practice, monitors multiple quality indicators spanning clinical departments, and develops system-wide utilization reviews. Other quality committees with cross-departmental membership reporting to the hospital quality improvement committee include patient safety, service, and regulatory compliance.

It should be noted that while at JHH the title “director” is actually used for the head of the department, for clarity we will use the more general term “chair” and “vice chair” to avoid confusion with staff positions which are also referred to as directorships. To help nurture the departmental quality structures, the health system created a role of vice chair for quality for most departments.¹ The physician vice chairs for quality organize departmental quality efforts and provide

representation for each clinical department at the hospital quality improvement committee. Additionally, in this environment a special central organization entity, the Armstrong Institute, was created to coordinate quality efforts across the health system, deliver training, and foster scholarly work in patient safety and process improvement.

Pathology Department Quality Structure

The pathology department chair has appointed 5 physician vice chairs, including a vice-chair for quality, patient safety, and service (the other vice chairs include clinical affairs, education, personalized medicine, and research). While a separate physician advisor maintains jurisdiction over matters of faculty credentialing and training, the vice chair for quality interacts with day-to-day matters in the laboratories. Both physicians attend hospital-wide meetings and report through both the normal departmental chain of command and the hospital-wide quality structure. Most importantly, the vice chair for quality attends weekly core leadership meetings with the chair and other vice chairs, bringing a continuous improvement perspective to discussion of issues such as faculty recruiting and development, space utilization, and implementation of new technologies. The vice chair for quality also meets monthly with the vice chairs for quality from the other clinical departments and with hospital quality leaders.

Pathology Divisions and Functional Units

Anatomic and clinical pathology at JHH are divided into divisions, each of which has a physician head and a staff manager. Some large divisions are further subdivided into “functional units” for quality monitoring purposes (Figure 2). Each division or unit has a staff member quality improvement representative, which in the case of smaller units may also be the manager of the division. Areas which have independent staff quality representation include surgical pathology, core laboratory, immunology, transfusion, hemapheresis and microbiology. Smaller community affiliate hospitals within JHM each have a single quality representative who interacts with the larger JHM system. All quality improvement (QI) representatives system-wide meet monthly in person or on a conference call to review significant hospital reported events as well as other issues. This allows for shared expertise, a more uniform response to issues, and fosters a cross-pollination of ideas.

Pathology Clinical Quality Management Unit

In addition to the “in the trenches” unit quality managers, the department of pathology also has a separate and independent quality unit with a staff director of clinical quality management who is involved with all aspects of quality across the department. This staff leader supervises an independent pathology continuous quality improvement (PCQI) group of 6 individuals including 3 quality assurance (QA) specialists, 2 quality assurance technologists, and 1 administrative

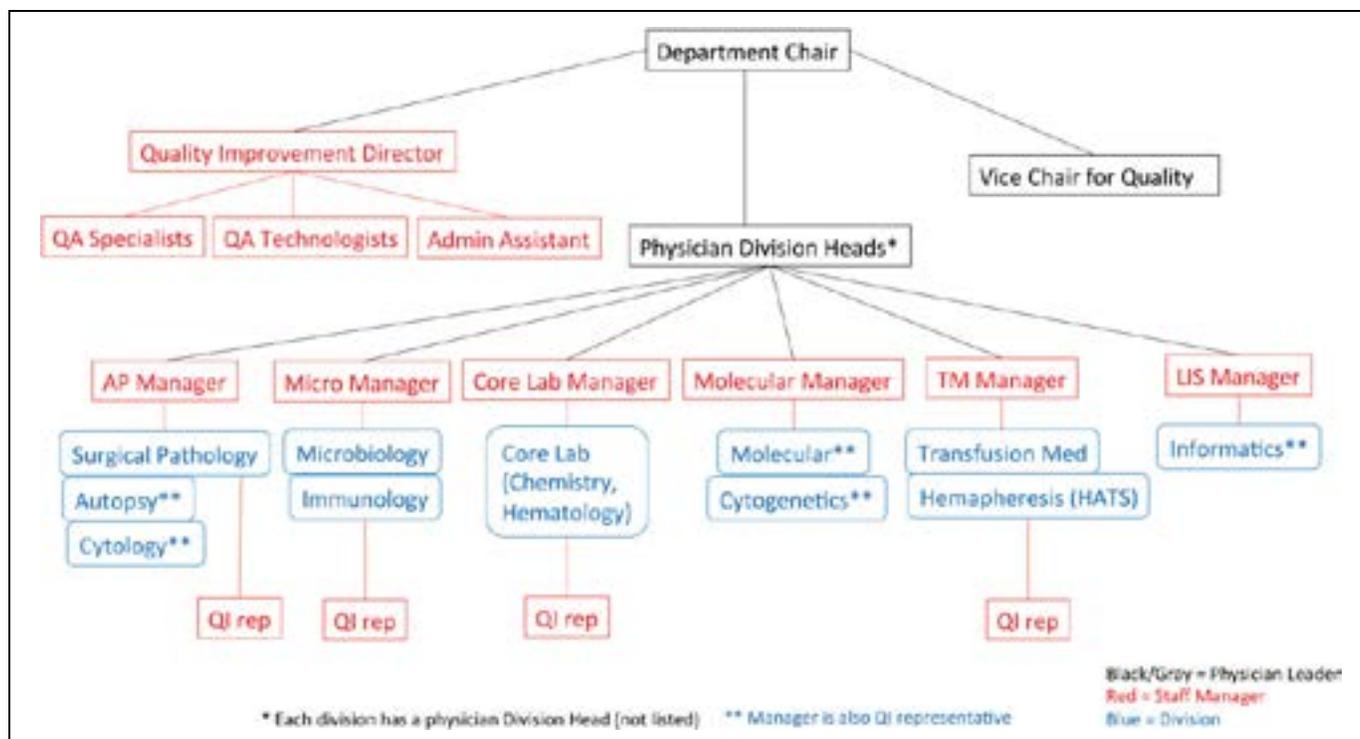


Figure 2. Pathology department quality improvement structure.

assistant. The PCQI staff are separate from the functional unit quality representatives.

Similar to the parallel way in which physician division heads (faculty) interact with divisional managers (staff), the vice chair for quality and the PCQI director work closely together on departmental quality matters, each bringing their unique perspectives to bear on quality problems confronting pathology. The PCQI provides support and oversight for such activities as federal and state regulatory requirements, accreditation inspections and requirements, proficiency testing and external quality assessment programs, laboratory health and safety, safety event reporting and data analysis, departmental performance indicator monitoring, emergency management, business continuity, process improvement activities, online document and policy control, and continuing education. The QI representatives from the PCQI office also liaise and facilitate process improvement activities between pathology and other clinical units, such as identifying and addressing training needs for those collecting laboratory samples and specimens. The PCQI staff also participate in many hospital-wide and departmental committees such as the emergency management committee, regulatory compliance committee, quality and safety clinical committee on policies, the laboratory advisory committee, and the pathology QA work group.

Departmental Performance Improvement Committee

The pathology department holds monthly performance improvement committee (PIC) meetings, chaired by the physician vice chair for quality, which includes QI representatives

and leadership from throughout the department, information technology (IT), financial staff, and invited visitors. This meeting agenda is structured utilizing 4 core functions: regulatory compliance, patient safety/risk, patient-centered care, and enhancing value. A work group meeting of QI representatives, chaired by the vice chair for quality (physician) and director for clinical quality (staff), is held in advance of this meeting to review all sentinel events and to examine trends including events with lower harm scores. A subset of these significant reported events is brought to the PIC meeting for review. Each functional unit gives a presentation at the PIC annually, providing an overview of the work they perform, challenges, and quality projects. This has enabled cross-pollination among diverse units and laboratories and contributed to discussion of positive as well as negative outcomes. The overall “fractal” structure (parts holding the same character as a whole), used throughout the JHM system quality structure, provides horizontal connections among divisions for peer learning and vertical connections for accountability.²

Results of Quality Structure: Patient Safety and Experience

An important example of the type of collaborative project enabled by the multilevel pathology department QI structure is the Courier Task Force assembled to address problems in critical specimen transit in the expanding health network, particularly for microbiology (Table 1). Although the Johns Hopkins Bayview Medical Center hospital was already a part of the JHM system, over time 3 additional affiliate hospitals (Howard

Table 1. Patient Safety and Experience Outcomes.

Item	Objective	Measures Implemented	Results
1	Improve TAT to within 4 hours for CSF specimens from affiliate hospital.	Additional courier runs added (Courier Task Force). Education on STAT couriers. Techs at affiliate institutions taught to read Gram stains.	Increase from 20%-30% to 80%-70% TAT within 4 hours. Working on telepathology Gram stain consultation.
2	Improve accurate labeling of primary and secondary reagent containers.	Online and in person education. Spot audits incorporated into regular safety walk-throughs.	98% compliance achieved in first half of 2017.
3	Ensure safety of outside visitors to autopsy.	Visitor policy established with HIPAA release. Personal protective equipment guidelines posted and reviewed.	30 visitors to autopsy with no adverse events.
4	Include molecular and cytogenetics in departmental monitoring.	The TAT for leukemia and prenatal diagnostic panels added to departmental dashboard.	12/12 months met target. 11/12 months met target.
5	Improve rapid assessment of diabetes.	STAT HgA _{1c} added to Emergency Department test panel.	Increase from <10% to 80% analyzed in 180 minutes.

Abbreviations: CSF, cerebrospinal fluid; HIPAA, Health Insurance Portability and Accountability Act; TAT, turnaround time.

County General Hospital, Suburban Hospital, and Sibley Memorial Hospital) were added to a large consolidated system ranging in distance from 4 to 42 miles from the main medical campus. Concerns arose about the impact of delays from these remote locations on the transportation of fragile specimens such as cerebrospinal fluid (CSF) and any impact that delayed entry of blood culture bottles might have on detection of bacteremia. For example, in May 2015, for Bayview, the mean time from collection to arrival in the JHH laboratory for blood cultures was 3.62 hours with a range from 48 minutes to 24.32 hours; while for the Howard County hospital, the mean time from collection to arrival at JHH was 5.39 hours with a range from 91 minutes to 18.97 hours. Satellite laboratories were found to be properly placing specimens for prompt pickup by couriers at this time and so delays did not appear to be created internally.

The departmental vice chair for quality chaired a Courier Task Force that consisted of 16 members including physician and staff laboratory directors, managers, supervisors, and customer service representatives with at least 1 member participating from each of the affiliate hospitals. Actual specimen transport data were manually collected from the Laboratory Information System (LIS), with microbiology selecting CSF for study due to the special sensitivity and manageable volume of specimens. Data show that both white blood cells and microbes in CSF deteriorate within a 4-hour period.³⁻⁵ Specific indicators to examine were determined in a collaborative “brainstorming” session by the task force and a 1-week time period of focused study was decided upon. Selected indicators for microbiology were collection date, collection time, receipt in sending lab, courier pickup and drop-off times, and microbiology received and plate time. Examination of the data revealed that in-laboratory processes were not creating delays from the satellite hospitals. Also, it was clear that delay in specimen pickup from certain of the outlying sites and long transit times also did not necessarily stem from greater geographic distances. The reason for the longer transit from some sites that were often actually closer was because couriers frequently made intervening pickups and routine runs to ancillary

clinics during specimen transportation, while carrying the more time-sensitive specimens from other hospital sites. It was also discovered that not all affiliate hospitals had the same number of courier runs.

After significant study and discussion, the primary recommendations made by the Courier Task Force were to (1) increase the courier pickups at Howard County General Hospital to match the number of times for Bayview Hospital, (2) encourage Suburban Hospital to request STAT couriers for sensitive specimens such as CSF, and (3) recommend regular hospital-only courier runs be instituted with no intervening pickups at other sites. After implementation of the task force recommendations, turnaround times for CSF specimens increased from 20% to 30% receipt within the target of 4 hours to 70% receipt within target.

Another significant opportunity for improvement was identified during interim self-inspections of multiple laboratory areas: accurate labeling of both primary and secondary containers. After discussion in the PIC group, an online and in-person education program on this topic was developed by staff within the core laboratory and disseminated to the different lab areas. Then, spot audits were incorporated into regular safety walk-throughs performed by the continuous quality improvement (CQI) office staff. As a result, 98% compliance was achieved in the first half of 2017.

A discussion of an incident involving a visitor fainting in a “brain cutting” educational session led to the discovery that there was no specific policy for tracking outside visitation to the autopsy suite. A policy was established guided by official Health Insurance Portability and Accountability Act (HIPAA) releases and an official visitor log was created. Guidelines for hydration requirements and use of proper personal protective equipment were developed, posted, and reviewed with the hosting neuropathology fellows. No further incidents occurred during 30 subsequent visitations to autopsy.

For the first time in the past year, quality measures for molecular pathology and cytogenetics were added to the departmental dashboard where previously these divisions had not been represented. Turnaround times of leukemia and

Table 2. Quality Performance and Value Outcomes.

Item	Objective	Measures Implemented	Results
1	Increase utility of report card measures and avoid multiyear repeats of achieved targets.	Graduated 2 to 3-year cycle of SMART measures.	Three new divisions participating; 11 of 15 measures for 2017. More improvement in measures monitored.
2	Ensure microbiology specimens for molecular testing are routed properly.	Restructured triage areas, workflow, and tracking methods for specimens.	Lost specimens reduced from several per day to none.
3	Enable sampling of fetal blood in labor and delivery.	Mobile hematology counting service created for monitoring of fetal blood.	Used 20 times in 2017 with highly positive comments.
4	Reduce use of nonsensitive or inappropriate stool parasitic testing.	Algorithmic approach to test ordering with prompts in EMR implemented. More sensitive nucleic acid testing used.	Testing volumes decreased from over 1000 to 200s and positivity rates increased from <2% to 5%.
5	Facilitate outreach between pathology and other departments.	Core laboratory participated in department of medicine annual nurses review.	Drop in uncollected specimens from department of medicine.

Abbreviations: EMR, electronic medical record; SMART, specific, measurable, attainable, and relevant.

prenatal diagnostic panels reached the target (over 95% resulted within 14 and 21 days) for 12 of 12 months and 11 of 12 months, respectively. Rapid assessment of diabetes was improved by the addition of a STAT hemoglobin A_{1c} (HgA_{1c}) to other tests available in the emergency department, resulting in an increase from less than 10% of specimens analyzed within 180 minutes to 80% analyzed within that time. Plans are in place to increase to continuous 24-hour availability for HgA_{1c} testing by the winter of 2017.

Results of Quality Structure: Quality Performance and Value

The pathology department maintains a “quality indicator report card” to monitor new departmental quality and safety initiatives and to process improvement activities (Table 2). The physician vice chair for quality and staff director for clinical quality recently examined all report card measures and determined that some measures were remaining on the report for multiple years after having met target while others were items that were not improvable by pathology department actions. Given this, a new policy was created to provide a standardized approach to metric development that included a checklist for labs to follow to ensure the metric met the required standards. This policy now includes a time line for the “lifetime” of a report card measure.

For quality indicators to be accepted for inclusion in the report card, they now must fulfill the following criteria:

- be identified under 1 of the 6 JHH strategic priorities,
- be an improvement opportunity to correct a defect, save money, or improve patient safety and/or service quality,
- be a new indicator (not present on the report card previously),
- be a previously presented indicator that:

- now has a tighter goal,
- has had significant changes to the indicator,
- is requested by hospital or departmental leadership to remain, or
- is moving from the improvement to the maintenance phase.
- follow the SMART goal format (specific, measurable, attainable, and relevant).⁶

Each indicator or metric is developed using a worksheet created by the PCQI office that provides laboratories and other units with guidelines and a framework to develop the metric. The report card is presented at the monthly departmental PIC meeting and the progress of each measure that is currently falling short of target is discussed with each area in a future-oriented nonpunitive manner. As a result of the new SMART measures, 3 new divisions have commenced report card monitoring and 11 of 15 measures for 2017 were added to the report card. Measures monitored have shown greater improvement through the year than previously.

A review of hospital reported adverse events revealed that microbiology specimens for molecular testing were not being routed properly and some specimens were being lost in transit, particularly from Bayview Hospital. In cooperation with a department-wide Specimen Loss Task Force, the microbiology division restructured the specimen triage area, instituted bar-coding for sample shipments, and created daily sample reports at Bayview for immediate follow-up on samples not resulted at JHH. These measures have reduced specimen misplacement from several per day to none.

Also in microbiology, innovations were made to reduce inappropriate use of parasitic stool testing. An algorithmic approach to test ordering was developed and launched, including prompts in the electronic medical record (EMR) with the assistance of IT staff and the simultaneous implementation of more sensitive nucleic acid testing. Testing volumes decreased from over 1000 per month to 100 to 200, while positivity rates

Table 3. Ongoing Quality Projects.

Item	Objective	Measures Implemented
1	In advance of new Laboratory Information System, evaluate processes in surgical pathology.	Task force formed including faculty cochairs, vice chair for quality, managers, and staff to study processes and workflow.
2	Increase efficiency and patient satisfaction in phlebotomy.	Service reorganized from individuals taking calls to zoned hospital system with specific technicians in designated areas and time intervals.
3	Encourage resident and fellow participation in quality activities.	New quality improvement/patient safety concentration instituted for 2017.

increased from less than 2% to 5%. This project met the dual goals of both cost savings and improved patient care. Finally, the core laboratory presented guidelines on specimen collection and labeling at the annual department of medicine nurses review. Along with other measures, this educational exposure has resulted in the reduction of “uncollected specimens” (specimens not logged into the EMR correctly and thus not able to be tested in the laboratory).

Discussion—The Future

Having an infrastructure that integrates physician and staff quality experts closely with functional units and with the hospital quality structure enables the swift identification of problems and harnesses cooperative knowledge to redirect efforts and implement change. New projects have been initiated from both the faculty and staff sides and the benefits from the close and continuous cross talk between participants of different levels are being realized (Table 3).

A Surgical Pathology Task Force to study the complex workflow of that unit has been assembled. It is chaired by 2 pathologists (1 a surgical pathologist) and includes the vice chair for quality and the staff director of CQI as well as managers and senior staff from all functional units in surgical pathology (accessioning, grossing, histology, immunohistochemistry) as well as a nurse liaison from the operating room. Thus far, workflows have been mapped and focus groups created for each pathway with the goal of identifying up to 3 or 4 major opportunities for change. The work of this task force is particularly important as anatomic pathology is anticipating adjusting to a new LIS in the next 3 years or so. Another recent initiative has been the reorganization of phlebotomy from individual laboratory technicians taking calls hospital-wide to a zoned approach with specific technicians in designated areas and draws at specified intervals. This has already reduced nighttime draws and shown a corresponding rise in patient satisfaction scores. Finally, as a part of department-wide efforts to involve residents in quality improvement, a new study

concentration has been created in quality improvement/patient safety that includes didactics, hospital meeting attendance, and a capstone thesis project for residents who choose to participate. The track will enable residents to contribute skills in quality improvement to future employment and to their own personal practice of medicine. Finally, participation of the pathology faculty in quality projects has been incentivized by assigning points that count toward a salary bonus and the vice chair has become a resource to guide the design of quality improvement projects. A yearly award for the best resident quality project has also been instituted with good response.

Innovative Features of the Program

There are 4 factors that differentiate the JHM quality improvement system from nearly any other in the country and produce the tight integration that is its hallmark. First, there is quality improvement leadership at the highest administrative levels of the hospital and these leaders actively guide and monitor system-wide policy, reporting to the board of trustees. Second, mirroring the actions of top hospital leadership, faculty-level vice chairs for quality (including pathology) act as quality leaders at the department level and bring considerations of process improvement to all discussions and decisions at that level, as well as carrying departmental priorities down to the staff committees who are in charge of implementation. Third, the department of pathology possesses a centralized continuous quality improvement office that functions as a full-time quality presence for the department, and fourth, the CQI office staff interact directly with functional unit quality staff in day-to-day operations. All phases of pathology patient care are covered by faculty and staff who are trained in quality improvement and each position touches and communicates actively with levels above and below itself. Though this type of complete full staffing is only possible with a certain level of resources, the approach of establishing key personnel at every level of work is one which can be adapted across settings. The key to JHH’s approach has been the daily integration of quality efforts with the ongoing work of the department and the close involvement of faculty and staff to the goals of greater efficiency and safety and cost savings.

Declaration of Conflicting Interests

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Evaluating Nonclinical Performance of the Academic Pathologist: A Comprehensive, Scalable, and Flexible System for Leadership Use

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Abstract

Academic pathologists perform clinical duties, as well as valuable nonclinical activities. Nonclinical activities may consist of research, teaching, and administrative management among many other important tasks. While clinical duties have many clear metrics to measure productivity, like the relative value units of Medicare reimbursement, nonclinical performance is often difficult to measure. Despite the difficulty of evaluating nonclinical activities, nonclinical productivity is used to determine promotion, funding, and inform professional evaluations of performance. In order to better evaluate the important nonclinical performance of academic pathologists, we present an evaluation system for leadership use. This system uses a Microsoft Excel workbook to provide academic pathologist respondents and reviewing leadership a transparent, easy-to-complete system that is both flexible and scalable. This system provides real-time feedback to academic pathologist respondents and a clear executive summary that allows for focused guidance of the respondent. This system may be adapted to fit practices of varying size, measure performance differently based on years of experience, and can work with many different institutional values.

Keywords

academic pathologist, guidance, nonclinical activity, practice leadership, promotion

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Introduction

Academic pathologists not only perform clinical work, most also have substantial activities beyond direct patient care. For this report, nonclinical work is any activity that does not directly impact individual patients and may consist of scholarly activities, like research, teaching, administrative, or professional academic activities. While numerous measures of clinical performance exist, such as the relative value units (RVUs) of Medicare reimbursement, there are few systematic measures of nonclinical performance.¹ Although nonclinical activities usually do not contribute directly to patient care or clinical income, they are integral to the academic pathologist's position and advancement and, as such, they have real value. Unfortunately, measurement of this value is difficult.² Only a few

studies exist which address methods of evaluation of nonclinical work by the academic pathologist. Each system uses different assumptions and methods to capture efforts in a quantifiable form. These evaluation systems serve 2 purposes: (1) to function as yardsticks of performance for members of an institution and (2) to make explicit the goals of an organization

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by translating abstract ideals into behaviors expected of individual members.^{3,4}

Evaluating clinical performance alone is insufficient for adequately appraising the performance of an academic pathologist.^{5,6} Decisions related to advancement in leadership roles, promotion, and tenure place significant emphasis on nonclinical activity. Despite its tremendous importance, there are few systems that adequately measure nonclinical performance. Often systems used by institutions have selected generic metrics for a “one size fits all” approach. An evaluation system that inadequately accounts for nonclinical activities may actually discourage scholarly activity by implicitly discouraging time spent on nonclinical activity.⁷ Positive outcomes, including increased physician satisfaction and increased utility, have been achieved with various methods related to continuing medical education.⁸ In addition, evaluation systems that have the capacity to recognize and reward the excellence of many diverse institutional members are stronger positive motivators than systems that simply reinforce the “elite performance” of a favored few.⁹ Therefore, a well-designed and balanced evaluation system can foster productivity of individuals as well as promote the aims of the institution.¹⁰⁻¹⁶

The method of evaluation itself should be understood by both respondent and supervisor. Transparency and clarity in evaluation systems will increase physician performance as subsequent evaluation cycles progress.¹⁷⁻¹⁹ Contrastingly, simply linking pay to academic performance does not have as clear a link to producing increased performance.^{20,21}

The format of measurement is important to the success of an evaluation system. Some systems measure units of time spent on various activities, reminiscent of RVUs, to monitor performance.²² These systems fail to establish substantive links between the reported information and real attending physician nonclinical productivity. Spent time does not equal valuable time. Time spent on research does not necessarily equate to valuable published literature. Such evaluation methods require meticulous, time-consuming, record keeping on the part of the academic pathologist. Detailed time-keeping systems may also be inaccurate due to conscious or unconscious misreporting.²³ In order to generate useful conclusions, a good evaluation system should be easy to complete from quantitative data readily at hand.

In 2009, our institution, Virginia Commonwealth University Health System, implemented a nonclinical performance review system, Faculty Activity Reporting and Evaluation System (FARES). This system requires multiple hours of preparation by the respondent as well as the supervising reviewer. It is used by all institutional physicians, regardless of specialization and therefore has very generic inputs. The FARES uses time in the form of hours per week averaged over a year to track activities. Due to the irregularity of academic pathologist schedules, alternating between clinical service, administration, educational activities, and research, the reported values were in fractions of hours per week, which was nonintuitive and required either guesstimates or extraordinarily meticulous record keeping. Additionally, it offered no immediate feedback to the

respondent who remained completely unaware of what level of performance review they might receive. While the form collected a large amount of information and had quantitative outputs, it was difficult to tell which pathologists were “good performers” according to the institutional and departmental missions and which pathologists were poor performers who needed growth in 1 or more specific areas.

Although our department used various additional metrics to evaluate individual achievement in academics, there was no formal, metric system. We developed a new format that addressed individual as well as group performance equitably with quantifiable metrics. This report describes this new method of evaluating nonclinical performance of academic pathologists that is easy to use and easily adaptable.

Materials and Methods

Presented herein is a simplified version of our institution’s evaluation. Categories and activities have been adjusted for clarity of presentation.

Microsoft Excel (from Microsoft Office 2013 for Windows; for Mac Version 15.35) was used to create an academic pathologist reporting form and a grading rubric on separate worksheets within the same workbook file. The grading rubric, containing the grading benchmarks, and activities in the form were generated by senior administrative faculty in conjunction with a review of the literature and took into account contractual job descriptions for the target faculty, the institutional mission, and criteria for promotion and advancement. The form was presented during a faculty meeting and was met with immediate buy-in due to its intuitive use by respondents, ease of result interpretation, and respect for individual career paths of the faculty being evaluated. This single file, containing both worksheets, was e-mailed to respondents by their supervisor. The rubric worksheet was protected from editing while the respondent worksheet allowed editing. Due to the inclusion of the grading rubric, the respondent was immediately aware of their performance as the form updated instantaneously. Upon completion, individual respondents forwarded this self-evaluation to their supervisor and each individual respondent worksheet was collated within a master Excel file and referred to a single common grading rubric worksheet allowing for simple indexing of respondents over time. The respondent form was paginated for clear printability and subsequent physical storage.

Each page of the form had separate activity categories for evaluation that were specifically designed for our institution. These were “Quality,” “Education,” “Scholarship,” “Administration,” and “Compensation Plan Thresholds.” Other institutions can adapt or replace these categories without compromise of the tool presented herein. Within each activity category, associated subcategories were created. For example, under the category “Education,” subcategories “Resident Education” and “Lectures” were established. These subcategories were assigned constitutive, discrete observable actions with associated point values. The respondents selected and entered the appropriate point value in the adjacent response

Evaluation	Quality		Education		Scholarship		Administration		Compensation Plan
	QualLESS	QualMORE	EducationLESS	EducationMORE	ScholarLESS	ScholarMORE	AdminLESS	AdminMORE	Comp
Needs Improvement	0	0	0	0	0	0	0	0	0
Needs Improvement	3	3	3	3	0	1	0	1	2
Satisfactory	4	4	4	4	1	3	1	2	3
Very Good	5	6	5	6	2	5	2	4	4
Excellent	7	7	7	7	3	6	3	5	5

LESS	Fewer than 5 years practice
MORE	Equal to or More than 5 years in practice

Figure 1. The grading rubric. This is an independent spreadsheet within the workbook containing the evaluation form. The physician’s responses will be compared against these values to determine performance. Four of the areas, “Quality,” “Education,” “Scholarship,” and “Administration,” are tiered for physicians practicing for greater or fewer than 5 years via the subcolumns within each category (eg, QualLESS for physicians practicing less than 5 years and QualMORE for physicians practicing more than 5 years). The “Compensation Plan” has the same thresholds of performance regardless of years in practice. More gradations for years in practice, or other practice styles, and other thresholds can be added easily. This spreadsheet within the workbook can also be locked to prevent editing by the respondent physician. The evaluation category of “needs improvement” is duplicated to define both the upper and lower boundaries of scores for this category for the technical necessity for the Excel INDEX and MATCH functions. This grading rubric is used in scoring the fictional respondent “Jane James” in Figures 2 and 3.

field commensurate with their level of activity in that subcategory. The response form summed these points for each activity category and displayed their level of performance in a summary field at the end of the form.

The levels of performance for each category were “needs improvement,” “satisfactory,” “very good,” and “excellent.” The point thresholds for these performance levels were set based on common clusters of behaviors, known to be attainable from previous evaluations systems, and deemed important by clinical and academic administration guidelines for our health system. The specific points assigned should be scaled for specific institutional concerns which is easily accomplishable with this tool. Two different grading schemes were used: 1 for pathologists who had practiced 5 years or fewer and 1 for pathologists in practice more than 5 years.

The primary Excel functions used in this form were INDEX, MATCH, and ERF. The nested INDEX and MATCH functions allowed for the completed respondent form to reference the grading rubric for the appropriate activity category accounting for the respondents’ years of practice and display the level of performance automatically. The ERF function is the Excel Gaussian error function which served 2 purposes in the visualization of the respondent’s overall performance. First, it mathematically normalized the scores between the different activity categories allowing for their symmetric and comparative display in a radar graph. Second, the ERF function accounted for the sigmoidal shape of the association between activity category raw scores and performance evaluation categories.

Results

This evaluation tool records and scores responding attending pathologist activities rather than time increments spent on activities. Completing this review takes approximately 10 minutes and the format and output are intuitive for both the reviewer and the respondent. A well-rounded respondent will

have a complete symmetric pentagon, whereas an asymmetric or incomplete pentagon indicates areas for improvement or more focused attention.

Importantly, the scoring of activities occurs on 2 levels. First, points are awarded for activities. The grouping of activities, the activities themselves, and the points awarded to various levels of participation in the activities may be adjusted to address departmental and/or institutional values. Second, the overall evaluation of a category (ie, research) receives a non-quantitative score (ie, very good) for an accumulation of points. Both of these activities may be adjusted by the institution or department for an individual pathologist (eg, a part-time faculty member) or an entire group of physicians (eg, division of anatomic Pathology or division of clinical pathology) to produce a sensible output.

The accrual of points in a category is linear, but the evaluation of accrued points within a category is sigmoidal. A sigmoidal function has a roughly linear central component buttressed by 2 planes. An attending pathologist can achieve excellence in many ways. Two pathologists might achieve excellence but using different methods. The topology of the ERF function and the manner of point accrual accepts the axiom that excellence is a multidimensional plateau that pathologists can explore with their careers. The ERF function was deployed to reflect this and normalize the scale between different categories of performance balancing the necessity of actionable conclusions for an evaluation and encourage diversity in academic pursuits.

Images from the (Figures 1–4) schematic grading rubric, form, and summary are included. The grading rubric shows the evaluation for the accrual of points for attending physicians in 2 tiers: less than 5 years of practice and more than 5 years of practice (Figure 1). Points were accrued via filling out the form which clearly depicts the number of points associated with each activity (Figure 2). Our institution’s actual form is not depicted here in order to clearly demonstrate the utility and function of

First Name Last Name Year in Practice	Year Points	Year Score	Scoring Criteria	Scoring Criteria	Year Score	Scoring Criteria	Year Score	Scoring Criteria	Year Score	Scoring Criteria
Jane James 3	Quality ONCO/AMC	2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
Jane James 3	Quality ONCO/AMC	2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
Jane James 3	Quality ONCO/AMC	2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4
		2	1. 100% AMO 2. 100% AMO 3. 100% AMO	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4	1	1-4 2-4 3-4 4-4

Figure 2. The complete, 3-page physician response form with sample data from a fictitious attending pathologist, "Jane James" who has been practicing for 3 years. The respondent selects the score commensurate with their activity level for each subcategory according to the rubric in Figure 1. Her executive summary is depicted in Figure 3, below. These activity point values can be adjusted independently of the grading rubric to allow for fine-tuning. The score for the categories is automatically tabulated. The form is paginated for easy printing for retention in physical files.

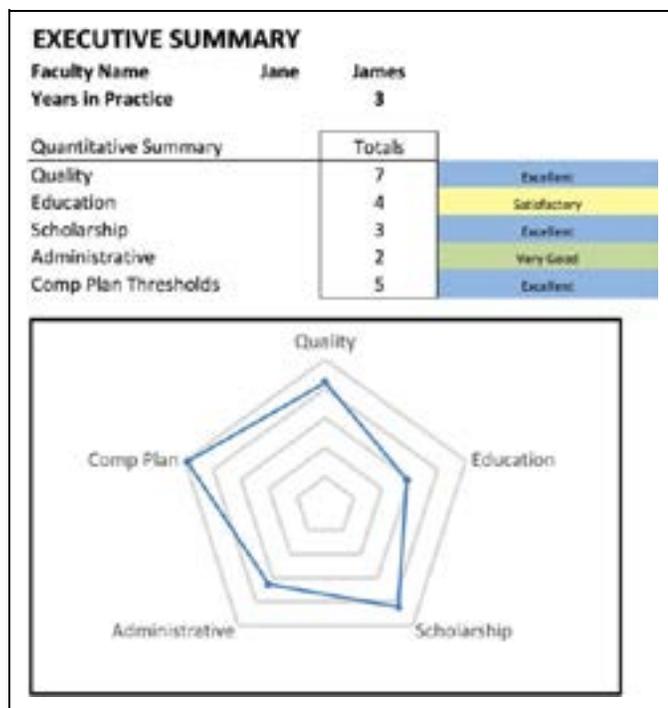


Figure 3. The summary of the individual physician's performance for the fictitious attending pathologist, "Jane James," continuing from Figure 2, who has been practicing for 3 years and is graded according to the rubric presented in Figure 1. It identifies the physician and their years in practice and summarizes their numerical scores, their evaluation, and demonstrates each of these dimensions graphically with a radar plot. The radar plot allows for rapid and multidimensional understanding of a physician's performance.

the tool. The activities in the form are sometimes mutually exclusive and not all activities must be performed in order to do well. For example, the "curriculum and development course" (Figure 2) at our institution is very time-consuming and not available to all faculty at all times. Therefore, "intent" to participate is valuable for both scheduling, and participation is valuable in terms of point accrual. These activities and their categories should be altered depending on the institution deploying the evaluation and the target respondent physician population. The dashboard executive summary summarizes the evaluation of the completed form under the grading scheme of the rubric (Figure 3). The form itself and executive summary were paginated for printing and physical storage. Finally, 3 years of noncumulative successive evaluation is overlaid for both a junior and senior faculty member to see progress and change with respect to their activities (Figure 4). These faculty are fictional and presented for schematic demonstration of the utility of this tool.

The terms deployed to summarize performance were skewed toward the positive. Three terms were overtly positive ("very good," "excellent," and "outstanding"), whereas one term was neutral ("satisfactory") and one was negative ("needs improvement"). This overall positive skewing of the category evaluations reflected an institutional desire for encouragement. This can be modified for deployment at other institutions.

Indeed, information can be extracted easily to provide other visualizations, like histograms or scatter plots. Faculty provided feedback after participating in the initial evaluation which resulted in several changes. These changes were easy to incorporate into the working system, taking only a few minutes. The evaluation system was then resubmitted to the physician respondents in a second deployment. The second deployment was uniformly approved by faculty in the time and effort it took to complete, as well as the value of activities it collected to evaluate.

Discussion

The desire for a new, more accurate evaluation tool arose from the multiplicity of critical comments from pathologists regarding the current system. The most common complaints were the length of time it took to complete and the relative inaccuracy of the calculations. Although the evaluation template was identical for all pathologists, the interpretation and calculations individuals used to self-report varied. As such, comparisons among pathologists or between specific groups were problematic. The new evaluation tool was specifically designed to be intuitive to complete and interpret. This tool is intended to result in a "dashboard" that allows the administrator to quickly sort through the numerous other evaluations, metrics, and products of academic physician activity. Due to this intuitive design and ease of completion, more than 1 response cycle can occur during a designated evaluation period, even before a final appraisal of the results. In our department, after initial construction, the form was provided to attending pathologists who completed their self-evaluation and forwarded to their supervisor. Comments and criticisms were then elicited from both respondents and supervisors. This feedback was incorporated in the context of the preliminary results and comments and the form adjusted. The faculty uniformly embraced the new system and their criticisms addressed adjustment of scoring for some areas and the inclusion of some activities. The new form was then redistributed to respondent pathologists and new results obtained. The responders reported no more than 20 minutes time spent for both response cycles, compared to the hours necessary for other evaluation tool previously used at our institution. The ease of response and refined clarity following incorporation of pertinent suggestions reassured responders that they had assisted in the development of a meaningful evaluation tool. They were more comfortable with the procedural aspects of the form and believed the subsequent evaluations were more accurate and comparable. The form also prompted productive conversations about resources, time, and goals on both the side of the institution and the individual pathology attendings.

Although the example presented herein is excerpted from our specifically designed form, this simplified format may be edited and repurposed for other institutions. The general categories as well as subcategories may be changed to suit the needs of the surveyor. In our version, "well-rounded" performance appeared as a symmetrical pentagon. The activities and categories will be altered to fit the institutional mission.

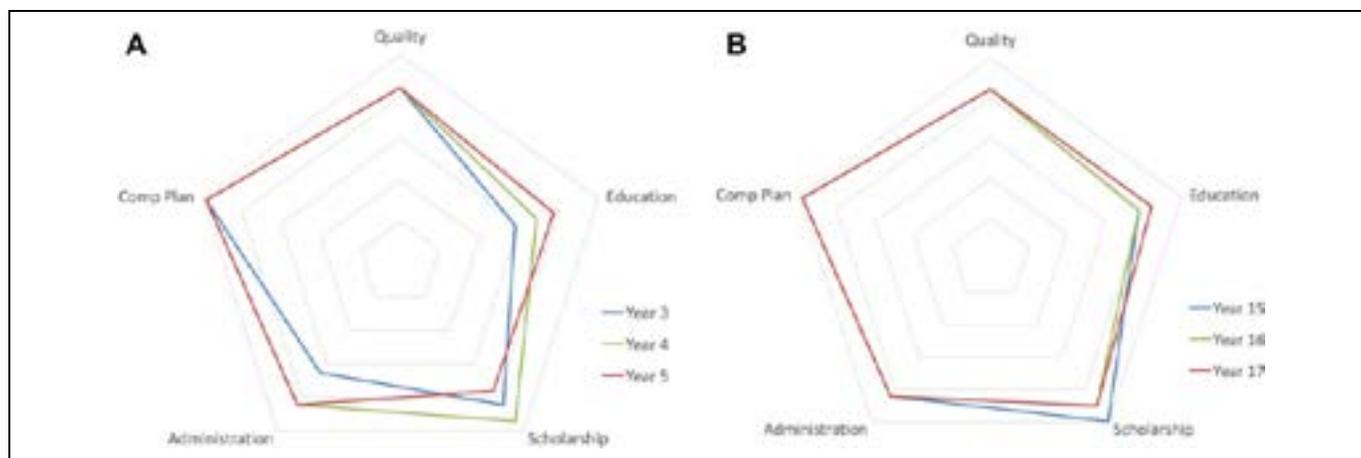


Figure 4. Two fictional physicians, a junior attending passing 5 years of practice (A) and an established senior attending (B) during 3 years of monitoring. The junior physician (A) has maintained their Compensation Plan and Quality performance and has acquired a new administrative role and educational duties. While this junior attending has increased their Scholarship during the third and fourth years, they have not maintained Scholarship performance as the thresholds evolved as they passed the milestone of 5 years of practice. In contrast, the senior physician (B) demonstrates relative stability during their 15th through 17th years of practice. This senior physician has acquired new education roles at the expense of their scholarship which has decreased since year 15. Specific guidance, with respect to focused performance, easily deduced from these depictions, despite their vastly differing stage in professional development.

However, this can be accomplished easily. The grading rubric is also easy to adjust for institutional thresholds (Figures 1 and 2). Though we selected grading nomenclature that was skewed toward positive feedback (very good and excellent) with only 1 neutral grade (satisfactory) and 1 grade with a negative connotation (needs improvement), this too can be changed to reflect different nomenclature or levels of achievement.

An additional positive feature of this evaluation tool is that both the evaluation form and linked grading rubric are provided to pathologist–responders. This means that responders can see in real time the effect their reporting of each item in the sub-categories has on their general category score and overall evaluation (Figure 3). In addition, the subcategories contain very specific metrics of achievement such that calculations are not required. Thus, inaccurate reporting is virtually nullified since these metrics are generally verifiable.

In general, our faculty performed “excellent” or “very good” in most categories. A good evaluation system should not simply reinforce what is already expected. A good evaluation system should uncover unexpected strengths to be nurtured and unearth weakness to be addressed. This tool made these outlier behaviors visible and allowed for quick indexing. The administration felt empowered to make specific recommendations to the evaluated physicians while appreciating the balance between the physician’s individual multidimensional interests and the institutional mission for the target physician respondent group.

Because of the flexibility of this system, different category scoring schemes are deployable for differing levels of experience (Figure 4). In our version, we wished to have a different grading scheme for junior (less than 5 years in practice) and senior pathologists since there are different levels of expectation for nonclinical activity between these 2 groups. Thus, both

junior and senior pathologists may receive a similar overall performance score of excellent but through very different metrics. The normalization steps provided by the ERF function and the establishment of tiered grading for differing years of practice allows pathologist progress to be tracked over time. The overall progression of an individual pathologist can be tracked throughout the years despite changes in expectations within the department or institution which may be implemented for attending pathologists based on their years of practice. Side-by-side or overlaid comparison of the summary pentagon is easily possible via Excel or simple comparison of the physical documents. In addition, the aforementioned INDEX and MATCH functions in Excel allow for as many tiers of practice experience as the administrator would wish to differentiate. Indeed, different grading schemes could easily be built in depending on different faculty work goals depending on individual contracts.

In summary, we present a new method of evaluating non-clinical performance of academic pathologists which captures observable activities in an auditable dashboard format, is intuitive and quick to complete, and has an easily understood immediate evaluation. This tool is flexible and scalable capturing specific, granular activities while providing a global perspective of a pathologist respondent.

Declaration of Conflicting Interests

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A “Pathology Explanation Clinic (PEC)” for Patient-Centered Laboratory Medicine Test Results

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Abstract

This concept paper addresses communication issues arising between physicians and their patients. To facilitate the communication of essential diagnostic pathology information to patients, and address their questions and concerns, we propose that “Pathology Explanation Clinics” be created. The Pathology Explanation Clinics would provide a channel for direct communications between pathologists and patients. Pathologists would receive special training as “Certified Pathologist Navigators” in preparation for this role. The goal of Pathology Explanation Clinics would be to help fill gaps in communication of information contained in laboratory reports to patients, further explain its relevance, and improve patient understanding of the meaning of such information and its impact on their health and health-care choices. Effort would be made to ensure that Certified Pathologist Navigators work within the overall coordination of care by the health-care team.

Keywords

communication, laboratory medicine, patient-centered care, Second Flexner Century, surgical pathology

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Introduction

This is the fifth in our series of Second Flexner Century papers on innovations in medical education and health-care delivery systems, published in *Academic Pathology*.^{1–4} Surgical pathology dates back to the early 20th century, but the major advances in immunohistochemistry, laboratory medicine, molecular diagnostics, pathology informatics, and personalized medicine have occurred in the last 40 years. However, in the words of Dr Edward O. Uthman, a “paraffin curtain” has been constructed between the pathologist and the patient, referring to the fixation of many surgical pathologists on rendering diagnoses on paraffin histopathology slides.⁵ Uthman was regretting that surgical pathologists rarely interact directly with patients. This does not mesh well with the emerging model of “patient-centered care” in which patients become integral to decision-making processes as members of their own

individual health-care teams. Nor need Uthman’s “paraffin curtain” metaphor apply exclusively to surgical pathology. Direct communication between patients and pathologists

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regarding the full spectrum of laboratory medicine test results is all too infrequent.

In this concept paper, aimed at expanding the role of pathologists in patient-centered care, we are proposing the broadening of the definition of “laboratory medicine,” making the term inclusive of all aspects of anatomic pathology, including surgical pathology in addition to what is currently defined as “laboratory medicine.” We envision the creation of Pathology Explanation Clinics (PECs) where discussing laboratory medicine test results with patients would involve “one-stop-shopping” including the integration of test results for the patients’ immediate consideration and appropriate conversations between patients and pathologists, along with relevant and necessary clarifications.⁶ We acknowledge that many practicing pathologists would require additional training in order to assume this role.

As clients of pathology services, physicians ordering diagnostic tests for their patients must grapple with the rapidly evolving diagnostic and therapeutic advances. They must continually realign, along with these advances in laboratory diagnostic technologies and medical imaging services, what they discuss with their patients. Newer models for health-care delivery could actually complicate a physician’s efforts to effectively communicate with the patient. Interdisciplinary care is now normative in the management of complex medical diseases, such as cancer. Individual members of teams, such as advanced practice nurses, might be unprepared to answer important questions about laboratory results coming from the patient within their own interdisciplinary care team.^{7,8} Electronic health records (EHRs) can add yet another layer of complexity to patient management. Increasingly, EHRs give patients direct access to their personal laboratory reports. Patients can bring up laboratory test results on their computers, including surgical pathology reports, and then contact laboratories directly to discuss their own test interpretations with a pathologist. However, they rarely do so. This concept article proposes an innovative approach to engaging pathologists in “patient-centered laboratory medicine.”⁹

Pathologist-to-Patient Communication Interventions

Since the year 2000, commentaries supporting direct pathologist-to-patient interactions have appeared sporadically in the literature.^{10,11} Currently, some patients seek out other trusted physicians for help in delineating, and deciding on, their health-care choices. In one study, women with breast cancer often consulted their primary care provider on a specialist’s diagnoses and treatment recommendations.¹² By participating in such discussions, pathologists could contribute valuable information to the patient about their laboratory reports, their diagnoses, how they were made, and the pathologist’s level of certainty in the diagnoses rendered. Potentially, knowing that information could help patients feel more confident accepting, and adhering to, their team’s treatment recommendations.



Figure 1. Organizational meeting of the “Sirmione Group,” at the lakeside resort city of Sirmione, in Northern Italy. Left to right: M. Sobrinho-Simões, MD; J. Rosai, MD (chair); R. J. Kurman, MD; F. Visinoni, Milestone Medical Inc., Bergamo, Italy (corporate sponsor); M. Dietel, MD; E. A. Montgomery, MD; R. S. Weinstein, MD; and J. I. Epstein, MD (see Table 1).

Recently, pilot pathologist-to-patient interventions have been described.^{13,14}

With respect to the question of sharing laboratory reports directly with patients, in studying patients’ personal understanding of their surgical pathology reports, Mossanen et al showed that “pathology reports are written at reading levels above the average reading capability of most Americans.”^{15(p1091)} They found that “deleting descriptive pathologic terms and replacing complex medical terminology with lay terms resulted in improved readability for some urologic oncology reports but complicated the readability for others.”^{15(p1091)} Another report by the same group was aimed at reworking urinary bladder surgical pathology reports so that patients could better understand them. The result was a significant improvement in patients’ ability to identify the stage and grade of their cancer and understand the clinical implications.¹⁶

Having personally observed the benefits of direct pathologist-to-patient communication in his own busy surgical pathology practice, Juan Rosai, MD, a leader in the surgical pathology field, organized an international meeting of pathology thought leaders at the lakeside resort community of Sirmione, in Northern Italy, from May 2 to 4, 2008 (Figure 1 and Table 1).

The challenge from the sponsoring organization, Milestone Medical Technologies, a laboratory equipment company headquartered in nearby Bergamo, Italy, was to “identify and address a major surgical pathology issue.”¹⁷ At the opening session, the attendees agreed that direct communication between patients and pathologists was a serious need. An outgrowth of the “Sirmione Group” meeting was the creation of an online patient resource, by Jonathan I. Epstein, MD, at Johns Hopkins Medical School in Baltimore, a member of the

Table 1. Invitees at the Sirmioni Group Meeting, May 2 to 4, 2008.

The Sirmione Group*		
Member	Institution	City/State/ Country
Juan Rosai, MD (Chair)	Centro Diagnostico Italiano	Milan, Italy
Manfred Dietel, MD	Institute of Pathology Charité Humboldt University of Medicine	Berlin, Germany
Jonathan I. Epstein, MD	The Johns Hopkins Medical Institutions	Baltimore, Maryland
Robert J. Kurman, MD	The Johns Hopkins Medical Institutions	Baltimore, Maryland
Elizabeth A. Montgomery, MD	The Johns Hopkins Medical Institutions	Baltimore, Maryland
Manuel Sobrinho- Simões, MD	University of Porto	Porto, Portugal
Ronald S. Weinstein, MD	The University of Arizona	Tucson, Arizona
Franco Visinoni (ad hoc member)	Milestone Medical Technologies	Bergamo, Italy

Meeting in Sirmione, Italy.

Sirmione Group. With the encouragement of the Sirmione Group, Epstein created a website entitled, “The FAQ (Frequently Asked Question) Initiative: Understanding Your Surgical Pathology Report.”¹⁸ The FAQs were developed by the Association of Directors of Anatomic and Surgical Pathology and have been endorsed by the College of American Pathologists. This Internet site is still active. It is maintained by the American Cancer Society as a public service for patients with cancer and their caregivers.¹⁸

Recently, The University of Arizona College of Medicine’s Department of Pathology followed up on the original Sirmione Group initiative, with the objective of further expediting direct pathologist-to-patient communication and increasing patient access to pathologist expertise. The Arizona group, inspired by the work of the Sirmione Group, but proceeding independently, compiled the set of “pathologist-to-patient” action items outlined in this concept paper (Table 2). Our intent is to seek input from, and partnerships with, pathology professional organizations, with the hope that the concept of a PEC can be validated through patient-centered outcomes research and then taken to scale in health-care delivery systems. Attention should also be given to advocating for specific pathologist-to-patient communication intervention billing codes (see Appendix B).

Communicating the Results of Surgical Pathology Reports to Patients

The communication of laboratory results directly to patients by experts will have its share of challenges, even in the new patient-centered care environment. In order to facilitate this level of pathologist-to-patient communication, we propose creating a specific category of specially trained laboratory test

Table 2. Pathologist-to-Patient Action Items to Enhance Access to Pathologist Expertise.

Patient-Centered Health Care (Pathologist–Patient Communications)	
Activity	References
A. Identify a need*	17,18
B. Create ACS “online/FAQ” website* [†]	17,18
C. Examine pathologist–surgeon–oncologist communication*	4,8
D. Explore pathologist–patient engagement and solutions*	10,11
Concept 1. Pathology Explanation Clinic [‡]	10,11,13,14
Concept 2. Certified Pathology Navigator (CPN) [‡]	-
E. CPN training and certification programs [‡]	-
F. Pilot program implementations ^{†,‡}	30,31
G. Validate with patient-centered outcomes research ^{‡,§}	28,29
H. Billing code reform ^{‡,‡}	24,25,26

Abbreviations: ACS, American Cancer Society; FAQ, frequently asked questions.

*The Sirmione Group.

[†]Johns Hopkins Medical Institutions.

[‡]The University of Arizona College of Medicine-Tucson.

[§]Appendix B: Funding for patient-centered outcomes research.

[‡]Appendix A: Pathologist payment models.

results-communicators, the so-called “Certified Pathologist Navigators (CPNs)” (see below). Clearly, not all pathologists would be interested in interacting directly with patients, nor would clinicians necessarily wish to share such responsibilities with pathologists. Those pathologists who are interested in being CPNs could opt into such programs and then train for the certification.

We envision that creation of this niche opportunity would include special training, extensive marketing of the concept on the part of organized pathology, and the proactive addressing of legal and regulatory issues that might emerge along the way. As for the participating pathologists, the training would be in such areas as interpersonal communication, cultural sensitivity, clinical medicine, standard and advanced therapeutics, statistics, precision medicine, population health, medical economics, and methodology for assessing patient health literacy.

Creation of Pathology Explanation Clinics

We propose that this practice model be called the “PEC.” For purposes of this introductory concept paper, we shall focus the discussion on how the PEC could be used for discussing a surgical pathology report with a patient, recognizing that this is one of a list of potential clinical applications. Another might be the discussion of results of genomic testing. In the surgical pathology example, a patient with a previous biopsy and its surgical pathology report would be provided with a handout, or the hyperlink to a website, that describes the PEC program. It offers instructions for an appointment at either a virtual PEC or a physical PEC location. The handout would explain the potential benefits and limitations of communicating directly with a pathologist. Alternatively, patients could learn about the

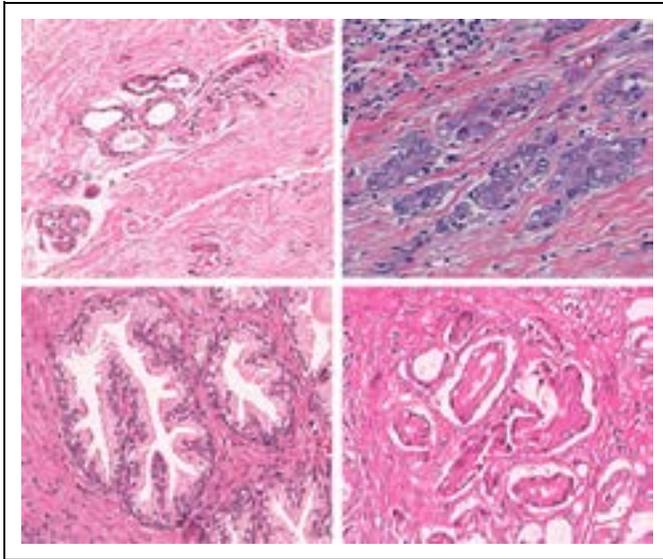


Figure 2. Atlas of medical images for both patients' supervised, or independent, study. Histopathology of benign and malignant human tissue. Upper left: Benign breast tissue in a 75-year-old woman. Upper right: Breast cancer. Lower left: Prostate gland, benign prostatic hyperplasia. Lower right: Adenocarcinoma of the prostate gland. Hematoxylin and eosin staining. $\times 20$ magnification. Whole-slide images (WSI).

PEC from an oncologist, oncologic surgeon, or their primary care provider or by word of mouth from a friend or family member. Initially, the PEC might be held one day a week, as are many subspecialty clinics in academic medical centers. For a PEC held at an academic medical center, glass histopathology slides or whole-slide images (WSI) would be retrieved for the pathology resident on service to examine, much as is done for tumor board conferences.¹⁹ Each PEC office will be equipped with a large video monitor for demonstrating the patient's WSI (Figure 2). This is included to provide patients with a frame of reference for the discussions, fully understanding that patients do not have previous experience with histopathology. Patients will also be provided with web-based instructional materials suitable for independent study.

Individual appointments would be 15 minutes to an hour in length, depending on the complexity of the case, the health literacy level of the patient, and level of interest of the patient in a discussion of their disease. We previously implemented some elements of the "PECs" in our "rapid breast care" clinics in Arizona.²⁰

For PEC sessions held at teaching hospitals, a resident pathologist or fellow would initially meet with patients and assess their interests, their understanding of common medical terminology, and then score their prior use of computers and the Internet for addressing personal health matters. The pathology case discussion would begin with a brief orientation on histopathology and WSI. The preselected WSI representing the biopsy from the case would be shared with the patient. Then, the resident would follow a script for talking points including: (1) steps taken to make the diagnosis, (2) whether the diagnosis

would be difficult to make and the level of certainty in the diagnosis, (3) the nature of the disease, (4) further testing needed to establish a definitive final diagnosis, and (5) implications of the biopsy results with regard to therapeutic options and prognosis. The discussion of these points, between the resident and the patient, might be videotaped for future reassessment by the staff pathologist. The pathology resident would then bring in an attending staff pathologist to answer any additional questions and ensure that all of the patient's questions have been answered adequately and accurately. Patient inquiries on treatment options, and their benefits and risks, could be referred to a "treating" physician if they are beyond the scope of expertise of the CPN. In cases where the patient has accompanying molecular diagnostics, those test results also would be explained in the context of the biopsy diagnosis. After the completion of the PEC visit with the patient, the CPN would write a brief EHR progress note summarizing the information covered with the patient and listing the recommendations and action plan.

In another version of a PEC clinic, the subspecialty pathologist CPN would be embedded into on-site clinics (ie, oncology clinics) during regular clinic hours. For example, at the head and neck oncology clinic held weekly at many academic medical centers, the subspecialty head and neck pathologist would be present at the clinic and see patients immediately after their pathology reports are provided to patients by their clinicians. This practice model eliminates the need for a separate PEC appointment, but it does not give patients time to adjust to their new diagnosis. The attendance of patients at the PEC appointment could be done virtually, with the patient, and the pathologist linked into sessions using bidirectional video conferencing. Video-enabled community tumor boards have been reported.²¹

Training Certified Pathology Navigators

At the Department of Pathology at The University of Arizona College of Medicine–Tucson, we are developing a training program for this new category of health worker, the "CPN." These CPNs will have special competencies for communicating directly with patients, regarding the interpretations and implications of their pathology reports.²² Initially, the CPNs would be boarded pathologists with additional training, through a certificate program, on communicating directly with patients. For purposes of creating the initial certificate program for the CPNs, we are assuming that the initial targeted interaction between a patient and the CPN will take place after the patient's primary care physician, oncologist, or surgeon has informed the patient of the results of their surgical pathology biopsy report. This timing is in deference to some patients' preferences for receiving "bad news" face-to-face with a physician or nurse in a physician's office, with no additional health professionals in the room.²³

We are in the process of developing the initial scripts, and visuals, to be followed and described by the CPNs during their appointments with the newly diagnosed patients with cancer

(Table 2). These scripts will be disease-specific (eg, breast cancer, prostate cancer, brain cancer, etc). In addition to discussing surgical pathology results, the scripts will include optional information on treatments and prognosis.

In seeking out the patient customers for the CPNs services, pathologists would be instructed to carry out this activity in the context of being an integral part of the interdisciplinary care team. After all, meeting with patients to discuss, and explain, a pathologic diagnosis is only one part of a patient's health-care experience.

Commentary and Summary

Patient-centered diagnostic pathology could open certain windows of opportunity for pathologists capable of performing additional communication functions that support direct patient care. The concept described in this paper is the PEC. In this model, pathologists would take responsibility for explaining laboratory findings, and their implications regarding therapies and prognosis, to patients often in greater detail and with the benefits of special expertise beyond that of a primary care provider. An enabling concept involves the creation of a new category of health-care service provider which we are calling "Certified Pathologist Navigators", or "CPNs." The CPNs would leverage their combination of patient communication skills and their mastery of diagnostic anatomic pathology and laboratory medicine. The CPNs would collaborate with the patients' primary care physician in recommending pathways for medical care. Ultimately, this initiative will depend on the demonstration of value of direct pathologist-patient interventions, in terms of patient outcomes and reduced health-care costs, as the health-care market moves from "volume to value" with regard to physician compensation.⁶

Appendix A

Payment Models for Face-to-Face Pathologist-to-Patient Consultations

At the time this paper is being written, no Medicare Current Procedural Terminology (CPT) code exists for billing a direct consultation between pathologists and patients. We acknowledge that the pathway to obtaining Medicare reimbursement for this service could be long, possibly convoluted, and time-consuming. It involves, at a minimum, pathology organization advocacy at the Centers for Medicare/Medicaid Services level. One option would be to initiate a new CPT code for pathologists to provide information and education directly to patients. A pathologist-patient education consultation, if tied to patient health literacy, could lend added legitimacy to the service. Nevertheless, this could be somewhat challenging as it is not customary for pathologists to interact directly with patients. Pathologist consultations, with the exception of some second opinion requests, have predominantly been conducted with other health-care providers. In fact, it is reasonable to expect that other providers might see a direct pathologist-patient

consultation as an intrusion into their domain. In addition, so do some pathologists, who might select this specialty with the understanding patient interaction would be minimal. Are there sufficient numbers of pathologists who would want to interact with patients on a more consistent basis? These are just some of the challenges in changing the current paradigm. On the other hand, much as primary care practitioners, through professional trade organizations like the American Academy of Family Physicians, successfully advocated for a CPT code to reimburse preventative medicine counseling on tobacco cessation and exercise, the College of American Pathologists and other pathology groups could advocate for a new pathology direct consultation CPT code to be created.

Another option might be to modify current CPT codes to include direct patient consultation. Currently, there are 2 clinical pathology consultation CPT codes, 80500 and 80502. CPT 80500 is a limited consultation that does not include a review of patient's history and medical records, whereas CPT 80502 is used for comprehensive consultation for a complex diagnostic problem that requires a review of the patient's history and medical records.²⁴ The patient's clinician must request the consultation, and the pathologist must render a medical opinion and report the findings. Typically, clinicians request consults for results of a previously performed test that are erroneous or out of the normal range.²⁴ Because CPT 80500 does not require the review of a patient's medical history and records, this code might not be appropriate for a rigorous or meaningful patient consultation. That leaves CPT 80502 as the most suitable code. The 2017 Medicare Reimbursement for CPT 80502 is US\$75.01.²⁵ Much like consultations in the evaluation and management section, this pathology consultation requires the 3 Rs: request from the treating clinician, rendering of a medical opinion by the pathologist, and report of the pathologist's findings.²⁶ If the requirement of clinician invitation were successfully managed and the interpretation of the 80502 codes could be expanded, PEC could likely satisfy the requirement of rendering medical opinions directly to the patient.

Also, it should be mentioned that another potential payment model already exists for direct pathologist-to-patient communications interventions. A cash payment model would allow pathologists to directly bill patients for their patient consultative services. This model is currently used when patients request a second opinion and insurance companies do not cover the service. Ultimately, it is incumbent on pathologists to demonstrate that patient counseling improves clinical care and patient outcomes in some meaningful way to justify reimbursement.

Appendix B

Potential Sources of Funding for Patient-Centered Outcome Research

Development and implementation of the PEC model would of course require a significant amount of fundamental research and work to validate its utility and impact on patient care and

outcomes. Efforts to involve patients more in their own care, to increase health literacy, and improve patient outcomes by tailoring medicine to the individual are increasingly being funded by federal (eg, National Institutes of Health, Agency for Healthcare Research and Quality, Department of Defense Medical Research and Materiel Command) and other grant agencies. In particular, the Patient-Centered Outcomes Research Institute (PCORI) is a relatively new, nonprofit, nongovernmental organization in Washington, DC. Funding for the PCORI was authorized by the US Congress in 2010.^{27,28} It could potentially be tapped for clinical research projects related to the “Patient-Centered Diagnostic Pathology” concept. The PCORI’s mandate is to improve the quality and relevance of information available to help patients, caregivers, insurers, and policy makers render better informed health-care decisions. Focusing the adequacy and suitability of communication at the patient-to-pathologist interface might fall within the PCORI mission. We can envision how funding from any of these agencies might be applicable to the study of issues regarding best practices in helping patients understand the content and ramifications of their laboratory reports. The University of Arizona Department of Pathology, which houses the state-wide multi-specialty Arizona Telemedicine Program, has been partially supported by a PCORI grant which funds a study on the use of telehealth to instruct colostomy and urostomy patients on the management of their ostomies.²⁹

Authors’ Note

The Sirmione Group Meeting, May 2 to 4, 2008, was sponsored by Milestone Medical Inc., a laboratory equipment company headquartered in Bergamo, Italy. The company president, Franco Visinoni, participated in the initial session and the closing session of this 5-day meeting.

Declaration of Conflicting Interests

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The Continuing Fellowship Conundrum

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Keywords

ethics, fellowship, honor code, medical education, professionalism

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Introduction

The debate for a fair, equitable, and reasonable pathology fellowship application and selection process has been an ongoing issue with ebb and flow over approximately the past 10 years. The authors of this commentary have been closely involved with the fellowship issue over the past decade and have been part of the effort to achieve a workable solution with widespread support. Possible solutions to the concerns raised by various parties have included efforts to implement a uniform timeline, a formal match through the National Resident Matching Program (NRMP), a formal match through the San Francisco Matching Program, and most recently (and the focus of this commentary) a Code of Conduct (Honor Code) and application clearing house overseen by the Association of Pathology Chairs (APC). Table 1 summarizes these efforts and their outcomes to date.

Resident dissatisfaction with the fellowship application process seemed to peak in the mid-2000s when the College of American Pathologists (CAP) Resident Forum and its Executive Committee put forward its concerns and voiced support for, and approval of, a “unified” or “common” application form. The intent was that this common application would be accepted by training programs around the country. A suggested time line for the application process was also approved at that time.^{1,2} This idea was examined and championed by the APC in the 2007 to 2010 time frame. Association of Pathology Chairs and Pathology Program Directors Section of the APC (PRODS) recognized the serious issues ingrained in the fellowship application process and dedicated resources to further explore these issues and concerns and to examine a possible move toward a match.²

Potential Solutions and the Fellowship Directors Ad Hoc Committee

Other medical subspecialties, when faced with similar fellowship application concerns, had successfully implemented a fellowship match through the NRMP. To evaluate the probability of a pathology fellowship match, the APC utilized surveys to identify subspecialties willing to be “first in line” for fellowship match implementation. It rapidly became apparent that the NRMP requirement for a time line more proximal to the fellowship matriculation date and the requirement for a high percentage of programs to agree to participate would be major hurdles. Only 2 subspecialties demonstrated a sufficient positive response to warrant pursuit of a match, and ultimately both felt that participation in a match would place them at a significant disadvantage relative to other subspecialties and nonparticipating programs. Discussion of the benefits and need for a match at the CAP Residents Forum also demonstrated that resident support for a match was not universally held. Many residents felt that being able to apply and accept positions outside the match helped them to accept multiple fellowships, to better plan for future moves, and to better support their lives outside

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Table 1. Potential Solutions and Outcomes to the Pathology Fellowship Conundrum.

Possible Solutions	Outcomes to Date
1. Voluntary adherence by programs to a uniform application and offer time line	1. Compliance has not been uniform
2. Voluntary adherence by programs to not pressure applicants into making “snap” decisions	2. Compliance has not been uniform
3. Voluntary adherence by applicants to abide by commitments made to a fellowship program	3. As noted in the text, last minute openings continue to be a problem
4. Formal fellowship match process (eg, NRMP or San Francisco Match)	4. Consensus among program directors and applicants have not supported a formal match process
5. Voluntary adherence by programs and applicants to an honor code with data collected by the APC and made available to programs and residents	5. No data to date, has not been tried

Abbreviations: APC, Association of Pathology Chairs; NRMP, National Resident Matching Program.

of graduate medical education. Subsequently, surveys of residents completing their in-service examinations through the American Society of Clinical Pathology (ASCP) saw a drop in trainees’ interest for a formal match process,^{3,4} even while interest in a uniform time line, common application, and a process that did not pressure applicants to immediately accept positions at the conclusion of their interviews was maintained. Needless to say, implementation of a matching process through the American Association of Medical Colleges and the NRMP did not succeed.

Both APC and PRODS continued to have serious concerns regarding the fellowship application process and to explore other means to effect change that might garner support and approval from all stakeholders (Table 1).^{2,5} In the spring of 2013, the APC formed a Fellowship Directors Ad Hoc Committee (FDAHC) with representatives from each of the boarded pathology fellowship subspecialties (and including surgical pathology), with the intent that the members would work through their respective subspecialty societies to effect change in the fellowship application process. A move to investigate the San Francisco Matching Program was made, and due to its increased flexibility relative to the NRMP, it garnered some interest and traction, with the dermatopathology fellowship program directors planning to “take the plunge” no later than 2020. The future viability of the San Francisco Matching Program to be the vehicle for a “pan-pathology” match across all subspecialties is unclear at this point in time.

The lack of a meaningful, structured fellowship application process and time line continues, and anecdotally, the same

ongoing issues continue to plague both residents and program directors.^{1,2,5} The push for earlier and earlier decision-making by residents and fellowship programs continue, with decisions not infrequently occurring in the resident’s PGY1 or early PGY2 year of training. These early decisions preclude, in many cases, significant exposure to some of the subspecialty areas with the greatest need for a pipeline to bolster their pathologist workforce, for example, pediatric pathology, neuropathology, blood banking/transfusion medicine, and forensic pathology. Thus, it is not surprising that the current state manifests itself in increased numbers of programs with the dreaded “unexpected fellowship opening” for the upcoming academic year, and not uncommonly in the month or two before the fellowship program’s matriculation date. Data presented at the July 2017 APC Annual Meeting, based on a review of unexpected fellowship openings posted on the PRODS list serve, demonstrated that 70 discrete fellowship positions were posted in the 2016 calendar year, with 17 of those postings occurring between January and March 2016 and 9 of those postings occurring between April and June 2016 for a July 2016 matriculation date.⁶ Programs throughout the country were adversely impacted.

A Proposed Honor Code

In light of this history and the fact that little has changed (Table 1), and perhaps even worsened, the FDAHC of the APC has developed a voluntary Honor Code for fellowship applicants and program directors (available online under Supplemental Material). In addition, the FDAHC has also proposed the establishment of a “clearing house” for available and filled positions. The clearing house would be a current, updated listing with information input from the fellowship program directors and would be maintained by the APC. Clearing house data would be available to candidates and programs in a timely manner. A platform to accomplish this has already been developed by the APC. These proposed ideas have been presented to PRODS at APC, to the ASCP Residents Council, and to the CAP Residents Forum in 2017. The Honor Code would be applied to both applicants and programs and would be put into place for those looking for positions no sooner than 2019 (as many programs have already selected candidates under the current system). The intent is to gradually move toward a common time line.

The beauty of a formal match process, such as the NRMP program, is not only the speed in which the process is done, allowing for the programs to enroll new trainees months before matriculation rather than years, but in the fact that there are penalties associated with withdrawal. To date, such a process does not exist with pathology fellowships, and the lack of penalties is perceived to be a weakness inherent in the enforceability and wide adoption of the Honor Code and clearing house concepts, even though there are clear-cut benefits for their adoption from both the applicant and program perspectives.

Individual lives change, along with the needs of families, and geographic limitations are part of the complex nature of the

fellowship decision-making process. With such a long time lag between selection and implementation of a contract, requiring someone to honor a contract after they have been exposed to a subspecialty they perceive as much more desirable or after their life circumstances have changed affecting their geographic and life style requirements is a recipe for disaster. Residents who feel forced to move to a location now deemed unattractive, or forced to complete a fellowship they now perceive as undesirable, cannot be expected to “do their best” and positively represent their training program. Therefore, a process which tightens (ie, shortens) the time line and allows individuals to experience all of the potential subspecialties through their PGY3 year of training in combined Anatomic and Clinical Pathology (AP/CP) or PGY2 year of training (AP- or CP-only) without forcing an early commitment is the one aspect of proposals for change in the fellowship application process that seems to be consistently supported^{1,2,5} and which is potentially achievable with or without a formal match process, as long as fellowship programs across all subspecialties perceive the need and benefits such a change would provide. The proposed Honor Code reminds every one of their professional commitment to excellence and to the principles of honesty, integrity, and ethical behavior.¹ A central clearing house would allow residents and programs to track openings and acceptances. The institution of an honor code may seem to be a small step, but it is a step in the right direction that encourages all of us to be ethical, moral, and professional physicians, working toward a process where both applicants and programs can find the best possible match.

Declaration of Conflicting Interests

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Supplemental Material

Supplementary material for this article is available online.

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Trends in Pathology Graduate Medical Education Programs and Positions, 2001 to 2017

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Abstract

The US medical workforce is facing an impending physician shortage. This shortage holds special concern for pathologists, as many senior practitioners are set to retire in the coming years. Indeed, studies indicate a “pathologist gap” may grow through 2030. As such, it is important to understand current and future trends in US pathology. One key factor is graduate medical education. In this study, we analyzed data from the Accreditation Council of Graduate Medical Education, to determine the change in pathology graduate medical education programs and positions, from 2001 to 2017. We found that pathology programs and positions have increased since the 2001 to 2002 academic year, even after adjusting for population growth. However, this increase is much lower than that of total graduate medical education. Furthermore, many pathology subspecialties have declined in population-adjusted levels. Other subspecialties, such as selective pathology, have grown disproportionately. Our findings may be valuable for understanding the state of US pathology, now and in the future. They imply that more resources—or technological innovations—may be needed for specific pathology programs, in hopes of closing the pathologist gap for both this specialty and its subspecialties.

Keywords

fellowship, graduate medical education, pathology, physician trends, residency

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A looming US physician shortage has special concern for those in pathology.^{1,2} With many senior pathologists expected to retire in the coming years, a “pathologist gap” is likely to increase through 2030.² As such, attention must be paid to the graduate medical education (GME) of future pathologists. However, limited literature exists on recent changes in pathology GME programs and positions. The present study addresses this limitation by analyzing quantitative trends in pathology GME programs and filled positions between 2001 to 2002 and 2016 to 2017. The insights gathered may help evaluate current and past predictions and contextualize the current outlook for US pathologists.

In order to analyze recent trends in pathology GME programs, we accessed the Accreditation Council of Graduate Medical Education (ACGME) Data Resource Book.³ We recorded the yearly quantity of ACGME-accredited pathology specialty and subspecialty programs between academic years

2001 to 2002 and 2016 to 2017. The quantity of on-duty residents and fellows (labeled “filled positions” for simplicity) was also documented. Only the “Pathology—Anatomical and Clinical” (AP/CP) specialty and direct subspecialties (as categorized by the ACGME) were included. For labeling purposes, AP/CP includes the sum of AP + CP, AP-only, and CP-only programs and filled positions.

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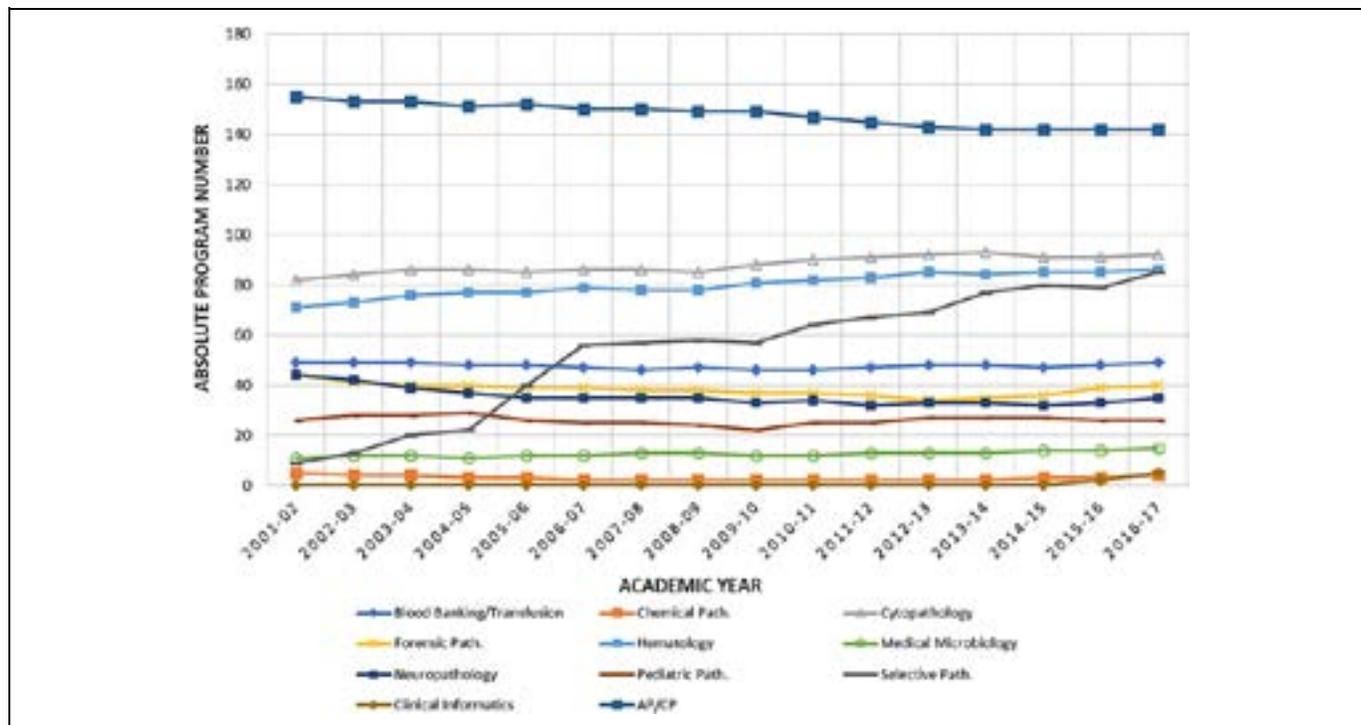


Figure 1. Absolute number of Accreditation Council of Graduate Medical Education (ACGME)-accredited pathology specialty and subspecialty programs, 2001 and 2002 to 2016 and 17. Anatomical and clinical pathology (AP/CP) category represents sum of AP + CP, AP-only, and CP-only residency programs. Data were sourced from the ACGME Data Resource Book. Data organization and analysis were done in Microsoft Excel, version 1711.

Population data from the US Census Bureau were used to adjust for population growth. When making such adjustments, we took the percent population growth between 2001 to 2017 and multiplied this by a given 2001 to 2002 GME quantity (eg, number of neuropathology programs). This product was then added to the original 2001 to 2002 quantity, giving the expected 2016 to 2017 quantity (in this case, expected number of neuropathology programs). The expected quantity was then subtracted from the corresponding actual 2016 to 2017 quantity (from ACGME). Finally, the actual–expected difference was divided by the actual quantity, and this quotient was multiplied by 100 to yield the population-adjusted percent change from 2001 to 2017. All data were organized and analyzed in Microsoft Excel (Microsoft Excel for Office 365, version 1711; Microsoft Corporation, Redmond, Washington). This study was not required for review by the Stanford University institutional review board.

Between the 2001 to 2002 and 2016 to 2017 academic years, total GME rose from 7838 to 10 672 programs. Accounting for the 14% US population growth across the same period, this was an increase of approximately 19%. In contrast, 4 pathology specialties and subspecialties declined in absolute program number: AP/CP (–13), chemical pathology (–1), forensic pathology (–4), and neuropathology (–9; Figure 1). Among the 3 pathology subspecialties which increased in both absolute and population-adjusted programs, selective pathology saw the greatest growth, from 9 to 85 programs (population-adjusted

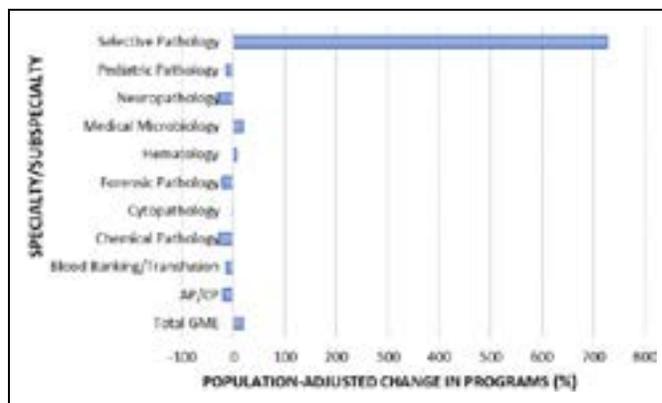


Figure 2. Percentage change in Accreditation Council of Graduate Medical Education (ACGME)-accredited pathology specialty and subspecialty programs, 2001 and 2002 to 2016 and 2017. Anatomical and clinical pathology (AP/CP) category represents sum of AP + CP, AP-only, and CP-only residency programs. Data were sourced from the ACGME Data Resource Book. Data organization and analysis were done in Microsoft Excel, version 1711. Population-adjustment calculation is described in text.

change = 727%; Figures 1 and 2). Hematology (71-86, 6.1%) and medical microbiology (11-15, 19.4%) were the others to increase in both absolute and adjusted program availability.

In total, pathology GME programs grew by just 2.2% after population adjustment. In fact, 7 of 10 ACGME-accredited pathology specialties and subspecialties declined in their

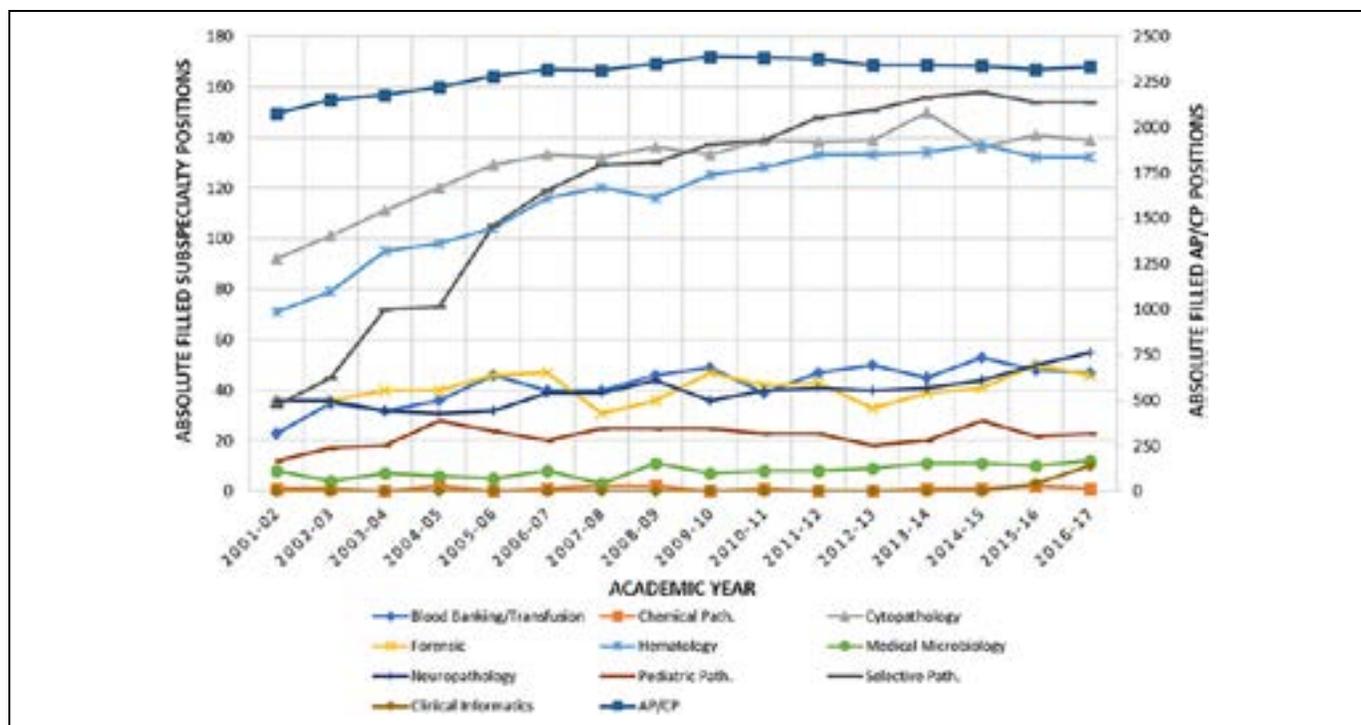


Figure 3. Absolute number of positions filled in Accreditation Council of Graduate Medical Education (ACGME)-accredited pathology specialty and subspecialty programs, 2001 and 2002 to 2016 and 2017. Anatomical and clinical pathology (AP/CP) category represents sum of AP + CP, AP-only, and CP-only residency positions. Right-hand side Y-axis values correspond solely to AP/CP positions; left-hand Y-axis corresponds to all subspecialties. Data were sourced from the ACGME Data Resource Book. Data organization and analysis were done in Microsoft Excel, version 1711.

population-adjusted program numbers. These included AP/CP (−19.8%), blood banking/transfusion (−12.4%), chemical pathology (−29.9%), cytopathology (−1.72%), forensic pathology (−20.4%), neuropathology (−30.3%), and pediatric pathology (−12.4%; Figure 2).

Total filled GME positions between 2001 and 2017 mirrored the trend in total GME programs, rising from 96 416 to 129 720 filled positions (population-adjusted growth = 17.8%). However, pathology-specific filled positions increased by just 8.4% after population adjustment.

Within pathology, 8 of 9 subspecialties grew in their absolute number of filled positions (there were 3 clinical informatics positions in 2015 to 2016, increasing to 10 in 2016 to 2017; Figure 3). The core specialty (AP/CP) grew from 2075 to 2334 filled positions between 2001 to 2002 and 2016 to 2017, and chemical pathology remained at 1 filled position (range = 0-2). Among the subspecialties which grew in filled positions, all 7 which had been ACGME-accredited since 2001 to 2002 also grew by over 10% after population adjustment: blood banking/transfusion (79.0%), cytopathology (32.3%), forensic pathology (11.9%), hematology (62.8%), medical microbiology (33.8%), pediatric pathology (67.9%), and selective pathology (297%; Figures 3 and 4). Although AP/CP did increase in filled positions between 2001 to 2002 and 2016 to 2017, its population-adjusted levels remained similar (−1.7%). And while chemical pathology positions remained constant in

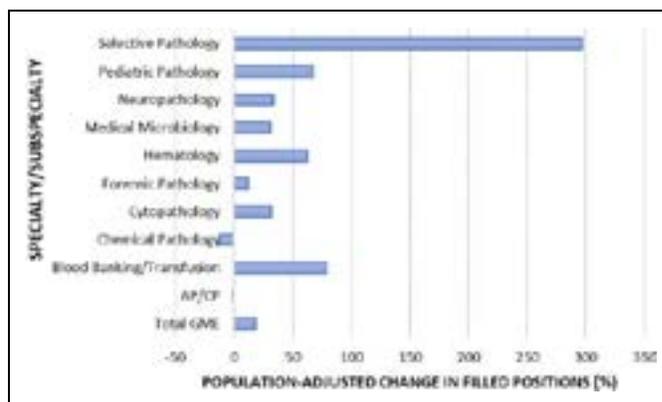


Figure 4. Percentage change in number of Accreditation Council of Graduate Medical Education (ACGME)-accredited pathology specialty and subspecialty positions filled, 2001 and 2002 to 2016 and 2017. Anatomical and clinical pathology (AP/CP) category represents sum of AP + CP, AP-only, and CP-only residency positions. Data were sourced from the ACGME Data Resource Book. Data organization and analysis were done in Microsoft Excel, version 1711. Population-adjustment calculation is described in manuscript text.

absolute number, the subspecialty yielded a population-adjusted decrease of 12.4% (Figure 4).

We compared our ACGME-based results with outside data to provide a more holistic view of pathology GME. The Inter-society Council for Pathology Information (ICPI) was the main

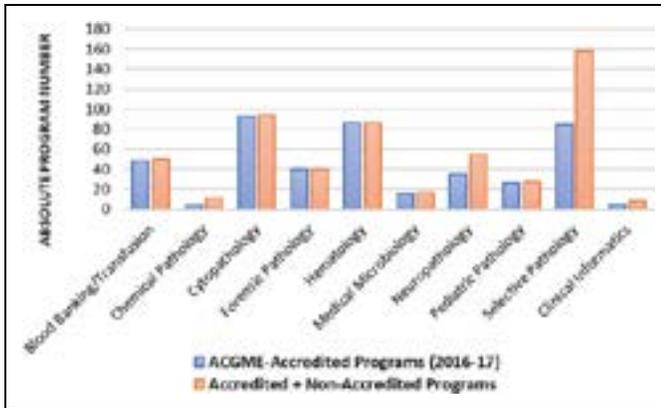


Figure 5. Absolute number of Accreditation Council of Graduate Medical Education (ACGME)-accredited pathology subspecialty programs, compared with accredited plus nonaccredited programs, 2016 and 2017 academic year. Data were sourced from the ACGME Data Resource Book (Accredited), as well as the Intersociety Council for Pathology Information (ICPI) and Pathpedia (nonaccredited). Data organization and analysis were done in Microsoft Excel, version 1711.

outside source. The ICPI is a nonprofit organization which collects data pertaining to clinical and academic pathology careers. Its database includes a directory of US pathology subspecialty programs (but no position data), whether they are ACGME-accredited or not.⁴ According to the database, in 2017, there were 94 cytopathology programs (accredited plus nonaccredited), 50 blood banking/transfusion programs, 27 pediatric pathology programs, 40 forensic pathology programs, 17 microbiology programs, and 55 neuropathology programs. The ICPI database did not contain data regarding most branches of selective pathology and hematology. For these subspecialties, we accessed data from the Pathpedia directory, which indicated a total of 158 selective pathology programs and 86 hematology programs in 2017.⁵ We then compared the quantity of ACGME-accredited subspecialty programs with the total accredited plus nonaccredited numbers (Figure 5).

These non-ACGME sources suggest that, for most pathology subspecialties, the majority of programs are ACGME accredited (Figure 5). Many subspecialties (such as those within selective pathology) do not have American Board of Pathology (ABP) certifications, so these high accreditation rates may be driven by greater funding opportunities and prestige.⁶ For selective pathology in particular, a noncomplete ABP/ACGME overlap may explain why, according to our results, 73 of 158 selective pathology programs remain unaccredited (Figure 5). Nonetheless, graduates from ACGME-accredited programs may be more competitive in their pathology careers.⁶ For example, though there is no ABP certificate for renal pathology, a fellow in this field may increase the probability of securing a future position at a major hospital by enrolling in an ACGME-accredited selective pathology program.

That said, one must note the resource disparity even among ACGME-accredited programs. In selective pathology, for instance, there were accredited 79 programs in 2015 to 2016,

with an average (mean) of nearly 8 pathologists on faculty per program. However, the range in faculty per program (1-34) was remarkably wide. The causes and consequences of such disparities almost certainly involve access to funding. As such, we also compared the number of different pathology subspecialty programs offered among US institutions, with respect to research funding. The top 10 pathology departments in total NIH funding awards for 2016 offered an average of 11.3 different subspecialty programs, while those in the bottom 10 offered an average of 3.0 ($P < .001$).⁷ This suggests a large national disparity between individual subspecialty programs, in addition to institutional pathology departments in general.

The ACGME-accredited pathology programs have grown in number between 2001 to 2002 and 2016 to 2017, according to our analysis. However, growth is much smaller than that of total GME programs. This comparison holds true for filled GME positions, as the proportional increase in pathology was over 2 times lower than that of total GME. Therefore, while pathology programs and filled positions have increased proportionally to the US population since 2001 to 2002, pathology GME has been outpaced by other specialties.

Across pathology specialties and subspecialties, program and position trends have not paralleled one another. Rather, certain subspecialties (such as selective pathology) have grown tremendously, while others (such as chemical pathology) have not grown at all. These changes reflect prevalent attitudes among young pathologists. Chemical pathology, for example, is relatively unpopular according to surveys of pathology residents.⁸ On the other hand, surgical pathology and gastrointestinal pathology (which fall under selective pathology) are increasingly popular.⁹ According to recent studies, young pathologists value marketability and job connections as the highest priorities in choosing a subspecialty.⁹

Nonetheless, pathology GME positions are still subject to changes in program availability. For example, between 2004 to 2005 and 2005 to 2006, selective pathology nearly doubled from 22 to 40 ACGME-accredited programs. In the same period, selective pathology positions increased from 73 to 105 on-duty residents. This began a continual, significant increase in selective pathology, which had a total of 85 programs and 154 positions in 2016 to 2017. Because many surgical pathology programs are unaccredited, this growth may reflect accreditation of existing programs, as opposed to development of new programs. Of course, program development is itself influenced by multiple factors, including relative interest and available funding.

It is important to note that clinical informatics programs in nonpathology departments are often open to applicants who have completed a pathology residency. Additionally, the ABP is allowing candidates to sit for the Clinical Informatics subspecialty examination using a practice-based pathway (in lieu of training) through 2022.¹⁰ Therefore, the total number of pathology residents pursuing some form of training in Clinical Informatics may be greater than presented by the ACGME.^{11,12} Similarly, the ACGME categorizes dermatopathology as a dermatology subspecialty and molecular genetic pathology as a

medical genetics and genomics subspecialty, but there are many fellows in both programs who have completed a pathology residency.

Although we accessed non-ACGME pathology program data using ICPI and Pathpedia, we were unable to quantify the number of accredited plus nonaccredited pathology fellowship positions. Even in databases such as ICPI, where data are available for individual programs, such details rarely include the number of GME positions.

In addition, it is difficult to comprehensively quantify the number of open versus filled ACGME-accredited positions. We have done so for a select group of pathology subspecialties, but a comprehensive list is beyond the scope of this study (future work may address this, by examining each individual program on the ACGME database, where data are presented for open vs filled positions). Chemical pathology programs, for instance, contained a total of 5 available positions in 2016 to 2017, but just 1 filled position. In medical microbiology, there was a similar lack of filled positions: 21 available positions, 10 filled. It is likely that more popular subspecialties, such as selective pathology, have a greater fill rate. Indeed, we accessed data from the National Residency Matching Program to assess fill rate in pathology PGY-1 residency matching.¹³ In the 2017 Match, there were 600 available US pathology PGY-1 residency positions, and 543 individuals were matched (90% fill rate). As such, it appears that any mention of a “pathologist gap,” if accurate and properly nuanced, must first examine the multifaceted distribution of filled versus vacant pathology GME positions. Certain subspecialties may face shortages, while others continue to grow.

With the Balanced Budget Act of 1997, US congress limited the number of Medicare-funded GME programs and positions. In order to keep up with US population growth and health-care demands, alternative funding sources will have to be utilized.¹⁴ This has already been occurring in many hospitals and GME programs.¹⁵ Special attention must also be paid to pathology: Over 75% of full-time pathologists are 45 years or older, making this one of the oldest specialties in the United States.² At first glance, then, greater pathology career interest and funding for pathology GME will be needed to fill any impending pathologist gap.

One might think such a shortage would have to be filled by additional pathologists. But this may not necessarily be true. Considering the broader context, pathology is in the early stages of a paradigm shift—with the burgeoning fields of digital pathology and image analysis promising to improve histologic diagnostics. These technological advances may bolster not only capability but also efficiency for individual pathologists. For example, image analysis of digital pathology slides may obviate the need for human semiquantification of immunohistochemical stains, mitotic figure counts, and other time-consuming practices.^{16,17} As a result, individual pathologists would be able to address more cases in less time. The portable nature of digital pathology may also allow pathologists to distribute their workloads more evenly across a widespread contingent. For instance, if one clinical group felt overburdened by

case volume, case overflow might be sent to pathologists working elsewhere in a low-volume setting. Such technologies and innovations are still in their early stages, but are rapidly evolving. They might greatly benefit this critical specialty, by the time any pathologist gap was felt in US health care. In short, pathology finds itself at an interesting crossroads—where workforce numbers may not be growing fast enough, but where technological and scientific advances may quell much of the resulting alarm. Time will tell if increased funding, career interest, and technological development will rise to meet a growing and aging US population in years to come.

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Outsourcing of Academic Clinical Laboratories: Experiences and Lessons From the Association of Pathology Chairs Laboratory Outsourcing Survey

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Abstract

American hospitals are increasingly turning to service outsourcing to reduce costs, including laboratory services. Studies of this practice have largely focused on nonacademic medical centers. In contrast, academic medical centers have unique practice environments and unique mission considerations. We sought to elucidate and analyze clinical laboratory outsourcing experiences in US academic medical centers. Seventeen chairs of pathology with relevant experience were willing to participate in in-depth interviews about their experiences. Anticipated financial benefits from joint venture arrangements often eroded after the initial years of the agreement, due to increased test pricing, management fees, duplication of services in support of inpatients, and lack of incentive for utilization control on the part of the for-profit partner. Outsourcing can preclude development of lucrative outreach programs; such programs were successfully launched in several cases after joint ventures were either avoided or terminated. Common complaints included poor test turnaround time and problems with test quality (especially in molecular pathology, microbiology, and flow cytometry), leading to clinician dissatisfaction. Joint ventures adversely affected retention of academically oriented clinical pathology faculty, with adverse effects on research and education, which further exacerbated clinician dissatisfaction due to lack of available consultative expertise. Resident education in pathology and in other disciplines (especially infectious disease) suffered both from lack of on-site laboratory capabilities and from lack of teaching faculty. Most joint ventures were initiated with little or no input from pathology leadership, and input from pathology leadership was seen to have been critical in those cases where such arrangements were declined or terminated.

Keywords

academic medical centers, clinical laboratories, clinical pathology, joint ventures, outsourcing, resident education in pathology

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Introduction

American hospitals face increasing cost constraints from declining federal and commercial reimbursement. Many hospitals have embraced outsourcing of services as a potential cost-saving measure. This trend began with nonmedical services such as food and laundry and has spread to medical services such as pharmacy, radiology, and clinical laboratory.¹ For clinical laboratories, 2 of the largest private laboratories offering such services are Quest Diagnostics and LabCorp.² Outsourcing may take several forms, ranging from full

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management of the hospital lab, in which all personnel are employed by the outside provider, to a lab management partnership, to an arrangement in which the hospital maintains all lab employees but sends all or part of its test volume to the outside provider. Such arrangements may include only inpatient testing or may also encompass outpatient and outreach testing.²

In recent years, a number of studies have examined the issue of clinical laboratory outsourcing. Many of these provide case studies or examine real or potential effects of hypothetical arrangements,¹⁻⁹ but very few provide a systematic analysis of outsourcing benefits or problems.^{4,10} Further, academic medical centers have mission demands beyond those of non-academic medical centers, and no study, to our knowledge, has specifically examined the experiences of academic medical centers with clinical laboratory outsourcing. We sought to survey chairs of pathology in academic medical centers to collect their experiences and impressions in this arena.

Methods

An initial, anonymous online survey (with SurveyMonkey) asked all chairs of pathology who are members of the Association of Pathology Chairs (APC) about their experience with laboratory outsourcing and about their willingness to follow-up with in-depth telephone interviews. The APC chairs' listserve includes 170 US medical teaching institutions, which represent virtually all of the 90 US academic medical centers who are members of the Association of Academic Health Centers (<http://www.aahcdc.org/About/Members>). There were 42 responses, representing approximately 47% of US academic medical centers. Of these, 25 reported some experience with laboratory outsourcing. Twenty of these respondents agreed to in-depth telephone interviews and provided identifying contact information. An additional 4 chairs later volunteered their experiences.

We were able to actually arrange interviews with 14 of these chairs, and received written comments from another 3 chairs, for a total of 17 surveyed chairs (68% of those with relevant experience in this area, identified in the initial SurveyMonkey study). The respondents represented major academic medical centers in the Northeast (9), Southeast (5), and Midwest (3). The in-depth telephone interviews were conducted by 2 of the authors (R.M. and J.T.). These generally lasted 30 to 60 minutes and were open-ended and wide ranging. This format was chosen to encourage respondents themselves to identify strengths and weaknesses arising from their experiences, rather than to focus on particular issues predetermined by the interviewers. The interviewers would occasionally ask questions to elicit clarifications and expansion of particular points raised. The authors took extensive and constant notes during the session, which were later reviewed, and points raised classified into various categories. Findings from the discussions were tabulated and analyzed by R.M. and J.T.

Results

Status of the Joint Ventures

Of the 17 surveyed chairs, 4 had current outsourcing arrangements at the time of the interview. Three had experienced outsourcing arrangements in the past that were subsequently terminated, and 1 was currently in the process of terminating such an arrangement. Six chairs reported that their hospitals had considered an outsourcing arrangement but rejected it. Two chairs reported outsourcing arrangements that had evolved over time through different partners as a consequence of mergers or acquisitions, and 1 chair had previously worked for a large private clinical reference laboratory.

Origins of the Joint Ventures

Most joint venture proposals and negotiations were initiated by the private laboratory and involved the health system CEO, without initial input from the chair of pathology. For 3 of the current joint ventures, there had been no input from pathology at all, and the arrangements were announced after most or all of the negotiations had been completed. For all 3 departments with previous arrangements that were subsequently terminated, the agreement had originally been put in place without the knowledge of, or input from, the pathology chair or before the current chair arrived.

Structure of the Joint Ventures

In most cases, the existing, past, or proposed arrangements involved outsourcing routine clinical laboratory testing to the joint venture laboratory, which was often geographically remote. Anatomic pathology services (surgical pathology and cytopathology) were generally not part of these arrangements. In 2 cases, the arrangement was for clinical laboratory outreach only and did not include hospital inpatients. In 1 case, the pathology department reported that it had benefitted from additional outside work in surgical pathology that was referred from the joint venture company to the pathology department. Two chairs cited the joint venture partner's tendency to focus on high-margin, high-throughput testing, leaving more esoteric and less lucrative testing as either local testing or send outs. Two chairs further stated that, in their opinion, the commercial lab's motivation for the agreement was to gain access to the inpatient book of business.

Input From Pathology

This was cited as critical in assessing and countering joint venture proposals in all cases in which no final agreement was ultimately reached and in the 3 cases in which an existing arrangement was terminated. Several chairs commented that a good working relationship with the health system administration had been a critical ingredient in gaining such input and in influencing the final decision. One chair cited a successful track record of laboratory utilization control as both a positive talking point and a positive trust building endeavor. In 1 failed joint venture negotiation, the inability to secure additional outpatient

volume for the joint venture partner ended discussions. Joint venture arrangements were reported to have had negative effects on clinician satisfaction with laboratory services (see below), and 1 chair was helped in achieving a decision to retain the hospital laboratory in part by enlisting support from chairs and chiefs of other services in the initial negotiations.

Impact on Finances

Monetary gain was seen as a (or the) major driving factor leading the medical center to consider an outsourcing arrangement in every instance. One respondent observed that the prospect of increasing efficiency as a pathway to improving finances was an additional motivation.

Initial financial results were generally reported to have been positive, both from 1-time cash infusions to the medical center (eg, from sale of the clinical laboratory) and from cost savings on outsourced tests due to favorable initial test pricing. Over time, however, the financial gains often fell short of expectations. This was the experience both of chairs with ongoing current outsourcing arrangements and of chairs under whom previous outsourcing arrangements had been terminated. Further, those chairs who had successfully argued against initiating such joint ventures based their arguments, at least in part, on insights gained from visiting other medical centers that had current joint venture arrangements involving the proposed partner and finding performance shortfalls and clinician dissatisfaction with those arrangements.

Two major factors were seen as having contributed to declining financial benefit of the joint venture agreements over time. First, cost savings eroded as initially favorable test pricing was followed in later years by price increases. Second, there was a lack of utilization control incentive on the part of the joint venture company, which facilitated excessive testing, excessive send outs, and excessive costs. This latter effect was cited as a major contributor to poor financial performance of joint venture arrangements. Indeed, 2 hospitals that terminated joint venture arrangements were reported to have realized US\$1 million to US\$4 million in immediate savings the first year after ending those agreements, and another hospital reportedly projected an estimated US\$21 million in extra costs for send outs with a proposed joint venture agreement that was ultimately not consummated. A more minor source of increased costs, cited by 1 chair, was the logistical difficulty and added expense of allocating anatomic (eg, surgical) specimens for anatomic pathology work to be performed in-house, while sending clinical laboratory studies (e.g., culture) to a separate, geographically remote laboratory.

Two chairs (one of whom had terminated a joint venture and one who had avoided such an arrangement) reported substantial growth in their own outreach efforts and earnings in the absence of a joint venture project and commented that those gains would not have been possible within the joint venture model.

Additional sources of dissatisfaction with joint venture arrangements were voiced by individual chairs. One chair cited the small size of the remaining on-site rapid response laboratory as being an obstacle to capital requests and negotiations, in

that the significance of this small residual laboratory was diminished in the eyes of the hospital administration. Another respondent noted that mandatory Medicare part A recognition of pathologist providers' effort went undocumented by the joint venture partner for years, engendering financial compliance risk on the part of the medical center.

Impact on Physician Satisfaction

Lack of clinician satisfaction was a commonly cited outcome. This was especially true for infectious disease clinicians, who lost direct access to culture procedures and results, with negative impact on their own teaching programs. Poor turnaround time for outsourced tests was a prime source of clinician dissatisfaction. In 1 hospital, the gastroenterology service opened their own gastroenterology (GI) pathology laboratory because of dissatisfaction with the test quality and turnaround times through the joint venture.

Lack of available expert consultation support for clinical laboratory testing was also a major source of dissatisfaction on the part of clinical faculty. This was generally a consequence of lost academic clinical pathology faculty, as noted below. One respondent also noted a negative effect on faculty retention that even extended to anatomic pathology faculty.

Impact on Clinical Pathology Faculty

Loss of clinical pathology faculty was cited by many of those with current joint venture arrangements. Faculty who became employees of the joint venture company often subsequently resigned, citing a lack of academic opportunities, or were fired as a cost-saving measure. Testing panel decisions, for instance, were made at the corporate (national) level rather than locally, precluding participation of clinical pathology faculty in test design, development, or selection. One chair also commented that there were no clear guidelines for handling raises and incentive payments for faculty employed by the joint venture and that coordinating these raises and incentives with those for other pathology faculty was difficult.

Impact on Test Quality and Turnaround Time

This was widely cited as problematic by chairs with current joint venture arrangements and was also cited by those who had considered but rejected such an arrangement. Molecular pathology, flow cytometry, and microbiology, in particular, were cited as areas with inconsistent or nonreproducible results, and turnaround times for nonrapid response specimens were universally cited as poor. For 2 long-standing agreements, there was a lack of compatibility between the laboratory information systems used by the joint venture company and by the hospital.

Impact on Teaching Programs

Education of medical students, of residents in pathology or other disciplines, and of other learners is a distinguishing mission of academic medical centers and engenders considerations beyond bottom-line financial analyses. Negative impacts on teaching programs were widely cited as a major problem with joint

venture agreements. For geographically remote joint venture clinical laboratories, resident travel proved to be an impediment to education, exacerbated further by scheduling difficulties for departmental conferences and teaching activities.

This was further complicated by the lack of academically oriented clinical pathology faculty (ie, those committed to teaching). In 1 current arrangement, the joint venture partner was reportedly trying to address this by making their technical personnel available to teach as part of the negotiated agreement, but proposed that the pathology department pay salary support to these technicians to compensate their teaching efforts. As mentioned above, other resident training programs, especially infectious disease, are also impacted adversely.

Discussion

Outsourcing of clinical laboratory services is increasingly seen as a potential source of cost savings by hospital administrators, and a careful analysis of the actual financial performance of such joint ventures is critical. Academic medical centers have missions that extend beyond patient care, and negative impacts on those missions must also be considered in evaluating any proposed outsourcing arrangement. Although there has been much discussion of clinical laboratory joint ventures with hospital clinical laboratories in general,¹⁻¹⁰ we are not aware of any previous survey specifically addressing the effects of such arrangements on the unique missions of an academic medical center.

In our survey of chairs of pathology at academic medical centers, respondents reported significant negative impacts of outsourcing arrangements on educational programs and on academic (teaching) clinical pathology faculty. We also found significant dissatisfaction regarding patient care, especially test turnaround time and test quality. The major findings of our survey are summarized in Table 1. In agreement with these findings, others have reported that poor test turnaround times are a prime source of dissatisfaction with outsourced clinical laboratory testing,^{2,4} and 1 study found significant numbers of medical errors resulting from laboratory outsourcing.¹⁰ Our survey found that these problems also led to considerable dissatisfaction on the part of clinicians, in accord with findings cited by others.^{5,8} Indeed, even the hoped-for cost savings often proved ephemeral, as price increases and management fees and lack of utilization-control incentives eroded initial financial gains. Although previous studies have frequently cited financial gains from outsourcing,^{2,5,7} at least 1 observer⁹ comments on long-term financial decrements similar to what we find here. Indeed, we identified academic hospitals that had actually realized substantial savings after terminating a joint venture agreement. We also found examples of increased outreach revenue after terminating or declining such arrangements; increases that would not have been possible under the joint venture arrangement.

A number of the existing or former joint venture arrangements were negotiated with little or no input from (or even awareness by) department of pathology leadership. The inclusion of pathology leadership often resulted in declination or termination of such agreements, presumably because potential

Table 1. Summary of Findings of the Survey.

Finances	<ul style="list-style-type: none"> • Monetary gain was a (or the) major driving factor in every instance. However, the financial gains often fell short of expectations.
In particular . . .	<ul style="list-style-type: none"> • There was increased test pricing after the initial contract period. • Lack of utilization control incentive on the part of the joint venture. • The small size of the remaining on-site rapid response laboratory rendered capital requests and negotiations much more difficult. • Outreach earnings: 2 hospitals reported substantial growth in their own outreach efforts and earnings that would not have been possible with the joint venture model.
Clinical pathology faculty	<ul style="list-style-type: none"> • Loss of clinical pathology faculty members was cited by those with current joint venture arrangements. • Faculty who moved to the joint venture company often subsequently resigned, citing lack of academic opportunities.
Test quality and turnaround time	<ul style="list-style-type: none"> • Both issues were widely cited by survey respondents. • Molecular pathology and flow cytometry, in particular, were cited as areas with inconsistent or nonreproducible test quality outcomes. • Turnaround times for nonrapid response specimens were universally cited as poor.
Physician satisfaction	<ul style="list-style-type: none"> • Lack of available CP consultation services was a major source of physician dissatisfaction. • Clinician satisfaction was especially low for infectious disease clinicians, who lost direct access to culture procedures and results, with negative impact on their own teaching programs. • Poor turnaround time for outsourced tests was another source of clinician dissatisfaction. • In 1 hospital, the gastroenterology service opened their own GI pathology laboratory because of dissatisfaction with the joint venture.

Abbreviations: CP, clinical pathology; GI, gastroenterology.

negative effects of such ventures were identified and brought to the attention of the negotiating parties. For those instances in which joint venture arrangements were terminated, or negotiations terminated without an agreement, the following points were cited as important in reaching these decisions:

Finances

These should be extrapolated beyond the first few years, with consideration of possible price increases, proposed management fees, and the consequences of lack of utilization control, especially for expensive send out testing. Foregone outreach efforts should also be considered.

Test Quality, Turnaround Time, and Physician Satisfaction

These should be considered carefully. Other clinical services that commonly experience negative effects from such arrangements,

Table 2. Anticipated Benefits Versus Considered Risks of Commercial Outsourcing of Clinical Labs for Academic Medical Centers.

Anticipated Benefits	Considered Risks
One time infusion of cash	Escalation of laboratory costs for purchased services in the out-years
Access to outpatient test volumes and new growth	Exclusion from regional growth opportunities
Access to a broader range of field services	Loss of local control over test menu and utilization
Cost efficiency in purchasing	Conflict between system goals and laboratory goals
Lab quality management at a national level	Clinician dissatisfaction with access to professional consultation services in laboratory medicine
	Selected quality concerns
	Turnaround time
	Loss of educational resource/access at all levels
	Recruitment and retention of laboratory professionals

especially internal medicine and infectious disease, should be brought into the discussion. The attendant implications for patient satisfaction and hospital expenses should be highlighted as well.

Education

Even with a cooperative joint venture company, geographic distance and lack of academically oriented faculty compromise this mission. Loss of academically oriented clinical pathology faculty, with consequent loss of research effort and research funding, was a commonly cited problem. These anticipated benefits and considered risks are summarized in Table 2.

Study Limitations

This was not a structured survey and hence is not subject to statistical analysis and testing. This format was deliberately chosen to enable the respondents, rather than the interviewers, to determine the scope and focus of the interview. We believe that this format has minimized potential author bias in selecting topics and questions and that the findings are thus of greater potential importance and relevance than might be the case with a questionnaire designed by the authors based on preconceived issues and concerns. As our study has now identified relevant issues and experiences as defined by the respondents, a more focused, question-based survey might be appropriate as a follow-up study. Further, the respondents to this survey were self-selected. We note that there was a very high response to our initial survey (47% of US academic medical centers) and participation in our follow-up survey (68% of respondents with relevant experience). Nevertheless, possible study bias resulting from such self-selection is possible.

Summary and Conclusion

In conclusion, a quality relationship between pathology leadership and hospital administration and a thorough analysis of the

downstream consequences of the proposed arrangement both on finances and on other missions of the hospital are essential elements in successfully assessing a joint venture proposal. Pathology input has been important in terminating preexisting joint venture arrangements, in influencing or ending negotiations in progress, and in obtaining good outcomes for new negotiations. A track record of cooperation, for instance, in laboratory utilization control efforts and general good relations between pathology and hospital administration can be very helpful in this regard, as can a financially successful laboratory outreach program. Consultation with, and on-site visits to, other medical centers that have joint venture agreements similar to the one under consideration can also be very helpful in identifying potential problems.

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Dealing With Deans and Academic Medical Center Leadership: Advice From Leaders

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Abstract

The 2017 Association of Pathology Chairs Annual Meeting included a session for department chairs and other department leaders on “how to deal with deans and academic medical center leadership.” The session was focused on discussing ways to foster positive relationships with university, medical school, and health system leaders, and productively address issues and opportunities with them. Presentations and a panel discussion were provided by 4 former pathology chairs who subsequently have served as medical deans and in other leadership positions including university provost, medical center CEO, and health system board chair. There was a strong consensus among the participants on how best to deal with superiors about problems, conflicts, and requests for additional resources and authority. The importance of teamwork and accountability in developing a constructive and collaborative relationship with leaders and peers was discussed in detail. Effectiveness in communication, negotiation, and departmental advocacy were highlighted as important skills. As limited resources and increased regulations have become growing problems for universities and health systems, internal stress and competition have increased. In this rapidly changing environment, advice on how chairs can interact most productively with institutional leaders is becoming increasingly important.

Keywords

advice, AHC leaders, conflicts, department chair, senior fellows

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Introduction

A key to the personal success of a clinical department chair, as well as the success of their department, is initiating and maintaining a positive and productive relationship with the university and health system leaders of their academic health center (AHC).¹ This follows the well-known precept that managing the relationship with one’s boss (“managing up”)² provides the best performance for both, as well as for the organization. Although AHC leaders are vested in the success of the chairs that they recruit and the departments they lead, in some cases relationships with AHC leaders can turn from supportive and collegial to contentious and even combative. The causes are manifold, with the major changes in academic and health-care operational environments of recent years significantly complicating the roles and responsibilities of chairs.^{3,4}

As the environment changes, so too is the advice to clinical chairs for dealing with their organizational issues and relationships with AHC leadership. In this context, teamwork and

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collaborative interaction have emerged as ever more pivotal keys to leadership success.⁵ This is reflected in the well-recognized leadership courses for department chairs given by Harvard⁶ and the Association of American Medical Colleges,⁷ where dealing effectively with institutional leaders is becoming an increasingly significant part of the curriculum.

The Association of Pathology Chairs (APC) was formed in 1967 as a professional society to assist chairs and other leaders of academic pathology departments in the United States and Canada.⁸ The annual meeting of the APC includes participation by pathology department chairs, undergraduate and graduate education program directors, administrators, and other department leaders to discuss issues and develop programs. For the 50th Anniversary Annual Meeting of the APC in July 2017, a half-day “chairs bootcamp” was organized to focus on important issues of particular interest to new chairs.

The closing session of the bootcamp was intended to discuss ways for new chairs, as well as senior chairs and other departmental leaders, to foster positive relationships with AHC leadership, avoid potential problems, and address issues and opportunities that may occur. A panel of 4 former pathology department chairs who have also served as deans and in other health center leadership roles addressed these topics. This report provides a broad range of recommendations based on these discussions that are of potential value to all departmental chairs as well as other program, center and institute directors for dealing productively with their AHC leaders.

Methodology

The APC senior fellows represent a group of past pathology chairs first organized in 2012 to help the APC, especially in providing advice to current chairs. The APC senior fellows evolved into an ad-hoc committee of the APC in 2014 and a permanent senior fellows group in 2017. In addition to providing advice, coaching, and mentoring to chairs, the senior fellows contributed to the APC Annual Meetings in 2015 and 2016 with formal “discussion group” sessions on transitioning from the chair,^{9,10} as well as group sessions to provide advice to all chairs (2015) and new chairs (2016).

Based on the positive feedback to the advisory session for new chairs in 2016, a half-day “chairs bootcamp” was developed for the 2017 annual meeting. The intent was to allow for a longer session that would encompass more topics that could help new chairs and also be of interest to senior chairs and other department leaders. The bootcamp was scheduled for the morning immediately before the start of the formal annual meeting program, and immediately after the 1-day Pathology Leadership Academy (PLA), in order to provide future departmental leaders who attended the PLA an opportunity to also attend the bootcamp.

As a final session of the bootcamp, the senior fellows developed a 1-hour program entitled “How to Deal with Deans and Academic Medical Center Leadership.” Four APC senior fellows who have served as past or present medical school deans and in other AHC leadership roles were invited to provide

Table 1. Advice in Dealing With AHC Leaders: Senior Fellow Panel Participants.

Fred Sanfilippo, MD, PhD (moderator)

- Former chair, Department of Pathology, Johns Hopkins University and Pathologist-in-Chief, Johns Hopkins Health System
- Former dean, College of Medicine and Public Health, senior vice president and executive dean of Health Sciences, and CEO of Ohio State University Medical Center, Ohio State University
- Former executive vice president of Health Affairs, CEO of Woodruff Health Sciences Center, and chair of the board of directors, Emory Healthcare, Emory University

Robert Folberg, MD

- Former chair, Department of Pathology, University of Illinois at Chicago
- Current founding dean, Oakland University William Beaumont School of Medicine, Oakland University

Deborah Powell, MD

- Former chair, Department of Pathology and Laboratory Medicine, University of Kentucky
- Former executive dean, School of Medicine University of Kansas
- Former dean, School of Medicine and assistant vice president for clinical affairs, University of Minnesota

Mark Tykocinski, MD

- Former chair, Department of Pathology and Laboratory Medicine, University of Pennsylvania
 - Former president, Jefferson University Physicians
 - Current dean, Sidney Kimmel Medical College, and provost, Thomas Jefferson University
-

advice in short presentations followed by a panel discussion of questions from attendees. Prior to the session, all the panelists shared summaries of their planned presentations with each other. The backgrounds of the 4 senior fellow panel participants (Drs Deborah Powell, Robert Folberg, Mark Tykocinski, and Fred Sanfilippo) are listed in Table 1. Dr Sanfilippo organized the session and served as moderator. This article represents a compilation of the advice provided in the presentations, discussions, and subsequent follow-up with the panelists.

Results

Advice on the Importance of the Relationship Between Chairs and Academic Health Center Leaders

There was strong consensus by the panel that a key to success of chairs, and to a large extent their departments, is the relationship they have with AHC leadership, especially their dean and hospital CEO. Academic health center leaders are committed to the success of the chairs they recruit and the departments they lead. The initial positive relationship between a new chair and AHC leaders can be enhanced by activities and behaviors that are mutually beneficial. However, due to the broad range of complex issues with which AHC leaders must deal daily, their relationship with individual chairs can deteriorate rapidly, especially over unresolved problems and conflicts.

Table 2. Advice in Dealing With AHC Leaders: Problems.**Provide a range of solutions**

- Always provide several solutions or options, identifying your preference in the context of other possibilities and providing positive and negative aspects of each option, along with potential unintended consequences
- Avoid presenting problems as zero-sum options or having only limited solutions
- Recognize that presenting problems without solutions will be viewed as complaints
- Appreciate that providing constructive solutions to institutional problems, especially for issues not involving your department, can enhance relationships with AHC leaders

Discuss problems and solutions with peers and AHC staff

- As appropriate, seek advice from other chairs, center directors and especially stakeholders before bringing problems to AHC leaders
- Discuss problems and solutions with appropriate leadership staff (especially those who likely will be involved in crafting solutions) before bringing them to AHC leaders

Be judicious and limit the number of problems brought forward

- Make sure that only problems of sufficient magnitude are brought forward to AHC leaders, realizing that many problems will resolve over time
- Avoid conditioning AHC leaders to associate your visits with problems
- Feel empowered to attempt to resolve certain problems without bothering leadership for permission, as it is acceptable to later ask for forgiveness if the solution doesn't work, assuming it was well intentioned, well informed, and reflected judicious prior advice from stakeholders

Understand local culture and processes for problem resolution

- Learn the characteristics of the local culture from peers and AHC leaders
- Appreciate cultural differences from where you have worked previously
- Identify preferred organizational processes for handling problems via peers and AHC leadership

Abbreviation: AHC, academic health center.

Advice in Dealing With Academic Health Center Leaders: Problems and Conflicts

Problems and conflicts often arise over faculty affairs, resource allocation (especially space and money), operational and administrative issues, and personal matters. There are many ways to avoid, manage, and resolve problems and conflicts, as well as to exacerbate them (Tables 2 and 3).

Before bringing problems to an AHC leader, it is essential to first discuss them with key stakeholders and, especially, the appropriate AHC leader's staff. Problems should be of enough importance to warrant engaging an AHC leader and should always be presented with a range of solutions that include potential consequences. Such selectivity, with a solution orientation, is advisable since bringing departmental problems to AHC leaders for resolution is

Table 3. Advice in Dealing With AHC Leaders: Conflicts.**Be a constructive critic**

- Support a position rather than argue a point
- Develop good negotiating skills through professional training
- Resolve conflicts with AHC leaders the way you would want a leader within your own department to resolve it with you

Be objective and dispassionate in a conflict

- Avoid threatening language
- "If-then" arguments are often viewed as threats
- Describe potential positive and negative consequences of resolution and nonresolution

Avoid bringing departmental conflicts to AHC leadership for resolution

- Try to resolve conflicts directly with stakeholders, especially if faculty or peer leaders are involved or affected
- Recognize that bringing departmental conflicts to AHC leaders is usually viewed as a failure and may result in a resolution worse than what could have been negotiated directly

Make sure disagreements with AHC leaders are important enough to warrant a conflict

- Avoid arguments when having a disagreement with AHC leaders
- Appreciate that most conflicts are avoidable, but some are not
- Embrace an "agreeing to disagree" stance as sometimes being the best solution

Do not overestimate your leverage, influence, or importance

- Never try to end-around your dean or hospital CEO by going to their superiors
- Never engage trustees, influential donors, or community leaders to pressure your superiors

Abbreviation: AHC, academic health center.

often counterproductive and can suggest that the chair is unable to manage their own department.

Conflicts are usually the greatest source of strained relationships between chairs and AHC leaders. Disagreements with leadership should be of sufficient significance to warrant a conflict, and in many instances, simply agreeing to disagree is the best approach. Every attempt should be made to resolve conflicts that are intradepartmental or involve stakeholder peers without involving institutional leaders.

When conflicts with AHC leaders are unavoidable, chairs should handle them in the way they would want one of their departmental leaders to resolve a similar conflict with them. An inevitable way to anger a dean or hospital CEO is to go around or behind them by engaging their superiors, trustees, influential donors, or community leaders. Conversely, being constructive and having good negotiating skills to resolve conflicts are viewed as positive attributes by AHC leaders. When conflicts cannot be resolved, the chair should remember that the desire of the AHC leader should be followed. The negative consequences of a chair ignoring or subverting an AHC leader's decision will usually outweigh any potential benefit to them or their department.

Understanding the organizational culture is very important in considering how best to deal with both problems and conflicts, especially for chairs that are relatively new to an institution. Culture clearly impacts consideration of what issues to

Table 4. Advice in Dealing With AHC Leaders: Requests.**Provide details on overall benefits to the institution**

- Be explicit as to how the institution and other units within it will benefit from the use of resources you request
- Never assume that what is best for your department is best for the institution
- Recognize that requests that add value or improve productivity of the AHC are well appreciated by AHC leaders

Vet requests with other stakeholders and unit leaders

- Engage other unit leaders (eg, chairs, center directors) who are impacted or would benefit from the request in the formulation of the request
- Ensure that key stakeholders agree on the priority and benefit of requests before bringing them forward to AHC leaders

Bring along other stakeholders when requesting resources

- Ask other unit leaders to join in the request and explain the benefits for their unit
- Ask other unit leaders to provide their assessment of institutional benefit

Do not make requests to one AHC leader that will benefit their organization (eg, dean/medical school) at the expense of another (eg, CEO/hospital)

- Realize that such requests will exacerbate the natural tensions between AHC entities and leaders in setting resource priorities
- Appreciate that granting such requests may provide short-term benefit but inevitably will create long-term problems for you and your department

Be sure requests are not zero-sum or cost-shifting

- Recognize that proposals that are zero-sum and cost/revenue-shifting are usually easily and quickly identified and rejected
- Understand that such requests will undermine trust in you and your department

Abbreviation: AHC, academic health center.

bring forward, how to deal with them productively, and how to resolve them. The wrong approach in dealing with problems and conflicts can exacerbate the issues and strain relationships with AHC leaders and peers. In contrast, being effective at solving problems and resolving conflicts, especially in helping to resolve institutional issues that don't primarily involve their department, can significantly enhance the relationship of a chair with their AHC leaders.

Advice in Dealing With Academic Health Center Leaders: Requests

A common issue that often leads to problems and conflicts between chairs and AHC leaders is requests for resources or approval. As with problems and conflicts, how requests are handled with AHC leaders can be as important as the nature of the request (Table 4). A frequent mistake made by chairs is the assumption that what is good for their department is equally as good for the institution. In fact, resources or approvals provided to one department can reduce assets or flexibility that might have greater institutional value if allocated elsewhere.

Of particular concern by AHC leaders are departmental requests that benefit one AHC unit (eg, medical school, practice plan) at the expense of another (eg, hospital). Such requests

exacerbate interorganizational tensions in funds flows and setting resource priorities. If granted, such requests may provide short-term benefit but inevitably precipitate problems between the AHC organizations and leaders that will be attributed to the requesting chair and his/her department.

When asking for departmental resources or approval, explicit details should be provided about the overall benefit to the institution as well as other units. To ensure overall institutional value, it is useful to engage other unit leaders and stakeholders in the formulation of requests for resources as well as in making the request. Just as requests that are zero-sum or reduce overall institutional assets are viewed negatively by AHC leaders, those that add value or improve productivity of a department and the institution are well appreciated by AHC leaders.

Advice in Dealing With Academic Health Center Leaders: Teamwork and Accountability

Two of the most important attributes of a high-performing organization are teamwork and institutional accountability. To optimize departmental and institutional success, chairs should consider themselves as members of the AHC leadership team (Table 5) and function as accountable team players (Table 6). Great team leaders of departments must also be great team players in AHCs. Likewise, great chairs should treat other chairs, center directors, and unit leaders as teammates rather than competitors, especially when dealing with resource issues (eg, space, money, and personnel).

It is important for chairs to remember that deans and hospital CEOs expect that the overall interests and welfare of the AHC should supersede that of any single department in the same way chairs expect departmental faculty and staff to put the overall interests and welfare of the department above that of their division or program. Unfortunately, as resources and regulations have become tighter, internal competition for resources and control have increased and created a counterproductive impact on institutional teamwork and accountability. Chairs who can overcome these pressures and prioritize institutional success are highly valued and trusted by AHC leaders.

Successful chairs also must understand and develop a realistic view of how their department fits into their AHC and work productively for the overall good of the institution. This entails understanding the different missions, values, culture, funds flow, and measures of success for each major unit of their AHC (ie, university, medical school, hospital, and practice plan), and being accountable for the intended use of resources provided by each. This is especially true for chairs of departments of pathology-lab medicine, which have a strong presence in both basic and clinical sciences as well as in health-care delivery.

Advice in Dealing With Academic Health Center Leaders: Communication and Advocacy

Effective communication and advocacy are invaluable in promoting a positive relationship with AHC leaders (Tables 7 and 8). It is important for chairs to keep AHC leaders and their

Table 5. Advice in Dealing with AHC Leaders: Teamwork.**Consider yourself a member of the AHC leadership team**

- Understand that medical school and hospital leaders consider you as a member of their teams and expect you to be a good team player
- Internalize the fact that great team leaders (eg, department chairs) are great team players

Treat other unit leaders as team-mates rather than competitors

- Appreciate that medical school and hospital leaders consider you a team-mate of your peer unit leaders and expect you to work with them as such
- Collaborate rather than compete with other chairs and center directors for resources (eg, space, money, staff, faculty) and control

Put the interests and welfare of the AHC above your department

- Act as the steward of your department rather than as its representative
- Make the AHC a priority in the same way you expect your departmental faculty and staff leaders to place departmental priorities ahead of their division or program

Understand the assets and liabilities of your department from the perspective of AHC leaders

- Understand how AHC leaders (eg, dean, hospital CEO) view your department relative to their component organization, as well as the AHC overall
- Determine how your peers (eg, chairs, center directors) assess and value your department

Promote alignment between medical school and hospital

- Appreciate the potential for opportunities and conflicts that you and your department have across the missions of the medical school and hospital
- Utilize relationships with clinical and basic science departments to enhance their interactions and understanding of each other's missions and priorities
- Work to build bridges, and never try to play one AHC leader against another

Abbreviation: AHC, academic health center.

peers well informed on important issues and particularly to avoid surprises. A chair should not be invisible, a pushover, or unnecessarily time-consuming, as such behaviors are not respected by strong AHC leaders. Academic health center leaders also have to deal with a lot of egos, so it is wise for chairs to keep their own ego in check and not be viewed as self-promoting. Good news and departmental successes that AHC leaders can brag about should be communicated more often than problems or requests.

Communications and advocacy require skill and experience. Messages should be tailored to the phenotype of the leader with whom a chair is communicating, that is, "*know thy audience.*" Deans and hospital CEOs have a wide range of backgrounds, career paths, and priorities, each of which impact their understanding of issues. Pathology-lab medicine departments are typically not well understood by AHC leaders, so chairs should provide sufficient background and limit assumptions when communicating about specialty-related issues.

Table 6. Advice in Dealing With AHC Leaders: Accountability.**Understand the different mission, vision, values, culture, and funds flow of the medical school, university, hospital, basic science units, and practice plans**

- Align institutional measures of success with your own and those of your department
- Be accountable for the intended use of resources provided to your department by each institution (eg, medical school, university, and hospital)

Put the priorities of AHC leadership ahead of your own

- Place the interests and success of your parent institutions ahead of your department
- Have your accountability to AHC leaders mimic the way you expect your faculty and staff to be accountable to you

Be accountable and responsible for issues arising in your department

- Recognize that AHC leaders assume that problems in your departmental are yours to resolve
- Avoid a victim mentality and blaming others for problems in your department

Make sure your accountability and responsibilities are commensurate with your authority

- Appreciate that delegated authority received from AHC leadership demands your responsibility and accountability to them
- Understand that accountability and responsibility without authority often causes conflict and problems

Convey a sense of accountability for the financial stability and quality of clinical services of your department, as the highest priority for most AHC leaders

- Accept the reality that clinical services are viewed by most AHC leaders as profit centers and research activities as cost centers, with the cost recovery of research less than its expenses
- Understand that clinical service revenue must be prioritized to ensure the quality of patient care over supporting academic activities
- Appreciate that departments with strong research but financial problems or poor clinical services are at high risk for leadership turnover

Abbreviation: AHC, academic health center.

Whenever possible in communicating important thoughts or opinions, the word "and" should be substituted for "but." The word "but" negates the first part of a sentence and is perceived as negative and conflicting, whereas "and" is considered supportive and contributory. Also e-mail should be used sparingly and carefully. Whenever appropriate, communication should be by phone or in person. E-mail messages sent to "document the facts" are often interpreted as threatening, and copying other individuals should be avoided when a message is intended for only one person. E-mails should be short and never sent when angry. It is best to draft critical messages, put them aside, and return to them a few hours later. Review of such drafts for content and style by an impartial and trustworthy colleague can be extremely valuable.

Departmental advocacy should be based on objective values that span missions and are in line with AHC and appropriate regional and national benchmarks. Chairs should help AHC leaders understand how high-quality pathology and lab

Table 7. Advice in Dealing With AHC Leaders: Communication.**Make communication with AHC leaders a positive experience for them**

- Do not be invisible, a pushover, or unnecessarily time-consuming
- Be recognized as a thought leader and constructive contributor, not a self-promoter

Keep AHC leaders and peers well informed about important issues

- Communicate potential serious issues before they occur and avoid negative surprises
- Provide good news and successes that AHC leaders can brag about

Tailor messages to AHC leaders considering their phenotype

- Try to understand the styles of your AHC leaders, as they vary widely in their backgrounds, career paths, and priorities, which impact their understanding of issues
- Recognize that pathology-lab medicine departments are not well understood by most AHC leaders

Substitute the word “and” for “but” whenever possible

- Avoid “but” as it negates the first part of a sentence and is perceived as negative
- Prefer “and” as it adds to a sentence and is perceived as supportive and contributing

Use e-mail sparingly and carefully

- Whenever appropriate, communicate by phone or in person
- Avoid using e-mail to document “facts,” which is often interpreted as threatening
- Copy only those who are directly engaged in the issue being communicated
- Keep e-mail messages short, since anything more than one screen will likely not be read entirely, if at all, by a busy AHC leader
- Do not send e-mails when you are angry, and instead, draft critical messages and hold them for at least an hour before reviewing and editing
- Ask a trusted advisor to review critical e-mails before sending

Abbreviation: AHC, academic health center.

medicine departments can provide clinical, academic, and financial value to the university, medical school, and hospital as well as other basic and clinical departments. Chairs also should position their department as a major AHC asset for the future of health care and academic medicine. This requires educating AHC leaders about high-value emerging areas that could be best developed in pathology and lab medicine, supported by tangible and credible evidence.

Discussion

The observations and advice given in this report reflect the combined experiences of 4 individuals who have served on both sides of the department chair: AHC leader interface at different institutions. Despite the significant range among these panelists in AHC leadership roles (dean, hospital CEO, AHC CEO), types of AHCs served (public and private, large, and small, research intense and clinically focused), and individual backgrounds, there was remarkable consensus among them on virtually all advice provided across a spectrum of issues.

Table 8. Advice in Dealing With AHC Leaders: Advocacy.**Evaluate your department’s assets and value propositions**

- Determine your department’s value in the context of your AHC and its constituent institutions (eg, medical school, university, and hospitals)
- Determine your department’s standing in the national context of the field of pathology, academics, and health-care delivery

Utilize multiple methods to promote the assets and value of your department

- Create departmental mechanisms (eg, newsletters, mailings, and social media) to inform stakeholders (eg, faculty, staff, alumni, and trainees) of assets/value
- Develop close relationships with institutional public relations/media staff to keep them informed of assets and newsworthy activities

Educate AHC leaders on the value of pathology-lab medicine

- Advise the dean/medical school/university leaders about the value of pathology to education and research missions, as well as to other basic and clinical departments
- Advise the hospital CEO and leaders about the value of pathology to the quality and cost-effectiveness of health-care delivery, as well as to the other clinical services

Determine and communicate the financial value of your department to AHC leaders

- Calculate net revenue and contribution margin across all departmental activities
- Make lab service contribution margin discussions transparent
- Build cases for requests recognizing that hospital leaders usually consider lab services as a commodity, pathologists as an expense, and margins as operating revenue

Position your department as an asset for the future of health-care and academic medicine

- Emphasize emerging areas such as telehealth, precision medicine, next gen lab-based technologies, artificial intelligence, multiplexed diagnostic ‘omics, cellular therapeutics, multiscale diagnostic imaging, etc.
- Explain the positive impact of such programs on institutional operations, finances, and prestige, and make the case for pathology-lab medicine’s pivotal roles in driving them for the AHC

Abbreviation: AHC, academic health center.

The major goal of the session was to provide advice on dealing with AHC leaders, especially for new chairs who must manage new relationships with AHC leaders as they confront many responsibilities and issues for the first time. Such challenges are inherently exacerbated when the new chair is in a new institutional environment where culture and processes may differ from their previous experience.^{11,12} Since senior chairs experience many of the same issues as new chairs, and often live through changes in AHC leadership during their tenure as chair, much of the panel’s advice and discussion is also clearly applicable to them. Interestingly, feedback following the session indicated that new chairs, experienced chairs, as well as senior and junior departmental leaders found this session to be one of the most useful in the entire annual meeting. Likewise, the group of 16 Society of ‘67 Scholars (5 medical students and 11 residents) in attendance identified this session to be of

great interest because it covered new and different topics to which they had not been previously exposed.

The panel reinforced that developing a productive relationship with AHC leaders,¹³ being regarded as a trusted team player, and demonstrating accountability for organizational resources and authority are essential qualities that deans and hospital CEOs expect of chairs.¹⁴ Too often chairs do not appreciate the time and practice needed to develop these attributes. Fortunately, they can enhance their skills and draw do's-and-don't lessons from industry, sports, and the military.^{15,16} Self-awareness, hubris management, and effective communication skills constitute important ingredients for strong and trusting relationships with leaders. Judicious choice of which issues to bring forward to leaders, as well as when and how to bring them forward, is as important for such relationships as is dealing with the issue itself.

The advice of others is an essential resource for chairs, as they seek to deal effectively with their superiors. For those who have not had the experience and responsibility of leading a medical school or AHC, it is often difficult to see departmental issues from the perspective of the AHC leader with whom they are interacting. Admittedly, getting candid advice from someone with the experience of a medical school dean or hospital CEO, to help understand leaders' viewpoints, is not easy, which is perhaps one reason why this panel discussion was so well received.

The previous chair, senior department faculty and staff, and other department chairs and center directors are useful local sources of advice in dealing with AHC leaders. Advice can also be sought elsewhere from peer chairs and colleagues at other institutions, although extrapolating their experience to a different environment and set of leaders can be risky. Specialty societies and professional organizations offer a valuable and simple means for obtaining advice from other chairs across a wide range of issues. Indeed, one of the major benefits of the senior fellows for the APC has been the personal advice they provide to individual members, which often encompasses issues in dealing with an AHC leader.

In summary, AHC leaders desire constructive interactions from chairs in dealing with both issues and opportunities. It is an enormous asset to a department when their chair is perceived by institutional leaders as a team player, constructive critic, positive change agent, value creator, and an engaged thought leader.

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A Next-Generation Sequencing Primer— How Does It Work and What Can It Do?

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Abstract

Next-generation sequencing refers to a high-throughput technology that determines the nucleic acid sequences and identifies variants in a sample. The technology has been introduced into clinical laboratory testing and produces test results for precision medicine. Since next-generation sequencing is relatively new, graduate students, medical students, pathology residents, and other physicians may benefit from a primer to provide a foundation about basic next-generation sequencing methods and applications, as well as specific examples where it has had diagnostic and prognostic utility. Next-generation sequencing technology grew out of advances in multiple fields to produce a sophisticated laboratory test with tremendous potential. Next-generation sequencing may be used in the clinical setting to look for specific genetic alterations in patients with cancer, diagnose inherited conditions such as cystic fibrosis, and detect and profile microbial organisms. This primer will review DNA sequencing technology, the commercialization of next-generation sequencing, and clinical uses of next-generation sequencing. Specific applications where next-generation sequencing has demonstrated utility in oncology are provided.

Keywords

diagnostic test, microbiology, mutation, oncology, sequencing

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Introduction

Although nucleic acid sequencing technology has only existed for about 40 years, the technology represents an outstanding example of progress resulting from continuous improvement and increases in cost efficiency. The newest sequencing technologies are frequently referred to as next-generation sequencing (NGS). The results from NGS testing have been translated into clinical laboratories to produce clinically relevant information that directly impacts patient care. Some molecular tests employ a “one-gene one-test” approach by using specific sets of primers and polymerase chain reaction (PCR) to detect one specific mutation. In contrast, NGS is able to detect thousands or even hundreds of thousands of genetic variants in a single test run. This primer is written to provide an introduction to NGS for those health-care professionals who may have heard of the technology in the lay press or in grand rounds. While not an exhaustive review, it does lay the foundation for understanding the power of this innovative technology.

First-Generation DNA Sequencing Technology

After the discovery of the chemical composition of DNA in the late 19th century, nearly 50 years passed before the structure of DNA was elucidated¹ and another quarter of a century elapsed prior to developing methods to sequence DNA.^{2,3} The principal method published in 1977 involves sequencing by synthesis (SBS) of a radioactively labeled DNA strand complementary to the interrogated template strand using the dideoxy chain termination

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technique. The resulting fragments were then analyzed by polyacrylamide gel electrophoresis. This method, known as Sanger sequencing, became the basis for the “first-generation” sequencing technology. The original Sanger sequencing method has subsequently been automated and commercialized.^{4,5} Major innovations include the introduction of fluorescent-labeled nucleotides instead of radioactivity,⁶ replacement of gel electrophoresis with capillary electrophoresis,^{7,8} and improvement of the DNA polymerases.⁹ Additional progress was achieved through adoption of molecular biology techniques, such as recombinant DNA technology¹⁰ and the PCR,¹¹ which allowed production and amplification of DNA fragments. The Sanger method-based sequencing technology was used to sequence a number of increasingly large genomes starting with bacteria and phages,¹²⁻¹⁵ and eventually mammalian^{16,17} and human genomes.^{18,19}

One of the major limitations of Sanger sequencing is that only one sequence reaction can be analyzed per electrophoresis lane or capillary tube, hence the necessity to divide the DNA from a biological sample into individual template fragments. This was achieved by randomly cloning the fragmented DNA from a biological sample (by insertion into vectors, transformation of the bacteria, and extraction of pure individual fragments from the resulting colonies). This very labor-intensive process was one of the reasons why the first human genome project took more than 10 years and cost US\$2.7 billion (<https://www.genome.gov/sequencingcosts/>). Subsequent improvements allowed another human genome to be sequenced using the same technology for approximately US\$10 million.²⁰

Despite these advances, the efficiency of this method has approached its limit and further use of this technology was considered time and cost prohibitive. It should be noted that Sanger sequencing remains the gold standard for confirming DNA sequences due to the stability of the technology and is still broadly used for targeted re-sequencing in research and clinical laboratories.

Next-Generation Sequencing

The terms NGS (sometimes subdivided into second- and third-generation sequencing) massively parallel sequencing or high-throughput sequencing usually refers to technologies that allow sequencing without the physical separation of individual reactions into separate tubes, capillaries, or lanes. Instead, the sequencing reactions occur in parallel on a solid surface (such as glass or beads, depending on the technology) and are only spatially separated. Thus, billions of sequencing reactions occur and are analyzed simultaneously, dramatically improving the throughput and decreasing the labor compared to Sanger sequencing. Regardless of the platform, NGS involves several common steps (see reviews²¹⁻²³ for details), which are outlined in Figure 1.

Commercialization of Next-Generation Sequencing Technology

These novel approaches introduced early in the 21st century were rapidly adopted resulting in strong competition in the

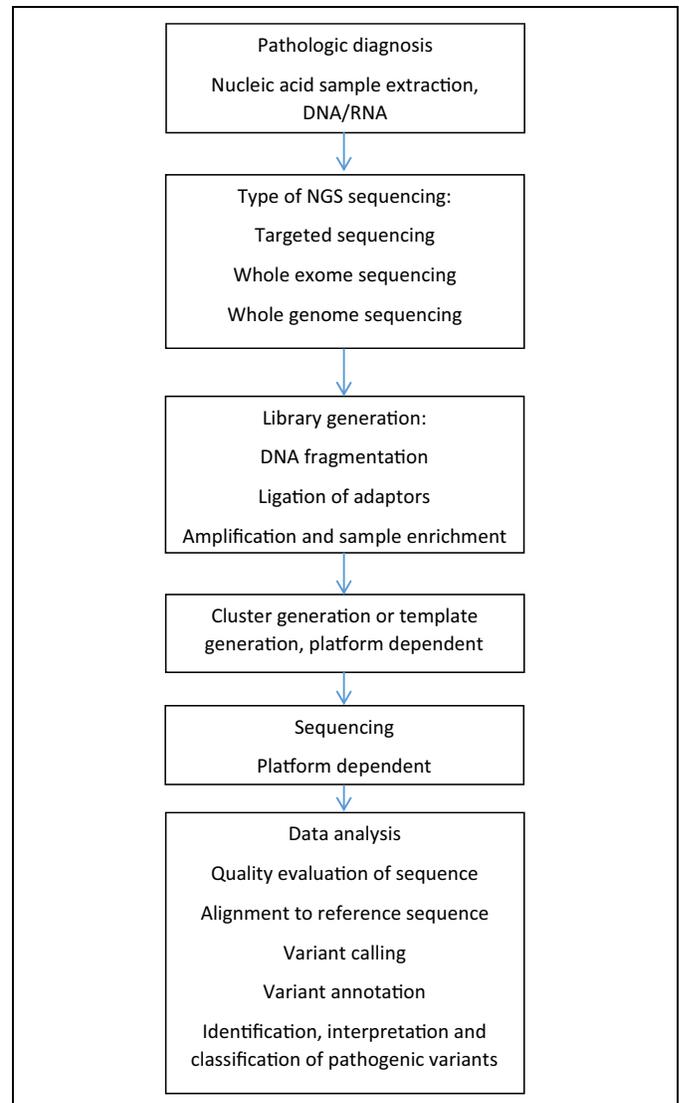


Figure 1. Schematic of sample processing for next-generation sequencing. See Table 1 for definitions of specific terms.

NGS market. There are several technical differences in the technologies.²¹⁻²³ A glossary of terms used in molecular biology terms is provided in Table 1.

The first commercial NGS technology was introduced in 2004 by 454 Life Sciences (later purchased by Roche). This technology²⁴ utilized luminescent detection of a pyrophosphate released upon incorporation of a correct nucleotide during SBS and produced relatively long sequences (called “reads”). This technology was used to sequence the genome of James Watson and the price dropped from US\$10 million with Sanger sequencing to about US\$2 million.²⁵ Within 2 years, other platforms emerged (Illumina/Solexa²⁶ and ABI SOLiD); however, they only produced very short reads. Illumina utilizes an SBS technology originally developed by a company called Solexa which uses reversibly terminated fluorescently labeled nucleotides.²⁶ Illumina scientists managed to significantly increase the sequencing read length and dramatically improve accuracy and

Table 1. Glossary of Molecular Biology Terms.

Adaptors	Single-stranded or double-stranded synthetic oligonucleotides that can be ligated to the ends of other DNA or RNA molecules
Bridge amplification	A polymerase chain reaction (PCR) technique that embeds DNA on an oligo-decorated solid surface for cloning
Cluster generation or template generation	The product for the NGS sequencing step, it is platform dependent
Copy number variation (CNV)	Variation in the number of copies of a particular gene compared to a reference standard
DNA sequencing	Determining the sequential order of nucleotides in DNA
DNA fragmentation	Separating or breaking DNA strands into pieces
Emulsion PCR	A PCR technique that is conducted on a bead surface within tiny water bubbles floating on an oil solution
Exome	Includes the coding region within the genome and does not include the introns or noncoding regions
Fluorescent in situ hybridization (FISH)	A molecular cytogenetic technique that uses fluorescent probes to bind to parts of DNA that have a high degree of sequence complementarity
Fusion gene	A hybrid gene formed from partial or complete sequences of 2 previously separate genes
Homopolymer	Repetitive stretch of single-nucleotide types (eg, TTT or GGGGGG)
Hybridization	The bonding of single-stranded DNA or RNA to form double-stranded DNA or RNA
Incidental findings	Variants identified that are not directly relevant to the diagnostic question
Insertion deletion	Insertion or deletion of nucleotide base(s) into the genome of an organism
Library generation	DNA/RNA prepared into a form compatible with the sequencing system used. This includes DNA fragmentation, shearing the DNA into smaller fragments, and adding common adapters to the DNA fragments
Microarray	A technology used to detect expression or copy number of many genes simultaneously
Point mutation	A mutation that affects a single-nucleotide base
Productivity	Number of bases sequenced per run
Quantitative PCR	An extremely sensitive PCR-based laboratory technique that allows the accurate measurement of the amount of specific nucleic acids in a sample
Multiplex PCR	Amplification of several different DNA sequences in a single PCR experiment
Output	Total length of sequenced genomic region
PCR	A technique in which segments of DNA can be amplified, generating thousands to millions of copies of a particular DNA sequence
Polyacrylamide gel electrophoresis	A technique used to separate biological molecules, usually proteins or nucleic acids, based on their molecular weight
Pyrosequencing	A method of DNA sequencing by measuring the synthesis of the complementary DNA strand (sequencing by synthesis)
Read	Segment of DNA that has been sequenced
Reference sequence	This is a consensus sequence of the DNA bases of an organism. The NGS sample is compared to the reference sequence to look for alterations
Sequencing by synthesis (SBS)	A technique in which sequencing is performed by detecting the nucleotide incorporated by a DNA polymerase
Sequencing depth	Number of times a given nucleotide in the genome has been read during the sequencing run (often referred to as depth of coverage)
Sequence coverage	Proportion of the targeted genomic region that is actually sequenced (found in the sequences from the generated data)
Single nucleotide variant (SNV) and single nucleotide polymorphism (SNP)	Variation of a single nucleotide of a particular gene between individuals (SNV). If this variant is present with some degree of frequency in a population, it referred to as a single-nucleotide polymorphism (SNP)
Sanger sequencing (chain termination method)	A technique for DNA sequencing based on the selective incorporation of chain-terminating dideoxy nucleotides (ddNTPs) by DNA polymerase during in vitro DNA replication
Targeted sequencing	Analyzing a panel of genes related to a disorder
Template DNA	The noncoding strand of DNA
Variant	Alteration of a DNA sequence as compared to the reference sequence that may or may not be associated with a disease state. Classification of variants include: <ul style="list-style-type: none"> • Pathogenic variant: Genetic variation with sufficient evidence to classify it as pathogenic (capable of causing a disease) • Likely pathogenic (LP): Genetic variation with strong evidence in favor of its pathogenicity • Variant of unknown significance (VUS): Genetic variation that cannot be definitively determined to be benign or pathogenic • Likely benign (LB): Genetic variation with strong evidence against its pathogenicity • Benign (B): Genetic variation with very strong evidence against its pathogenicity

(continued)

Table 1. (continued)

Variant annotation	The process of linking sequence variants with functional information, for example, the effect of a variant on protein function
Variant calling	The process by which variants are identified from sequence data
Whole exome sequencing (WES)	The process of determining the DNA sequence of all the coding exons of a genome
Whole genome sequencing (WGS)	The process of determining the complete DNA sequence of a genome

throughput. As a result, the costs were decreased and several protocols were developed for a variety of NGS applications.^{27,28} More recently, Illumina introduced 2 new instruments, the HiSeq X and NextSeq 500. The first is able to sequence a human genome at $\times 30$ coverage for less than US\$1000,^{29,30} and the latter does the same for a slightly higher price but in less than 20 hours. Moreover, a new series of instruments introduced in 2017 (NovaSeq) should reduce the costs by almost another order of magnitude.

A conceptually different sequencing platform called Ion Torrent³¹ was introduced in 2011. This SBS technology detects the minute changes in pH caused by H⁺ ions released during the incorporation of the correct nucleotide in the microenvironment around the beads with the attached clonally amplified DNA template molecules. Consequently, it does not require fluorescently labeled nucleotides and expensive optics to detect the fluorescence (see the study by Heather and Chain²¹, Reuter et al²², and Morey et al²³ for details). Currently, the most popular applications from this company (now part of ThermoFisher) are targeted disease panels used in clinical settings (eg, cancer).

In the last decade, the amount of sequencing data has increased exponentially, accelerating translational research, clinical usage of genomics findings, and development of new genomics tests to support precision medicine approaches.^{32,33} Progress in sequencing technologies was also facilitated by the expansion and adoption of improved molecular biology methods. While early protocols required microgram quantities of high-quality nucleic acid, now samples with very low (ie, picograms) quantities of nucleic acid may be sequenced. Sequencing of samples from formalin-fixed paraffin-embedded material has become routine. These advances also led to the discovery of new circulating biomarkers,^{34,35} a revolution in prenatal diagnostics (genetic testing of fetal DNA from mother's blood samples^{36,37}) and single-cell genomics approaches.³⁸⁻⁴⁰

Comparison of Ion Torrent and Illumina

Illumina has developed an impressive line of instruments that differ in their productivity, speed, and price tags from small benchtop sequencers (producing 1.65-7.5 Gb per run) to production scale systems (producing thousands of Gb of data per run). All these instruments implement similar chemistry with the sequencing performed by synthesis using reversibly terminated fluorescently labeled nucleotides and capturing the fluorescent images after each nucleotide incorporation event. The sequencing data are deconvoluted from the image data based on the color of the labels.

In the clinical setting, the majority of the existing NGS tests provide a limited amount of sequence information. MiSeq is an instrument with relatively low productivity which fits the current need. Depending on the specific test, the instrument may produce from 500 Mb up to 15 Gb of data in 4 to 56 hours. Currently, Illumina produces a validated, Food and Drug Administration (FDA)-regulated custom amplicon kit that enables clinical laboratories to design custom NGS assays for the FDA-approved MiSeqDx and NextSeq550Dx instruments.

Ion Torrent has 3 instruments in their portfolio. The sequence is determined by measuring the change in pH in the microenvironment around the beads with the attached clonally amplified identical template molecules immediately after addition of a nucleotide (one at a time). There is no definitive stop at each position and the synthesis immediately continues in case of repeats on the template. The pH change in such cases is stronger than when just 1 nucleotide is incorporated allowing the calculation of the nucleotides in the repeat. However, this technology is more prone to homopolymer detection and frameshift errors.⁴¹ The first instrument by this company, the Personal Genome Machine, is also approved by the FDA for clinical NGS tests (Ion PGM Dx). This instrument produces up to 2 Gb of sequencing data (200-400 bp) in 2 to 4 hours. The newer instrument S5 uses the same sequencing approaches and produces up to 15 Gb data (200-400 bp) in 2- to 4-hour runs. Both instruments require additional time and instrumentation for library preparation prior to sequencing.

Currently, Illumina has the largest market share and was the first to obtain FDA approval for their MiSeq instrument. A comparison of the 2 reveals advantages and disadvantages. The initial cost of both instruments is similar. The Ion Torrent will generate sequence data faster than Illumina, an important consideration for a clinical diagnostic test with urgent requests for results, that is, prenatal samples. The Ion Torrent system offers automated library preparation, template preparation, and automated chip loading with the purchase of a separate piece of equipment, the Ion Chef, and does not depend on a technician once the Ion Chef has been loaded. This should lead to more reproducible results by removing the variability between technologists. The manual library preparation workflow for the Illumina occupies the technician's time and requires considerable molecular biology expertise. The actual applications for both instruments appear to be comparable and both will perform targeted resequencing and whole-exome sequencing (WES). The Illumina system has a lower cost per base of sequence. The FDA-approved Illumina MiSeqDx is able to generate a complete report for its cystic fibrosis assay, while

the Ion Torrent needs manual analysis. An attractive feature of the Ion Torrent in the cancer field is the ability to generate a report that matches the sequence results with ongoing clinical trials. While this may be done with the Illumina data, the report requires third-party software. The S5 is the latest instrument from Ion Torrent; consequently, there are limited user data for comparison. It should be noted that the Ion Torrent's underlying technology has not changed with the release of the S5. Comparison of the Illumina and Ion Torrent systems has been published in several articles in areas such as clinical microbiology, germline variant detection, and prenatal testing as well as somatic variant in oncology. Both platforms performed well and the results are comparable.^{42,43}

Requirements for Performing Clinical Next-Generation Sequencing

Next-generation sequencing results for clinical purposes have substantially increased the amount of information available by generating massive amounts of sequence data. As a result, the overall detection rate of disease-causing alterations has grown significantly. Next-generation sequencing has allowed the creation of targeted gene panels that will sequence hundreds of genes at once for less expense compared to the Sanger method or PCR assays. A clinical setting has many factors to consider in choosing a platform compared to a research setting. Factors to consider in a clinical laboratory system include specificity and sensitivity, reproducibility, and analytical accuracy to ensure clinicians receive accurate results.^{44,45} Next-generation sequencing technology yields massive amounts of data that require substantial analysis to produce a clinically relevant, concise result. This analysis requires appropriate infrastructure including analysis software, data storage, and accessibility.⁴⁶⁻⁴⁸ The report provided to the clinicians needs to be appropriately formatted. For example, a genetics or oncology report should include the classification of the variant (ie, pathogenic), literature describing the reportable variant(s), recommendations for further testing, and for oncology reports, indicate whether the variant is inherited or somatic. The data analysis usually involves massive genetic, genomic, and oncologic bioinformatics research and data analyses. Fortunately, there are jointly proposed guidelines from professional organizations for NGS testing, validation, proficiency testing,⁴² reporting, and quality assurance/quality control requirements and documentation.⁴⁹ These articles will help standardize the proper application and interpretation of the NGS data for clinical utilization. Interested parties should refer to the extensive documentation in these articles for additional information.

Next-Generation Sequencing for Hereditary Disorders

Next-generation sequencing testing for hereditary disorders faces technical challenges, data management issues, reporting on incidental findings, and variant interpretation.⁵⁰ Despite these challenges, NGS has been valuable in identifying the

underlying molecular cause of disorders, especially for those diseases which are genetically heterogeneous. In addition, NGS has been valuable in the detection of rare variants after single-gene analysis has been negative or when multigene panels were too labor-intensive and costly for Sanger sequencing.⁵¹ For complex, rare phenotypes, NGS has also been a powerful tool in reducing the diagnostic odyssey often required to arrive at a diagnosis.^{52,53} For example, in Usher syndrome, an autosomal recessive disorder characterized by sensorineural hearing loss, retinitis pigmentosa, and vestibular dysfunction (in a subset of cases),⁵⁴ NGS has allowed the development of targeted gene panels to survey all causative genes associated with Usher syndrome. Previously, a comprehensive analysis was limited by the labor-intensive, high cost of Sanger sequencing and turnaround times. Providing an earlier diagnosis for children with Usher Syndrome affords the opportunity for earlier medical management for patients and their families.⁵⁴

Next-generation sequencing has enabled diagnostic laboratories the ability to offer targeted disease panels for genetic disorders, such as connective tissue diseases, in addition to whole-genome sequencing (WGS) and WES. For patients with nonspecific clinical presentations, such as moderate to severe intellectual disability,⁵⁵ WGS is recommended. The diagnostic rate of WES is approximately 25% to 31%^{53,56} similar to WGS⁵⁷; however, WGS has the additional advantage of detecting larger numbers of copy number variations.^{57,58} Additionally, the reporting of incidental findings, defined as variants unrelated to the primary medical reason for testing,⁵⁹ need to be addressed in the context of exome and genome sequencing. The American College of Medical Genetics and Genomics updated their guidelines in 2017 for reporting incidental or secondary findings in 59 medically actionable genes in which known or expected pathogenic variants were identified.⁵⁹ Reporting known (or expected) disease causing mutations in conditions where preventive measures and/or treatments are available highlight the benefit of returning incidental findings to patients.⁵⁹ However, there are also limitations and challenges in identifying and reporting such findings including the consent process, follow-up diagnostic evaluation, and additional laboratory resources.^{51,60,61}

Next-Generation Sequencing for Detecting Microbial Organisms

The utility of NGS has been demonstrated for several applications involving pathogen biology and genomic epidemiology. These include targeted sequencing and unbiased interrogation of clinical samples for pathogen detection and identification (regardless of whether the organism can be cultivated or is viable), drug resistance profiling, strain typing and epidemiological outbreak investigation, microbiome studies, genomic determinant analysis of microbial functions including metabolism, and comparative ribosomal RNA phylogenetic studies. Next-generation sequencing brings added throughput, sensitivity, and informatics-based prowess to pathogen interrogation. It is emerging as a valuable diagnostic alternative when other

methods fail to identify an organism or cannot decipher complex specimens such as in patients with polymicrobial infections. The use of NGS to detect evidence of *Leptospira* in the cerebral spinal fluid of a critically ill pediatric patient was a landmark case that demonstrated the clinical utility of unbiased NGS to achieve an actionable diagnostic result when other approaches failed, including phenotypic, immunologic, and targeted PCR-based assays.⁶² Also, NGS can perform complete de novo genome sequencing for pathogens not yet fully characterized, providing reference genomes for further study.⁶³

HIV-1 genotyping for drug resistance prediction is a prototypical example of another value added by an NGS approach since it is more sensitive than Sanger sequencing and can detect small percentages of mutant quasi-species of potential importance to clinical management. A caveat is the technical and informatics challenges associated with authenticating minor variant calling in these applications.⁶³ There are several challenges for pathogen testing such as separating microbial nucleic acid from human DNA, library preparation from non-sterile site samples, de novo sequence assembly of uncharacterized organisms, and assigning clinical significance to microbial sequences. Microbial profiling by NGS for clinical purposes is currently limited to laboratories with the expertise and resources to support independently developed assays since none have yet been commercialized to the extent necessary for widespread adoption. Several academic and commercial reference laboratories now offer NGS services to laboratories without the means to employ NGS technology on their own.

Next-generation sequencing can be applied to comparative microbiome characterizations in healthy and disease states or pre- and postinterventions. Next-generation sequencing characterization of the intestinal microbiome before and after fecal microbiota transplant (FMT) in cases of *Clostridium difficile* colitis has added to our knowledge of microbiome protection, microbial pathogenesis, and therapeutic efficacy of FMT.^{63,64} What we learn from NGS studies may create “personalized medicine for infectious diseases” by informing clinical management options and prognostication.⁶⁵

Next-generation sequencing utility has been demonstrated for microbial strain typing in epidemiological outbreak investigations, at least for those involving a limited number of strains or a single strain. A highly publicized example is the 2011 European shiga-toxin *Escherichia coli* outbreak during which NGS provided real-time de novo characterization of a novel outbreak strain.^{63,65}

Improvements are needed in order to make NGS an effective or adjunct tool for routine use in clinical microbiology, including commercialized, cost-competitive, user-friendly library preparation and instrumentation and software, standardized protocols and proficiency testing, well-curated reference genomes, and regulatory mandates revised to align with changing technology and practice. As previously mentioned, appropriate improvements in infrastructure may be required to accommodate the complex data to produce a succinct clinical report.

Next-Generation Sequencing Applications in Oncology

Next-generation sequencing tests for diagnosing and managing oncology patients have been used since the technology was utilized to diagnose patients with solid tumors⁶⁶⁻⁶⁸ or hematologic abnormalities.⁶⁹ The advantage of NGS lies in its ability to conduct large-scale inquiries for many sequence variants that are comprehensive, inclusive, and sensitive.^{70,71} Consequently, the technology can actually save costs compared to multiple, individual nucleic acid-based tests (such as fluorescent in situ hybridization, PCR/sequencing, etc). The small amount of tissue required may also obviate the need for an additional procedure, such as a repeat biopsy, to obtain sufficient material for analysis. Older methods required more nucleic acid which could not be extracted from biopsies, but the smaller amounts of tissue necessary for NGS may allow successful sequencing of the original biopsy.⁷² Next-generation sequencing offers clear advantages compared to the traditional one-gene one-test approach. Germline or somatic variants can be detected by NGS depending on the goal of testing. Libraries for somatic changes may be created from off-the-shelf panels or customized for individual types of malignancies. Previously, WGS and WES were not considered practical for routine clinical use; however, many academic laboratories and commercial vendors are developing test panels, using several genes or hundreds of genes,⁷³ to detect a variety of genetic/somatic variants in cancers. Testing somatic variants in tumor specimens requires sequencing at a higher depth (ie, 1000× average coverage) that is offered by targeted panels, in contrast to germline testing in which a lower sequencing depth (ie, 30× average coverage) may be undertaken to reliably detect variants.⁴² To assess the clinical relevance of sequencing results, several determinants are considered, including single-nucleotide polymorphisms, point mutations or single-nucleotide variants, nucleotide insertions or deletions, gene fusion/rearrangements, and copy number variations (see Table 1 for definitions). Next-generation sequencing tests can be DNA or RNA based, or both, depending on the purpose and design of the test. As the technology matures, test panel costs are becoming affordable for routine clinical use and are being rapidly deployed in laboratories. This is especially true in the field of oncology for diagnostic and prognostic purposes, as well as the selection of appropriate therapies.^{74,75} The NGS tool has become an important part of a personalized medicine approach to target therapy.

Next-generation sequencing has been used as a molecular diagnostic test for many solid tissue cancers as well as hematologic malignancies. Test results can be helpful for the initial diagnosis, tumor classification, determining the origin of the cancer, and prognosis.⁷⁶ Table 2⁷⁷⁻¹³⁰ provides a partial list of cancers where NGS information has provided value for managing patients. Thyroid nodules are a specific example where fine needle aspiration and cytologic examination may not yield a definitive diagnosis, while NGS has been shown to have high specificity and sensitivity for cancer detection.⁷⁷ However, not

Table 2. Examples Where NGS Provides Additional Information.*

Cancer	Clinical Application and/or Research Area
Thyroid cancer ⁷⁷⁻⁷⁹	Clinical application: Adjunct test to fine needle aspiration for the diagnosis of indeterminate thyroid nodules
Breast, ovarian, and endometrial cancer ^{45,80-86}	Clinical application: Diagnostic testing and identifying familial mutations
Melanoma ⁸⁷⁻⁹¹	Clinical application: Therapeutic decisions, prognostic value, and identifying inherited cancer risk
Colon cancer ⁹²⁻⁹⁶	Clinical application: Differential diagnosis, therapeutic decision, and inherited risk assessment for cancer
Lung cancer ⁹⁷⁻¹⁰²	Clinical application: Therapeutic decisions for non-small cell lung cancer (NSCLC)
Leukemia ¹⁰³⁻¹⁰⁵	Clinical application: Classification and prognosis at the time of diagnosis, therapeutic decisions, and determination of a different gene mutation profile at the time of relapse
Lymphoma ^{106,107}	
Head and neck cancer ¹⁰⁸⁻¹¹²	Research area: Potential prognostic implication and association with response to treatment
Sarcoma ¹¹³	Clinical application: Diagnostic, prognostic, and therapeutic decisions
Brain tumors ¹¹⁴⁻¹¹⁸	Clinical application: Prognostic and therapeutic decisions
Paraganglioma and pheochromocytoma ¹¹⁹⁻¹²³	Clinical application: Evaluation for hereditary paraganglioma/pheochromocytoma
Prostate cancer ¹²⁴⁻¹²⁶	Clinical application: Inherited risks for cancer and therapeutic decisions
Gastrointestinal stromal tumors ¹²⁷⁻¹³⁰	Clinical application: Inherited syndromes and prognostic and therapeutic decisions in KIT/PDGFR α wild-type GIST

Abbreviations: GIST, gastrointestinal stromal tumor; NGS, next-generation sequencing.

*Partial list of tumors/cancers where NGS has been shown to provide additional information.

all patients will derive enough clinical benefit to justify the cost of using NGS testing and careful test utilization is prudent.

A clear, clinically important use of NGS is to identify the most appropriate therapy for the individual patient.¹³¹ The National Cancer Institute's Molecular Analysis for Therapy Choice trial is a good example of how NGS technology can be utilized in clinical practice.^{74,75} Despite the promising clinical utility of NGS, the influence of molecular profiling on individual patient's targeted therapy has yet to reach its full potential. For example, the Integrated Molecular Profiling in Advanced Cancers Trial and Community Oncology Molecular Profiling in Advanced Cancers Trial (IMPACT/COMPACT) trial showed that only 5% of patients received targeted treatments based on their profiling results.¹³² While this is a relatively low number, the study did not comprehensively evaluate factors that may have influenced the targeted therapy. The trial was limited to specimens obtained many years prior to the molecular testing and did not profile the metastatic lesions, which may have yielded different molecular profile. Also some of the patients included in the study were heavily pretreated and were not well enough to receive further treatment based on the results of molecular testing. Molecular testing also did not include copy number variation or recurrent translocations, which may have influenced the therapeutic decision.

With the availability of clinical trials matching drugs targeting specific genetic alterations, many academic medical centers¹³³ and even larger community hospitals have begun to adopt NGS into their routine practice. Companion tests for targeted therapy are also in development. Among the current obstacles, preventing even wider adoption are the initial cost to purchase the instrument and complex bioinformatics to interpret the sequence data. Recently, commercial laboratories have entered into this market and competition will ultimately lower the cost and improve the quality of products. Future development will allow the NGS

technology to be more affordable with wider applications such as cell-free DNA for circulating tumor DNA detection or liquid biopsy.¹³⁴ These can potentially be used for monitoring disease progression, finding secondary mutations (such as mutations in epidermal growth factor receptor), minimal residual disease management,¹³⁵ and occult tumor detection.

Conclusion

Next-generation sequencing has become a widely used technology in the field of pathology. Several advances have reduced the time and cost of the test, while data analysis has extended the utility. Routine histopathology and diagnostic work will not be replaced in the near future, but NGS offers significant advantages in selected cases.

Declaration of Conflicting Interests

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The Pathology Workforce and Clinical Licensure: The Role of the PhD Clinical Laboratorian in the United States

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Abstract

There has been a recent recognition of the need to prepare PhD-trained scientists for increasingly diverse careers in academia, industry, and health care. The PhD Data Task Force was formed to better understand the current state of PhD scientists in the clinical laboratory workforce and collect up-to-date information on the training and certification of these laboratorians. In this report, we summarize the findings of the PhD Data Task Force and discuss the relevance of the data collected to the future supply of and demand for PhD clinical laboratory scientists. It is clear that there are multiple career opportunities for PhD scientists in academic medical centers, commercial clinical laboratories, biotechnology and pharmaceutical companies, and the federal government. Certified PhD scientists have and will continue to form an important resource for our technologically advancing field, bringing training in scientific methods, and technologies needed for modern laboratory medicine. The data gathered by the PhD Data Task Force will be of great interest to current and future PhD candidates and graduate PhD scientists as they make decisions regarding future career directions.

Keywords

laboratorian, pathology and laboratory medicine workforce, PhD clinical scientists, postdoctoral training

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Introduction

The workforce of professionals involved in pathology, laboratory medicine, and clinical laboratory science has been the subject of recent study. Much of this research has focused on the number of pathologists currently in practice,¹ the training of new pathologists,² the anticipated future demand for pathologist services,³ and the potential shortage of pathologists in the coming years.¹ The clinical laboratory technologist workforce has also been the subject of surveys and other studies.⁴ Less work has been done to address the supply of and demand for other members of the clinical laboratory team.⁵

In 2013, representatives of major pathology and laboratory medicine professional organizations gathered to assess the current state of the overall clinical laboratory workforce. The Pathology Workforce Summit, held in December of 2013 and cosponsored by the American Society for Clinical Pathology (ASCP), Association of Pathology Chairs (APC), College of

American Pathologists (CAP), and United States and Canadian Academy of Pathology (USCAP), involved a total of 24 pathology and other medical organizations (Table 1). Following a full day of live discussion, augmented by pre- and postmeeting

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Table 1. Pathology Workforce Summit Participating Organizations.

Participating Organizations
Academy of Clinical Laboratory Physicians and Scientists (ACLPS)
Accreditation Council for Graduate Medical Education (ACGME)– Pathology Residency Review Committee (RRC)
American Association of Neuropathologists (AAN)
American Board of Oral and Maxillofacial Pathology (ABOMP)
American Board of Pathology (ABP)
American Medical Association (AMA)
American Pathology Foundation (APF)
American Society for Clinical Pathology (ASCP)*
American Society for Investigative Pathology (ASIP)
American Society of Cytopathology (ASC)
American Society of Dermatopathology (ASD)
Association for Molecular Pathology (AMP)
Association for Pathology Informatics (API)
Association of American Medical Colleges (AAMC)
Association of Clinical Scientists (ACS)
Association of Directors of Anatomic and Surgical Pathology (ADASP)
Association of Pathology Chairs (APC)*
Canadian Association of Pathologists (CaAP)
College of American Pathologists (CAP)*
National Association of Medical Examiners (NAME)
Program Directors Section (PRODS) of APC
Society for Hematopathology (SH)
Society for Pediatric Pathology (SPP)
United States and Canadian Academy of Pathology (USCAP)*

* Summit cosponsors.

Table 2. Pathology Workforce Summit–Consensus Future Needs.

Workforce-related needs for the future
Better describe the work done by pathology and laboratory medicine professionals to a variety of audiences (the public, policy makers, medical students, each other, etc)
Recruit bright students into careers in pathology and laboratory medicine
Train students and residents to be highly employable upon graduation
Assess whether the current paradigm for training pathologists needs to be reformed, integrating residency, and fellowship training, to meet the needs of employers and of new-in-practice pathologists
Keep a continuous, real-time cycle of review that allows periodic assessment of evolving skills used in practice
Propagate an outlook of lifelong learning to maintain and enhance career opportunities and applicability to current health-care delivery systems and payment models

exercises, participants reached consensus on a series of workforce-related needs for the future (Table 2) and multiple follow-up activities to support these needs. An executive summary of the Workforce Summit and the Propositions can be found at the following links: <https://www.sponline.org/files/galleries/WorkforceSummitExecSummary14-01.pdf>; <https://www.sponline.org/files/galleries/WorkforceSummitPropositions14-01.pdf>.

One of the topics discussed during the Summit was the important role that PhD clinical scientists play as members of the clinical laboratory team. For many years, PhD-trained scientists have served as participants or leaders in various sections of clinical

Table 3. PhD Data Task Force Participating Organizations.

Organization Names
Academy of Clinical Laboratory Physicians and Scientists (ACLPS)
American Board of Bioanalysis (ABB)
American Board of Clinical Chemistry (ABCC)–American Association for Clinical Chemistry (AACC)*
American Board of Histocompatibility and Immunogenetics (ABHI)– American Society for Histocompatibility and Immunogenetics (ASHI)*
American Board of Medical Laboratory Immunology (ABMLI)– American Society for Microbiology (ASM)*
American Society for Clinical Pathology (ASCP)
American Society of Cytopathology (ASC)
American Society for Investigative Pathology (ASIP)
Association for Molecular Pathology (AMP)
Association for Pathology Informatics (API)
Association of Clinical Scientists (ACS)
Association of Pathology Chairs (APC)
College of American Pathologists (CAP)–Laboratory Accreditation Program (LAP)*

* Involved in certification of PhD clinical laboratory scientists or accreditation of clinical laboratories.

laboratories and as clinical laboratory directors. Although these roles are well established and many PhD scientists have received special training and, in most cases, subspecialty certification for this work, Summit participants agreed that there has never been a comprehensive accounting of the PhD clinical laboratory scientist workforce. Specifically, the number of PhD-trained scientists currently engaged in clinical laboratory practice is unknown, and there is no published national data on the number of PhD-holding scientists who currently receive fellowship training and/or subspecialty certification each year in clinical laboratory disciplines.

To better understand the current state of the PhD clinical laboratory scientist workforce and collect up-to-date information on the training and certification of these laboratorians, the PhD Data Task Force (PDTF) was formed as a follow-up to the Pathology Workforce Summit. Managed by the APC and made up of representatives of 8 pathology and clinical laboratory organizations and 4 additional organizations involved in the certification of PhD clinical laboratory scientists or accreditation of clinical laboratories (Table 3), the PDTF has compiled the most complete data set available, to date, on this important component of the overall clinical laboratory workforce.

In this report, we summarize the findings of the PDTF and discuss the relevance of the data collected to the future supply of and demand for PhD clinical laboratory scientists. There has been a recent recognition of the need to prepare PhD-trained scientists for increasingly diverse careers in academia, industry, and health care.⁶ The information gathered by the PDTF adds a significant new data set that may help inform organizational decisions and/or government policy regarding the future training and/or certification of PhD scientists for work in the clinical laboratory. These data will also potentially be of great interest to current and future PhD candidates and graduate PhD scientists as they make decisions regarding future career directions.

Background

Accreditation

Most clinical laboratories in the United States that test human specimens for the diagnosis and treatment of patients fall under the jurisdiction of the Clinical Laboratory Improvement Amendments (CLIA). There are a few exceptions such as drug testing laboratories for forensic or Department of Transportation testing, clinical trial testing, and government laboratories. The CLIA sets the minimum standard for clinical laboratories in the United States and is not limited to those laboratories receiving Medicare payments. Although states may enact statutes that are more stringent than CLIA, laboratories subject to CLIA must conform to both CLIA and state requirements.

The current form of CLIA was passed by the United States' Congress as Public Law 100-578 in 1988 (<https://www.gpo.gov/fdsys/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903.pdf>). Originally proposed in the late 1960s, CLIA'67, and its update CLIA'88, instituted standards for quality laboratory testing in the United States. These public laws were incorporated into regulations that were finalized in the Code of Federal Regulations (CFR) in 1972 and updated in 1992. Since then, there have been periodic updates, all of which are published in the Federal Register.

The CLIA is administered by the Centers for Medicare and Medicaid Services (CMS). In addition, other federal agencies such as the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention play roles in regulating how clinical laboratories operate in the United States. The CMS is tasked with enforcing regulatory compliance through conducting inspections for CLIA standards, approving private accreditation organizations that perform inspections, or approving exempt states (currently the only exempt states are Washington and New York). The CMS deems various accrediting organizations (AOs) to accredit laboratories for various specialties or subspecialties under CLIA. The 7 CLIA-approved AOs and the number of laboratories in their programs are listed in Table 4. The specialties or subspecialties that each AO can accredit can be found at www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOS-specialtiesSubs.pdf. In addition to this list, some of the AOs accredit laboratories for which CMS has not yet made a determination of CLIA coverage. Some examples of these types of laboratories are embryology and molecular diagnostic laboratories.

Credentialing

Personnel requirements for CLIA—covered clinical laboratory personnel are clearly outlined in the CLIA regulations. Although accreditation is a laboratory-focused process, credentialing an individual for a certain role in a clinical lab is a person-focused process.

Credentialing can take 2 forms, either certification or licensure. Certification is a process of recognition by a private certifying board (Table 5). Certification by a CLIA-approved board is based on education, experience, and knowledge (typically judged by examination). Licensure is a state-by-state system that defines, by statute, the tasks and function or scope of practice of

Table 4. CLIA Deemed Accrediting Organizations.

Organization	Number of Participating Laboratories*
Commission on Laboratory Accreditation (COLA)	6614
College of American Pathologists (CAP)	6237
The Joint Commission (TJC)	2209
American Association for Blood Banks (AABB)	202
American Osteopathic Association (AOA)	129
American Society for Histocompatibility and Immunogenetics (ASHI)	101
American Association for Laboratory Accreditation (A2LA)	Data not available

Abbreviations: CLIA, Clinical Laboratory Improvement Amendments; CMS, Centers for Medicare and Medicaid Services.

* As reported by CMS to CLIAC November, 2016.

Table 5. CLIA-Deemed Certification Boards*.

Board Names
ABB—American Board of Bioanalysis
ABB public health microbiology certification
ABCC—American Board of Clinical Chemistry
ABFT—American Board of Forensic Toxicology (limited to individuals with a doctoral degree) [†]
ABHI—American Board of Histocompatibility and Immunogenetics
ABMGG—American Board of Medical Genetics and Genomics (formerly known as American Board of Medical Genetics (ABMG))
ABMLI—American Board of Medical Laboratory Immunology
ABMM—American Board of Medical Microbiology
NRCC—National Registry of Certified Chemists (limited to individuals with a doctoral degree) [†]

Abbreviations: ABMGG, American Board of Medical Genetics and Genomics; CLIA, Clinical Laboratory Improvement Amendments; NRCC, National Registry of Certified Chemists.

*https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certification_Boards_Laboratory_Directors.html

[†] These boards certify nondoctoral individuals also.

a profession and provides that these tasks may be legally performed only by those who are licensed. As such, licensure prohibits anyone from practicing the profession who is not licensed, regardless of whether or not the individual has been certified by a private organization. Of those states that have licensure, some license the testing personnel (Medical Technologists and Medical Laboratory Technologists) only, some only the director and/or supervisor, and a few license both. However, the majority of states do not license clinical laboratory personnel. Most states use CLIA as the standard for qualifying personnel. Many states that require licensure use certification or passing a certification examination offered by an accepted board as part of their licensure requirements. Therefore, many individuals hold both a license and a certification. Accrediting organizations, in part, use certification and licensure in determining whether the laboratory personnel meet CLIA requirements as part of the laboratory's accreditation process.

The CLIA has defined 4 areas of complexity for laboratory testing, with different personnel requirements, or credentials, for each. The 4 test categories are: (a) waived, (b) provider-performed microscopy (PPM), (c) moderate complexity, and (d) high complexity. Waived tests are intended to employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; pose no reasonable risk of harm to the patient if the test is performed incorrectly; and have been cleared by the FDA. Examples include dipstick urinalysis, fecal occult blood, urine pregnancy, and group A *Streptococcus* antigen (Morbidity and Mortality Weekly Report Reports and Recommendations <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm>). No personnel requirements are found in the CLIA regulations for waived tests. All other categories are described as nonwaived. Non-waived tests are categorized in section 493.17 of CLIA.

A grading system is used to determine whether a test is moderate or high complexity. This system is outlined in subsection A of the CLIA regulations. In this system, each criterion receives a score of 1, 2, or 3, with 1 being the lowest level of complexity, and 3 indicating the highest level. If a test system or assay receives an aggregate score of 12 or less, then it is moderate complexity; scores greater than 12 are classified as high-complexity tests (42 CFR 493.17). Examples of moderate complexity tests are certain microbiological tests (such as bacterial culture, Gram staining, microscopic examination of certain slide preparations), urinalysis (such as osmolality or sediments), hematology (eg, automated procedures, manual white blood cell differential), and PPM such as analysis for fecal leukocyte examination or nasal smears for eosinophils (<https://www.cdc.gov/mmwr/preview/mmwrhtml/00016177.htm> and <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf>). All other clinical laboratory testing is referred to as high complexity, including, but not limited to, immunohematology, chemistry, cytology, histopathology, and histocompatibility.

The CLIA requirements differ for personnel who perform PPM, moderate- and high-complexity testing and thus are defined separately in 42 CFR 493 Subpart M. The regulations specify qualifications for the various positions and also define the functions and responsibilities for the persons who fill those positions. Moderate complexity laboratories require the following: (a) director, (b) technical consultant, (c) clinical consultant, and (d) testing personnel. High-complexity laboratories require the following: (a) director, (b) technical supervisor, (c) clinical consultant, (d) general supervisor, and (e) testing personnel. Persons who are qualified may perform the functions of more than one position in either moderate- or high-complexity testing. In other words, the same person may function as both the laboratory director and the clinical consultant or in some extreme cases, one person could qualify and function in all of the positions listed. A doctoral degree is not required to direct moderate complexity laboratories.

The remainder of this section will focus on high-complexity testing. The information provided here for high-complexity personnel requirements will be limited to those entering the field

today. If an individual works in a state that requires licensure the individual must meet that state's licensure requirements and maintain a current license in order to perform testing. Clinical laboratory directors and clinical consultants entering the laboratory field today must have earned a clinical doctorate (MD, DO, and DPM) or an earned doctoral degree (PhD, DSc) in a chemical, physical, biological, or clinical laboratory science. If acceptable to a CLIA-approved certifying board, the following degrees may also be acceptable: Doctor of Dental Surgery (DDS), Doctor of Dental Medicine (DMD), Doctor of Veterinary Medicine (DVM), Doctor of Public Health (Dr PH). In addition, all nonphysician directors must become certified and continue to be certified by a board approved by the US Department of Health and Human Services (42 CFR 493.1443; Table 5). Physicians must be licensed to practice medicine in the state in which they are serving as a director or clinical consultant. MDs and DOs must also be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent.⁷

Holders of other doctoral degrees (such as PhDs) must also be certified and continue to be certified by a board approved by the US Department of Health and Human Services (42 CFR 493.1443). The current approved boards are the following (Table 5): the American Board of Bioanalysis (ABB), the American Board of Clinical Chemistry (ABCC), the American Board of Forensic Toxicology (ABFT), the American Board of Histocompatibility and Immunogenetics (ABHI), the American Board of Medical Genetics and Genomics (ABMGG), the American Board of Medical Laboratory Immunology (ABMLI), the American Board of Medical Microbiology (ABMM), and the National Registry of Certified Chemists (NRCC; https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certification_Boards_Laboratory_Directors.html).

Certification requirements for the boards vary and there are no national education requirements for curricula for PhD laboratory directors. To be eligible to take the ABCC and ABMM/ABMLI certification examination or be certified to be an American Society for Histocompatibility and Immunogenetics (ASHI) director, postdoctoral fellows must complete 1 to 2 years in postdoctoral training programs approved by the Commission for Accreditation in Clinical Chemistry (ComACC), the Commission for Postdoctoral Education Programs (CPEP), or the ASHI, respectively.⁸⁻¹⁰ Candidates can also sit for the ABCC examination with 5 years of experience. Other boards, such as the ABB, require 4 years of experience, 2 of which must be at the supervisor or director level, to ensure that an individual meets CLIA requirements and has the appropriate level of experience to be a director.

Results

AAMC Faculty Roster

One source of data to inform our understanding of the current state of the PhD clinical laboratory scientist population in the

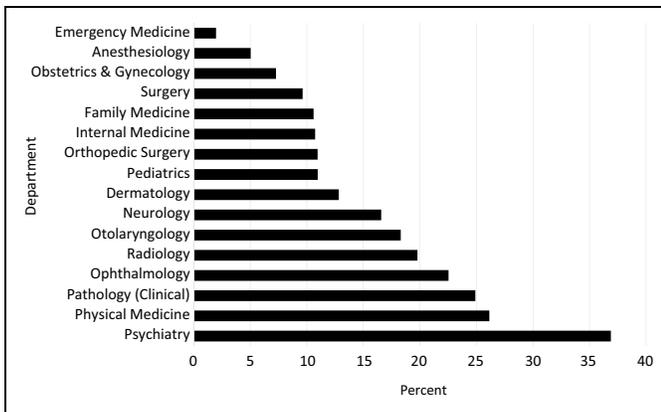


Figure 1. The percentage of US Medical School faculty who had PhDs or other health doctorates as reported by the AAMC Faculty Roster. The AAMC Faculty Roster (<https://www.aamc.org/data/facultyroster/reports/486050/usmsf17.html>) Table 6 was accessed on April 7, 2018 to determine the data shown. Other Health Doctorates are defined as doctorates in dentistry, veterinary medicine, public health optometry, and other health-related fields. This number does not include M.D./PhD faculty. For the purposes of the AAMC Faculty Roster report, faculty counts are broken out by department classification as opposed to exact department name (ie, Radiation Oncology and Diagnostic Radiology are both reported as “Radiology”).

clinical laboratory and pathology workforce is the Association of American Medical Colleges (AAMC) Faculty Roster.¹¹ The Faculty Roster contains records on active, full-time faculty at AAMC accredited allopathic US medical schools. As of April 2018, an average of 14.03% of US Medical School faculty in clinical departments had PhDs or other health doctorates (Figure 1). Perhaps not surprisingly, Pathology ranked third in the percentage of PhD faculty members, with 25%. Although these data indicate the significance of PhD scientists to the life of academic departments, PhD scientists included in these figures play a variety of important roles in pathology departments, with major contributions not only to the clinical workforce, but also to the research and teaching missions of their departments. However, it is important to keep in mind that academic medicine is only one small part of the clinical laboratory world.

College of American Pathologists (CAP) Laboratory Accreditation Program

A second approach to determine the size of the PhD clinical laboratory workforce is to evaluate the percentage of laboratory directors with PhDs. In March 2017, the CAP Laboratory Accreditation Program data indicated that in CAP-accredited laboratories, 740 of 8356 (8.9%) Laboratory Directors have PhDs (not including MD-PhDs, or DO-PhDs; Table 6). These laboratory directors must have both an earned doctoral degree and achieve board certification by ABB, ABCC, ABFT, ABHI, ABMGG, ABMLI, ABMM, or NRCC. However, CAP accredited laboratories represent less than half of the accredited clinical laboratories (see Table 4). It is possible that other AOs

Table 6. Degrees of the Clinical Laboratory Workforce as Determined by the College of American Pathologists (CAP) Laboratory Accreditation Program*.

Role	PhD			PhD Total	Non-PhD [†]	Grand Total
	PhD Only	MD-PhD	DO-PhD			
Director	740	754	13	1507	6849	8356
Staff pathologist	161	2046	10	2217	17622	19 839
Consulting pathologist	9	48	0	57	247	304
Administrator/manager	255	15	1	271	6485	6756
Section director	2626	2987	41	5654	29 272	34 926
Supervisor	911	148	0	1059	29 161	30 220
Cosupervisor	395	53	1	449	10 251	10 700
QA contact/manager	239	27	0	266	5457	5723

* These data are additive, meaning that every time the same person is identified in a different role, different section of the same lab, and/or in a different accredited lab, he/she is counted again, causing the numbers to be artificially high. In other words, the numbers represent the number of times a PhD and/or non-PhD is listed in any accredited lab.

[†] “non-PhD” means a person with any degree (eg, MD, DO, BS, MS, etc) other than a PhD.

may accredit laboratories that have proportionately different numbers of PhD directors.

National Science Foundation (NSF) Survey of Doctorate Recipients (SDR)

The NSF SDR managed by the National Center for Science and Engineering Statistics is a longitudinal biennial survey that provides statistical demographics about individuals with a research doctoral degree (PhD) in science, engineering, or a health field from a US academic institution (<https://www.nsf.gov/statistics/srvydoctoratework/>). In the most recent data published (2013 survey cycle), occupations related to a “clinical laboratory” are only broadly categorized, for example, “biological scientists,” or “medical scientists.” Likewise, the sectors of employment are even more broad, such as, “biochemistry/ biophysics,” “cell/molecular biology,” or “microbiology.” Although the intent of this biennial survey is to provide employment demographics and statistics on the science and engineering workforce, this lack of granular data limits the current usefulness of this survey to provide an accurate estimate of PhDs employed in the clinical laboratory workforce.

National Certification

An alternative method to assess the size of the PhD clinical laboratory workforce is to evaluate the number of board-certified specialists in various clinical specialties that are components of the clinical laboratory workforce. Several board examinations exist to certify individuals with PhD (and MD) degrees and these board are analogous to medical certifying

Table 7. Total number of MD, MD/PhD, and PhDs Certified by National Organizations (Current Through 2016).

Certifying Board	MD	MD/PhD [#]	PhD (%)	Unknown/Other	Total
ABB*	37	23	474 (86)	19	553
ABCC-Clinical Chemistry [†]	18	10	258 (85)	17	303
ABCC-Toxicology [†]	1	1	43 (91)	2	47
ABCC-Molecular Diagnostics [†]	11	4	35 (69)	1	51
ASM-ABMM [‡]	144	18	433 (62)	109	704
ASM-ABMLI [§]	25	5	94 (57)	42	166
ASHI-DTRC [‡]	22	17	58 (59)	1	98
ABFT-Fellow	-	-	183 (100)	-	183
Total:	258	78	1578 (75)	191	2105

Abbreviations: ABB, American Board of Bioanalysis; ABMM, American Board of Medical Microbiology; ABMLI, American Board of Medical Laboratory Immunology; ASHI, American Society for Histocompatibility and Immunogenetics. *Director (High-complexity Clinical Laboratory Director [HCLD] & Bioanalyst Clinical Laboratory Director [BCLD]) certifications only. There are additional PhDs with nondirector certifications.

[†]Active Diplomates as of January 1, 2017 (<http://www.abclinchem.org>).

[‡]17.8% International.

[§]8% International.

[‡]Number of HLA Lab Directors credentialed by ASHI Director Training Review and Credentialing Committee (ASHI-DTRC) from 2010 to 2016; Board Certifications: D(ABHI), HCLD(ABB), ABMLI.

[#]ASM database can only track one degree per account; therefore, the number of MD/PhD diplomates may be higher than documented.

boards organized by the American Board of Medical Specialties. These certifications are recognized by various federal and state agencies as necessary components to meet laboratory licensure requirements. The results of our analysis are shown in Table 7 for each of the deemed certifying boards (Table 5). However, it should be cautioned that once again these data are not complete or all inclusive.

The ABB is an international organization that certifies individuals as Technical Supervisors, Clinical Consultants, and Directors in chemistry, diagnostic immunology, hematology, microbiology, molecular biology (diagnostic), public health microbiology, andrology, and embryology (https://www.aab.org/aab/American_Board_of_Bioanalysis.asp). The ABB has indicated that of the 553 Director level diplomats, 86% are PhD-only individuals. The ABCC is the national organization that certifies individuals to practice clinical chemistry, toxicological chemistry, and molecular diagnostics (<http://www.abclinchem.org/>). The ABCC register of active diplomates indicates that there are 401 current active diplomates of which 336 (84%) are PhDs (Table 7). The ABMM and the American Board of Medical Laboratory Immunologists (ABMLI; both overseen by the American Society of Microbiology [ASM]) certify microbiologists and immunologists, respectively, to direct clinical and public health laboratories (<https://www.asm.org/index.php/professional-certification/abmm>). There are 870 diplomates certified by ABMM and ABMLI, of which 527 (61%) are PhDs. The ASHI provides training and credentialing for HLA Laboratory Directors. In the 7-year period

(2010-2016), there were 98 laboratory directors credentialed of which 58 (59%) were PhD scientists. The ABMGG certifies both MDs and PhDs in medical genetics and genomics. Several of their specialty examinations are available to both MDs and PhDs (http://abmgg.org/pages/training_options.shtml). Although ABMGG does not provide a breakdown of the number of certified specialists by degree, there have been a total of 1788 specialists certified according to statistics extending back to 1982 (http://abmgg.org/pages/resources_certspecial.shtml). These include 333 in Clinical Biochemical Genetics, 770 in Clinical Cytogenetics and Genomics, and 685 in Clinical Molecular Genetics and Genomics. It should be noted that these numbers may be slightly higher than the actual number of PhD Clinical Laboratorians, as some PhD may have more than one certification.

Fellowship Programs

Fellowship programs are one way to train PhDs in clinical laboratory sciences, and the other is on-the-job training. Fellowship programs are postdoctoral training programs that provide curricula that include not only traditional testing in clinical chemistry and/or microbiology/immunology but also emerging fields of study. In order to evaluate the capacity for training PhDs for the clinical laboratory workforce and for passage of the certification examinations discussed above, we evaluated the number of Clinical Chemistry Fellowship programs accredited by the ComACC, the number of Microbiology/Immunology Fellowship programs accredited by ASM/CPEP, and the number of Histocompatibility and Immunogenetics ASHI-approved Fellowship programs available for training of PhD graduates. These are postdoctoral training programs that provide curricula that include not only traditional testing in clinical chemistry, microbiology/immunology, and/or histocompatibility and immunogenetics but also emerging fields of study.¹² As of 2015, there were 20 ASM/CPEP accredited programs (17 that focused on Microbiology and 3 on Immunology), 32 ComACC accredited programs (30 in United States and 2 in Canada), and 7 ASHI-approved programs (Table 8). These programs have graduated a total of 164 fellows (68 in microbiology/immunology and 96 in clinical chemistry) over a 4-year span (2013-2016). This averages approximately 30 new fellows entering into the clinical laboratory workforce each year. However, as these fellowship programs are open to both PhD and MD postdoctoral trainees, this number will not be equivalent to the actual number of PhD scientists entering this workforce each year. Also, in August, 2017, the ABMLI will phase out its certification examination, but will continue to do recertification and maintain an active list of Diplomates. The ABMGG lists 44 accredited clinical laboratory training programs (24 in clinical biochemical genetics, 7 in laboratory genetics and genomics, 43 in clinical cytogenetics and genomics, and 42 in clinical molecular genetics and genomics). The list can be found at http://abmgg.org/pages/training_accredprog.shtml. However, it should be noted that this is not

Table 8. Accredited Training Programs*.

Fellowship Program Details	CPEP (Immunology)	CPEP (Microbiology)	ComACC [‡]
Total number accredited programs	3	17	32
Typical program length	2 years	2 years	2 years
Average total number applicants, per year*	138	689	NA
Average number applicants per individual program (2016)	40	40.5	NA
Average number positions annually per program	1 (0-2)	2 (1-3)	1 (0-2)
Approximate percent of positions filled in past 5 years [†]	95%	95%	86%
Number of graduates in past 5 years (total)	8	60	96

Abbreviations: ComACC, Commission for Accreditation in Clinical Chemistry; CPEP, Commission for Postdoctoral Education Programs.

*2013 to 2016; no data for CPEP Immunology in 2015.

[†]Calculated from the number of entering trainees (past 5 years) divided by the total number of available slots (in all programs during the past 5-year period).

[‡]There were 53 active trainees as of July 1, 2016.

a comprehensive data set, and the difficulties in finding comprehensive data on these types of postdoctoral clinical laboratory fellowship training programs may be one of the reasons that PhD scientists do not adequately consider directing clinical laboratories as one of their career options.

National Associations

There are a number of national and international associations for individuals who work within the clinical laboratory. The associations in many cases represent not only the workforce but laboratory owners as well. Their members form a very heterogeneous group with regard to the field of laboratory medicine. They represent not only medical schools and major hospitals but also small hospitals, independent laboratories, specialty laboratories, reference laboratories, niche laboratories such as molecular, embryology, and andrology laboratories, and emerging clinical laboratory fields. All of these offer opportunities for the PhD scientist. In fact, it is likely that directorship opportunities for PhDs are greater in some of the areas outside of the medical school and large hospital environment. Determining just where the greatest opportunities are made more difficult by the lack of data maintained by many organizations involved in laboratory medicine.

Discussion

This article provides data regarding the scope of involvement of PhD scientists in clinical laboratory oversight, and the pathways to preparation for careers in clinical laboratory medicine and certification in clinical laboratory specialties. However, defining the numbers of PhD scientists engaged in our clinical laboratories has been more challenging. Our data indicate that

there are 3536 PhD scientists currently serving as Directors, Section Directors, or Pathologists in clinical laboratories accredited by CAP (Table 6). This is 5.6% of the total workforce in these positions and this is potentially an underestimate, as these data are only representative of a fraction of the laboratories within the United States and because PhD scientists contribute to our clinical laboratories in roles other than laboratory directorships. Estimates of PhD workforce size could also be derived from data about entry and attrition, but these data, to our knowledge, are either not available (attrition) or incomplete (entry). Nonetheless, the descriptive overview offered in this article highlights organizations involved in the preparation of PhD scientists for employment in clinical laboratories and provides insights into the training programs and certifying examinations pursued by PhD graduates on the way to establishing careers in clinical laboratory science and medicine.

Certifying examinations exist for most clinical laboratory disciplines, representing important milestones on the way to laboratory directorships (Table 5). These examinations offer an objective approach to measuring knowledge and proficiency in one's area of specialization, and they are accepted components of meeting CLIA-specified qualifications for laboratory directorship. Our data indicate that there are only 1578 PhD scientists currently certified by national organizations (Table 7). This is <50% of the number of PhD scientists currently serving as Directors, Section Directors, or Pathologists in CAP-accredited clinical laboratories, and would appear to support the need for additional accredited training programs and training slots within the currently accredited programs. There are currently only ~34 CPEP (Microbiology) and 32 ComACC (Chemistry) positions available in any single year (Table 8). However, one limitation to expansion of these programs is funding. The current programs are usually supported by local institutional/departmental funds. This is in contrast to Graduate Medical Education for MDs (ie, residency/fellowship), which are primarily supported by the US government (Medicare). Since PhD scientists are being trained and certified alongside MD clinicians, one idea would be to make PhD clinical laboratory trainees also eligible for this type of US government funding. Another innovation might be to cross-train PhD clinical laboratorians, so that they have optimal job options (ie, have multidisciplinary programs that train in chemistry, microbiology, immunology, etc).

Training programs can represent an important pipeline of PhD entrants into the world of the clinical laboratory. As discussed, accredited programs offered by ComACC, ASM/CPEP, and ASHI provide educational experiences in clinical chemistry, microbiology, immunology, and histocompatibility and immunogenetics, which prepare PhD graduates for careers in laboratory medicine. Although the numbers of graduates from these programs are still relatively small, as needs for well-trained PhD laboratory directors grow, the potential for expansion of training opportunities exists.

One of the largest sources of information regarding potential workforce opportunities available to PhDs may be the many national organizations in the realm of laboratory medicine. However, the PhD scientist may not know of the existence of these sources. Efforts need to be made to educate PhDs and Fellows

about these sources of information during their training. National organizations can offer many training opportunities through conferences, workshops, hands-on workshops, seminars, webinars, and online learning for the PhD scientist. In addition, they are an excellent way to network with individuals already in the field and to explore options available to the PhD scientist. These organizations can spotlight the many, and diverse, opportunities available to the PhD scientist outside of the medical school or large hospital environment, many of which may offer greater leadership options for the PhD scientist.

Expanding PhD graduates' awareness of the excellent career choices that exist in clinical laboratory science and medicine represents a current need and opportunity. Many graduate school curricula do not dedicate much time to introducing this sector of career opportunities to students, and brief observational experiences may be the entire exposure that a student receives to clinical laboratory medicine. Integrating more information into these programs, either through curricular or extracurricular experiences, could enhance interest in pursuing a career direction that offers many advantages. In addition, national organizations like the National Postdoctoral Association (<http://www.nationalpostdoc.org/>) and the AAMC's Group on Graduate Research, Education, and Training (<https://www.aamc.org/members/great/>) provide professional development to and foster the exchange of information and ideas among the faculty and administrative leaders of biomedical PhD, MD/PhD and postdoctoral programs and would be excellent partners to enhance the involvement of academic pathology in order to inform trainees about certified training opportunities in the clinical laboratory for PhDs.

Whether targeting PhD graduate students, postdoctoral fellows, or faculty and administrators, a coordinated effort should be made to promote and advocate for the career opportunities available to PhD scientists in clinical laboratory medicine. These career opportunities exist in academic medical centers, commercial clinical laboratories, biotechnology and pharmaceutical companies, and the federal government. PhD scientists will likely form an important resource for our technologically advancing field, bringing training in scientific methods and technologies needed for modern laboratory medicine. Their integration into the laboratory workforce offers much to enhance the future of Pathology and Laboratory Medicine. Furthermore, strategies for collecting data and demographic information on PhDs in the clinical laboratory setting should be considered to provide a more complete and longitudinal perspective on the PhD workforce.

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The Evolution of Earned, Transparent, and Quantifiable Faculty Salary Compensation: The Johns Hopkins Pathology Experience

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Abstract

Faculty value equitable and transparent policies for determining salaries and expect their compensation to compare favorably to the marketplace. Academic institutions use compensation to recruit and retain talented faculty as well as to reward accomplishment. Institutions are therefore working to decrease salary disparities that appear arbitrary or reflect long-standing biases and to identify metrics for merit-based remuneration. Ours is a large academic pathology department with 97 tenure-track faculty. Faculty salaries are comprised of 3 parts (A + B + C). Part A is determined by the type of appointment and years at rank; part B recognizes defined administrative, educational, or clinical roles; and part C is a bonus to reward and incentivize activities that forward the missions of the department and medical school. A policy for part C allocations was first codified and approved by department faculty in 1993. It rewarded performance using a semiquantitative scale, based on subjective evaluations of the department director (chair) in consultation with deputy directors (vice chairs) and division directors. Faculty could not directly calculate their part C, and distributions data were not widely disclosed. Over the last 2 years (2015-2017), we have implemented a more objective formula for quantifying an earned part C, which is primarily designed to recognize scholarship in the form of research productivity, educational excellence, and clinical quality improvement. Here, we share our experience with this approach, reviewing part C calculations as made for individual faculty members, providing a global view of the resulting allocations, and considering how the process and outcomes reflect our values.

Keywords

academic relative value unit (RVU), performance-based incentive compensation (PBIC), research RVU (rRVU), faculty salary, Bonus/Supplement/Incentive (BSI) component

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Introduction

Johns Hopkins University School of Medicine is a well-known, top-tier medical school which opened in 1893 in Baltimore, Maryland. Since its inception, the medical school has been intimately associated with The Johns Hopkins Hospital, a medical center complex now comprising 37 buildings, 226 clinical services, and more than 1000 inpatient beds over 44 acres in East Baltimore. Nearly 1600 physicians and more than 600 trainees studying in 29 clinical residencies and 56 fellowship programs work at the hospital. The pathology department was one of the 4 founding departments of the medical school. It currently employs 97 full-time, tenure-track academic faculty with appointments at Johns Hopkins University. Its clinical faculty provide anatomic pathology and clinical pathology (AP and CP) services to The Johns Hopkins Hospital and several of its affiliated institutions. Our compensation plan does not apply to non-tenure-track faculty or staff pathologists. All faculty in our department have an academic component to their career, and all of our pathologists have “protected time” for scholarship and are expected to publish original research and teach. The mission of Johns Hopkins Medicine is to improve the health of the community and the world by setting the standard of excellence in medical education, research, and clinical care.

Faculty appointees in the School of Medicine are “tenure track” at the ranks of instructor, assistant professor, or associate professor, and professors are tenured. Each faculty member is hired with a complement of clinical, research, teaching, and administrative responsibilities, and all faculty are promoted through the same (one-track) process which evaluates candidates based on the quality of their scholarship and their impact on a field.¹ A departmental compensation plan comprised of 3 parts (A + B + C) was instituted by former Department Director (Chair) Fred Sanfilippo, MD, PhD, in 1993. It was the first of its kind implemented at the School of Medicine and informed recommendations of a school-wide Faculty Compensation Committee that convened between 1993 and 1997. Part A is formulaic and determined by the type of appointment (MD-trained, clinical faculty; PhD-trained, clinical faculty; and research faculty); academic rank (instructor, assistant professor, associate professor, and professor); and years at rank. Clinical faculty are paid on the same scale regardless of whether they contribute to AP or CP services. Part B is supplemental salary for leadership activities not directly related to scholarship, including administrative, educational, or clinical roles which are not directly related to scholarship. Part C (also known as the Bonus/Supplemental/Incentive [BSI] component) is a bonus to reward and incentivize activities that forward the academic missions of the department and the institution. These terms are unrelated to Medicare parts A-D.²

The compensation plan implemented in 1993 was shaped by numerous discussions involving the department’s Executive Committee and all department faculty and approved at a department-wide faculty meeting prior to its approval at the level of the School of Medicine. The 1993 policy for part C allocations rewarded performance “above expectations” in

Table 1. Recommendations of a Taskforce on Faculty Compensation.

- All clinical and basic science departments should have a transparent faculty compensation plan.
- Compensation plans should provide faculty with options for impacting their total compensation.
- All departmental compensation plans will be submitted and reviewed by the newly formed Faculty Compensation Committee.
- The Faculty Compensation Committee will be comprised of 8 members with representation for surgical, medical, hospital-based, and basic science departments as well as representation from the Office of Johns Hopkins Physicians and the Vice Dean for Faculty.
- Faculty Compensation plans should offer a minimum level of the Association of American Medical Colleges (AAMC) 25th percentile with an overall average compensation at the AAMC median.

research, teaching, patient care, and citizenship. Faculty could earn between 0 and 12 points; the monetary value of a point was assigned annually based on available funds. This plan was generally very well received as it provided feedback to faculty on their performance and rewarded outstanding accomplishments. It did, however, place authority over part C decisions solely with the department director in consultation with deputy directors (vice chairs) and division directors. Over the ensuing years, the need for transparency grew in importance, and 2 decades later, in 2013, a Johns Hopkins School of Medicine Faculty Satisfaction Survey found that school-wide nearly half of faculty were dissatisfied with the equity and transparency of their compensation.³ In response to the survey findings, an institution-wide Taskforce on Improving Faculty Compensation was convened, which made a series of recommendations in 2015 (Table 1).⁴ In keeping with these recommendations, we developed and implemented a transparent faculty part C compensation plan for our department. As with its predecessor, the updated plan uses a point system, and the value of each point is determined at the end of a fiscal year based on available funds. However, those activities that accrue points are now specifically delineated, so that each faculty member is able to calculate the impact of accomplishments on his or her bonus.

In developing the compensation plan presented here, we considered a number of broad issues. Foremost, we wanted to develop a plan to reflect the values of the department and of the institution. It goes without saying that these values are the major determinant to our work environment and bring exceptional faculty to the institution who are not here because of their compensation. We thus wanted a compensation plan that would align with and reinforce these values. Inherent in this concept is that the plan should reward activities in all areas of our tripartite mission. Research, teaching, and patient care are all incorporated in elements of the (A + B + C) compensation plan. Specifically, part C is intended to recognize and reward the myriad of individual faculty achievements and innovations that characterize large, multifaceted academic departments.⁵⁻¹² Second, transparency was paramount.¹³ Even an inviolably fair

plan that perfectly balances different interests, if opaque to our faculty, would fail to effectively communicate values and would fail to address a growing need for transparency. Third, while we wanted to use objective criteria wherever possible, we also wanted to avoid a plan that would be too prescriptive, and in so doing blunt creativity, especially in activities not as readily quantified. We wanted to invite faculty to document their work in select areas, develop processes for reviewing achievement, and find opportunities to highlight successes in venues that could be instructive for trainees and junior faculty. Finally, we wanted a plan that would promote diversity and not compound gender biases.¹⁴⁻¹⁶ Equal opportunity was considered in its design, and periodic reviews of dollars awarded were expected to show equitable distribution between men and women.

Having now 2 years of experience with this policy, we took the opportunity to review part C point distributions and consider how well the process and outcomes are serving the interests of the department and its faculty.

Methods

Part A Predicted Salary Regression

Linear regression formulae (coefficients), correlation (r^2) and significance (F) values, and residuals were determined using the Analysis ToolPak add-in in Microsoft Excel for Mac (version 16.12). Salaries (dollars earned) are plotted on a linear scale without log transform. Clinical faculty were restricted to MD (or equivalent)-trained, practicing pathologists on the AP or CP services. The Department Director was excluded.

Density Plots

Density plots were generated using *R* via the Rstudio console. The (*S3*) generic function *density* was used with default parameters for kernel and bandwidth. For overplots, individual graphs were generated to determine axis settings (*xlim*, *ylim*), and then the *par()* function was used to generate the combined graphic. Transparent fills were added using the *polygon()* function with $\alpha = 0.5$.

Bar Plots

Bar plots to compare faculty of different academic ranks were generated in Microsoft Excel. These are not conventional box and whiskers plots; they show the average (mean) points earned rather than the median points earned for each group. "Whiskers" indicate the standard deviation. Gray boxes show boundaries of the first (lower) and third (upper) quartiles. *AVERAGE()*, *STDEV()*, and *QUARTILE.INC()* functions were used.

Findings

Parts A and B

Part A salary is intended to reflect 3 factors: (1) type of appointment (eg, MD-trained, clinical faculty; PhD-trained research

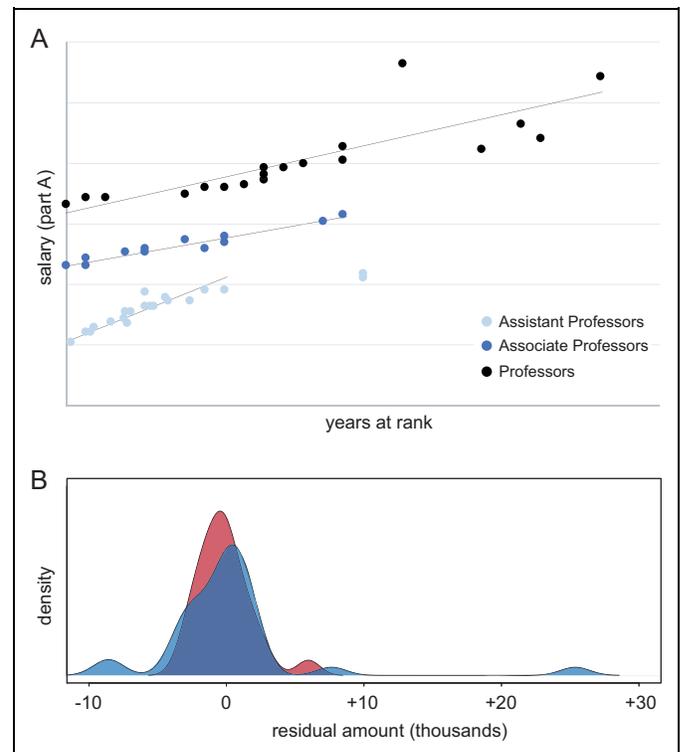


Figure 1. Base salary (part A) analysis. A, Base salaries for MD-trained, clinical faculty are shown. Faculty salaries are plotted in dollars on the y-axis versus years at rank on the x-axis. These are color coded as 3 groups corresponding to academic rank: assistant professors (light blue), associate professors (medium blue), and professors (dark blue). For each group, a linear regression shows the relationship between salary and years at rank. B, Residual amounts by gender. For each point, the distance between actual salary and salary predicted by the corresponding linear regression (ie, the residual) was determined. The density plot shows the frequency of residual amounts by gender (men, blue; women, red). A vertical line is drawn at zero; faculty paid exactly what would be predicted by their academic rank and years at rank contribute to area under the curve at this mark. Most residual variations in salary are less than $\pm \$5000/\text{year}$. Outliers on the right side of the plot are paid more than predicted; outliers on the left are paid less than predicted. These include 1 woman (residual more than $+\$5000$) and 4 men (2 residuals less than $-\$5000$; 2 residuals more than $+\$5000$). The 4 men are professors with more than 15 years at rank.

faculty), (2) academic rank (eg, assistant professor, associate professor, and professor), and (3) years at rank. To examine how well these factors alone predict actual salaries, we plotted salaries versus years at rank for different types of appointments and academic ranks. Figure 1A illustrates this for clinical faculty. Only MD-trained practicing pathologists were used in this analysis ($n = 61$), and the Department Director was excluded. Linear regressions were used to assess the relationship between seniority and salary. Part A dollar amounts were used directly without log transform or outlier exclusion, and we included all professors, and all assistant and associate professors at rank for less than 15 years.

Overall, regression analysis showed strong linear correlations between salary and years at rank. The correlation

Table 2. Part B.

- Deputy directors of the department
- Division directors
- Associate division directors
- Educational roles (residency program director, fellowship director, and director of the pathobiology training program)
- Institutional review board member
- Director of clinical service or specific labs
- Physician advisor*

*Helps the department meet regulatory requirements for staff and faculty appointments and acts as a liaison with other clinical departments.

coefficient (r^2) values range from 0.70 to 0.95 (0.70 [for professors], 0.89 [for assistant professors], and 0.95 [for associate professors]); F values are highly significant ($P < .0001$) for all faculty subgroups. The large majority of residual values (ie, discrepancies between predicted and actual pay) were less than 5000/year. Most (4/5) “outliers” with higher or lower salaries than predicted (residuals $> \pm \$5000$) represent historical commitments made to senior professors at rank for more than 15 years, where the linear relationship is less strong. For the second major group of faculty (PhD-trained researchers, $n = 22$), r^2 values range from 0.65 (for associate professors) to 1.0 (for assistant professors), and F values range from 0.016 (for associate professors) to <0.0001 (for assistant professors; data not shown). Two “outliers” had actual salaries $> \pm \$5000$ discrepant with predicted.

To test for gender equity, we compared residual values for men and women (Figure 1B). This showed a small difference of the means ($d = -\$227.$) favoring male faculty which was not statistically significant ($P = .82$, t test). Residual values for female clinical faculty were less variable; the standard deviation for women was $\pm \$843$ as compared to men $\pm \$1812$. The latter reflects the effect of the senior professor “outliers” on both sides of predicted, all of whom are men.

Part B salary is attached to specific administrative roles, as detailed in Table 2.

Historic Process for Part C

Our original part C policy was developed in 1993 using recommendations of a dedicated subcommittee, followed by discussions with the department’s Executive Committee, and the full faculty. A guiding principle of the policy was that the system be straightforward: “First, it was felt strongly that the plan should be simple in concept and implementation.” Four categories of consideration were outlined (Table 3), and the director assigned points to each faculty member based on performance relative to expectation. Expected levels of productivity in a category were recognized with 1 point, and achievement above (or below) expectation would be assigned more (or fewer) points up to a total of 3 points/category, or 12 points total. The policy eschewed objective measures of accomplishment, “the distribution formula should not be tied directly to quantitative measures of activity in any area (eg, dollars of

Table 3. Rating Factors for Determining Part C Compensation, 1993.

- 1) Clinical service:
 - Clinical effort
 - Entrepreneurship
 - Attendance and participation in clinical conferences
- 2) Teaching:
 - Medical student teaching
 - Resident/fellow training
 - Graduate student teaching
 - Entrepreneurship
 - Interdepartmental conferences and seminars
- 3) Research:
 - Grants and contracts
 - Publications
 - Development of technology
 - Entrepreneurship
- 4) Department/institutional activity/recognition:
 - Committee work/service (departmental, institutional, extramural)
 - Participation in departmental activities
 - Special awards/recognitions/presentations
 - Extraordinary contributions to department income
 - Entrepreneurship

clinical revenue generated, dollars of grant support, number of publications, number of hours teaching, etc.). It was considered far preferable to use a relatively subjective scale for each of the four major areas under consideration.” Subjectivity was introduced in assessing accomplishment but also in gauging this against expectations for productivity; the policy statement specifically noted these would vary for each member of the faculty.

Part C assignments were made annually after individual one-on-one meetings between each faculty member and the department director to discuss their achievements relative to expectations and to agree on expectations for the coming year. Further, each faculty member’s division chief, as well as appropriate members of the executive committee also provided scored input on each faculty member’s achievements, roles, and responsibilities.

Current Process for Part C

Our current iteration of part C policy borrows 2 aspects from its predecessor: (1) using a point-based system to determine proportions for some profit sharing and (2) considering the totality of each faculty member’s contributions across the distinct missions of Johns Hopkins. Our major departures from the 1993 policy are a new emphasis on quantitative, objective measures of accomplishment, and increased transparency. Part C payments are accessible to all tenure-track faculty. However, individuals who do not fund a minimum of 50% of their salary through either clinical or research activities for 2 years in a row, receive salary support in lieu of part C bonus. In practice, this jeopardizes part C for research faculty who rely on external sources for salary support and whose part A salaries become the obligation of the department when there are shortfalls.

Table 4. Part C Point Assignments for Teaching, 2015.

- National or international teaching award, 25 each.
- Teaching award presented by the School of Medicine, 10 each.
- Lecturers ranking in the top 20th percentile of the medical school, 10 per course.
- Books, 10 each.
- Completing a faculty development course to improve teaching or mentorship, 5.
- Electronic media teaching applications, 2 each.
- Invited presentations to national or international meetings,* 2 each.
- Disproportionate effort in formal teaching as determined by deputy director for education, 5.

*Restricted to junior and midcareer faculty.

Minimum standards of professionalism and civility are also deemed prerequisite for part C eligibility. Faculty are provided with a worksheet each year (Supplemental File 1) for reporting points earned. Completed worksheets are reviewed for accuracy by the department assistant administrator.

Clinical work is rewarded monetarily through all salary components (A + B + C). Part A salary scales for clinical faculty are higher than for research faculty, and Part B payments for Division Directorships are almost always given to physicians and PhD-trained clinical faculty. Because we value subspecialty clinical expertise, and because clinical relative value units vary extensively across different subspecialty services, we do not use these as measures for determining part C compensation. However, we do recognize those few exceptionally productive (outlier) clinical faculty with a percentage of revenues generated (profit–loss) above a defined threshold. Although clinical revenues are not used to assign points for part C compensation, clinical activities in the areas of patient safety and quality assurance (QA) are considered in part C calculations (see below).

Teaching excellence and educational efforts are recognized using a hybrid of fixed part C monetary payments and earned part C points. Administrative educational roles within the department come with an associated part B component (Table 2). For example, the directors of our Residency Training, Fellowship Training, and Pathobiology Graduate Programs receive part B remuneration for these roles. In addition, annually, trainees in the department select recipients of the Anatomical Pathology Faculty Teaching Award, Clinical Pathology Faculty Teaching Award, and the Pathobiology Graduate Program Teaching Award. These are given as monetary awards rather than bonus points, as we did not want their value to fluctuate year to year. Other educational accomplishments earn part C points (Table 4). For example, part C points are used to recognize teaching awards received from outside the department (10–25 points each), medical school lectures ranked in the top 20th percentile (10 points each course), disproportionate educational effort (time commitment), and key contributions in lasting media including books and iPad applications (2–10 points each). Reflecting departmental priorities, authoring

Table 5. Part C Point Assignments for Research, 2015.

- First or senior author publication, impact factor (IF).
- Second author publication,* IF/2.
- Middle author publication, IF/10.
- Principal investigator (PI) of an awarded, nationally competitive research grant, 10 each.
- PI of a submitted, large (division/department-wide) funding application, 20 each.

*Restricted to junior faculty.

review articles or book chapters is not incentivized. Participation in faculty development courses to improve teaching is rewarded (5 points each). Invited presentations at national and international meetings are credited only for assistant and associate professors to encourage their engagement in their respective fields. Faculty can objectively tally part C points earned for all teaching categories with the exception of that for *disproportionate effort in formal teaching*, which allows additional points to be assigned by the deputy director for education for those faculty whose student contact hours exceed 2 standard deviations above the departmental mean.

Research accomplishments are rewarded exclusively through the part C point system (Table 5). We recognize 2 categories of achievement, (1) primary peer-reviewed research publications and (2) grants awarded for research projects. Points are earned for publications proportional to the impact factor (IF) of the publishing journal (Thomson Reuters [Toronto, Canada] IF). This reflects the value we place on high-impact original science and allows us to contemporaneously recognize publications without a waiting period for a paper's citations to accrue. We reward first and senior authorships (point value = IF) more than middle authorships (point value = IF/10). To promote equitable collaborations, shared first and senior authorships are equivalent in weight to those that are solely first or last authored. There is a special category for second authorships for instructors and assistant professors (point value = IF/2). Principal and coprincipal investigators (PIs) of nationally competitive, peer-reviewed research grants greater than \$100,000 in direct costs/year are assigned 10 points for each year of the grant. Coinvestigators and collaborators do not earn points for grant awards since these roles typically require less effort and since the awards are not credited to our department for national and institutional rankings. In recognition of the extraordinary effort required and the value of large grant awards to the department, points are also earned for PIs or overall Program Leaders on first-time *submissions* of Institutional Training (T32) grant applications, Research Program Project and Center grant applications, and Specialized Programs of Research Excellence applications. These must be submitted through our department and directly benefit trainees and teams of investigators beyond a single faculty member's research program.

Rewarding faculty achievements in QA and quality improvement (QI) is an important new addition to the new part C policy, recognizing contributions to patient safety, reduction

Table 6. Part C Point Assignments for Quality Assurance (QA) and Quality Improvement (QI), 2015.

- Significant achievement, as approved by the deputy director for QA and QI, 25.
- Mentoring a trainee project, as approved by the deputy director for QA and QI, 10.
- Contributing to practice guidelines, as approved by the deputy director for QA and QI, 5.
- College of American Pathologists (CAP) inspection team leader, 20.
- CAP inspection team member, 5.

of costs, and efforts to increase value in clinical encounters (Table 6). Determining whether a project meets criteria for point allocation requires judgment, and points are therefore reviewed and approved (or withheld) by the deputy director for QA and QI and the staff Director of the Pathology Department Continuous Quality Improvement Office. All faculty can prepare a project summary for consideration (as detailed in our School of Medicine Professional Development Guide for Faculty¹⁷), and projects deemed excellent (25 points) are presented at our Department Grand Rounds to highlight faculty opportunities in QA and QI. Faculty who mentor clinical residents or fellows addressing a patient safety situation, conducting projects to improve outcomes, or achieving cost savings can submit descriptions of these activities (10 points). Faculty who contribute meaningfully to new practice guidelines (5 points) or who conduct lab inspections for College of American Pathologists (5-20 points) are also recognized. It should be noted that in the second year of offering quality-associated part C points, submissions of faculty quality projects tripled.

Finally, additional categories exist for rewarding and incentivizing efforts that enhance the broader academic community. The department is dedicated to promoting diversity, and considerable bonus points (25 points) can be earned for significant contributions to support diversity in the department as determined by the director of diversity for the department. Recognizing the potential of disease-specific websites to bring philanthropic donations to the department, a one-time bonus (US\$2000) is given to faculty who create a new disease-specific website. Our department director also reserves the capacity, in exceptional circumstances, to add to faculty bonuses through part C. These director-assigned dollars have comprised less than 10% of the total part C dollars allocated.

Part C Point Distributions

In the first year (2015 to 2016), a total of 2895 part C points were earned: 2202 (76.1%) for research, 513 (23.3%) for education, and 180 for other categories. Similarly, in 2016 to 2017, a total of 2729 part C points were earned: 2034 (74.5%) for research, 450 (16.5%) for education, and 245 for other categories. Table 7 shows points earned in each category, and Figure 2A illustrates the distribution of total points earned over both years. Subdividing 2016 to 2017 research points: 1109 (54.5%) were earned for primary publications where the faculty member was the first or

Table 7. Part C Points Awarded, 2015 to 2017.

Category	2015-2016	2016-2017	Total
Research	2202	2034	4236
First or senior author publications	1219	1109	2328
Research funding	580	624	1204
Other authorships	403	301	704
Education	513	450	963
Teaching	160	150	310
Presentations	186	160	346
Books, media	152	110	262
Faculty development	15	30	45
Quality	155	170	325
Diversity	25	75	100
Total	2895	2729	5624

last author of the paper; 301 (14.8%) were earned for other authorships including middle authorships; and 624 (30.6%) were earned for research grant funding. Education points from this more recent year can be similarly subdivided: 150 (33.3%) were earned for in-house teaching; 160 (35.5%) for presentations outside of Johns Hopkins; 110 (24.4%) for books and iPad applications; and 30 (6.7%) for faculty development activities. A total of 170 points were approved for QA/QI projects, and 75 points recognized faculty engagement in activities to promote diversity.

Most faculty acquired points for publishing first or last author primary peer-reviewed research papers (average = 13.4 ± 17.2 , and 11.4 ± 15.2 , respectively, for 2015-2016 and 2016-2017, Figure 2B). While most earned fewer than 20 IF points for these publications in total, 18 (18.5%) faculty exceeded this amount in 2016 to 2017. Five "outliers" had more than 50 points that year, with 1 individual with a single high-impact paper (*New England Journal of Medicine*) earning 72 points. Forty-one (41.2%) of our faculty received points as PIs of qualifying research grants (Figure 2C) in 2016 to 2017. Of funded investigators that year, 4 were "outliers" with more than 30 points in this category. To test whether we are rewarding essentially the same individuals across these 2 subcategories (ie, individuals obtain grants which allow them to publish more), we looked at the relationship between points awarded for research funding and points for first and last author publications (Figure 2D). These 2 variables are not entirely independent (correlation coefficient, $r^2 = 0.45$). That is, productive faculty on 1 axis were likely to also be successful on the other. However, there are several whose annual accomplishments would not be recognized were we to use *either* publications or funding as a simpler surrogate for research productivity. Insufficient time has elapsed since instituting the policy to allow for longitudinal analyses to see whether publications follow influxes of research funding. Successful faculty tended to perform well over both years of the analysis ($r^2 = 0.33$, Figure 2E).

No consistent differences were apparent considering average part C points as a function of the type of faculty appointment (clinical vs research), area of pathology (AP vs CP), or

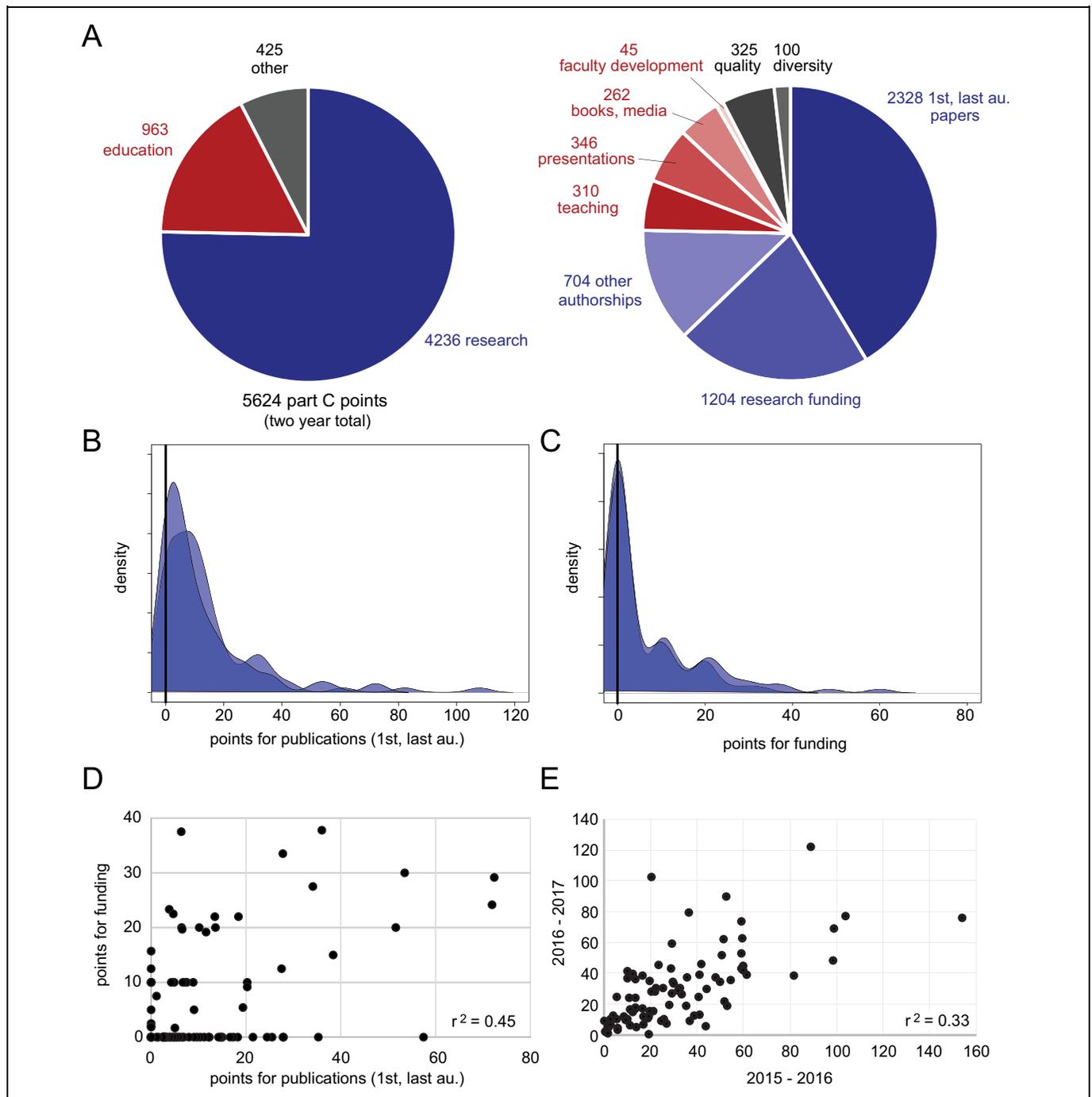


Figure 2. Bonus (part C) analysis by activity. Note that some activities, including clinical productivity, are not recognized with part C points. A, Part C points allocated over 2 years, 2015 to 2017. About 3 quarters of points were awarded for research activities (blue, 4236 points, 75.3%) with the remainder recognizing educational (963, 17.1%) and other (425) contributions. These categories are further subdivided in the pie chart on the right. Research is subdivided as: (1) points for first and last author publications (2328, 55.0% of research points), (2) points for research grant funding (1204, 28.4%), and (3) points for other authorships including middle authorships (704, 16.6%). Education is subdivided as: (1) points for in-house teaching (310, 32.2% of education points), (2) points for presentations outside of Johns Hopkins (346, 35.9%), (3) points for books and iPad applications (262, 27.2%), and (4) points for faculty development activities (45, 4.7%). Other includes 325 points awarded for quality assurance and quality improvement projects (5.8% of total) and 100 points for contributions to promote trainee and faculty diversity in the department (1.8% of total). B, Density plots showing the distribution of faculty receiving points for research publications (x-axis) each year. A vertical line is drawn at the origin. Most faculty received some points for first and last author publications. Data for 2015 to 2016 and 2016 to 2017 are superimposed. C, Density plots showing the distribution of faculty receiving points for research funding (x-axis) each year. D, Pairwise comparison of points for first and last author publications versus points for research funding, 2016 to 2017. Correlation coefficient (r^2) = 0.45. E, Pairwise comparison of total part C points for 2015 to 2016 versus 2016 to 2017 (r^2 = 0.33).

department division (for divisions with >5 faculty). Dually trained faculty with MD and PhD degrees received more part C points than those with either MD or PhD degrees both years, averaging 6.9 points more than the second-ranked group (MD faculty) in 2015 to 2016 and 3.5 points over the second-ranked group (PhD faculty) in 2016 to 2017.

Part C Points as a Function of Gender

We next looked at gender as a factor in part C point allocations. The 2016 Report on the Johns Hopkins School of Medicine Faculty Salary Analysis found that when A + B salary components were considered, women faculty across the entire School of Medicine were paid 1.9% less than their male colleagues in FY2015; this difference increased to 6.8% when A + B + C components were considered.¹⁸ Thus, across the entire medical school, part C payments have been a source of significant differences between male and female faculty. Analyzing our Department's total part C point allocations under the new policy, we find nearly equal distributions of points between male versus female faculty (Figure 3A).

In 2015 to 2016, women made up 39% of our faculty (35/91) and earned 33% of part C points (943/2895). Although men thus earned more part C points per person (mean = 35 points/male vs 27 points/female), the difference was not statistically different (2-tailed *t* test, *P* = .18). Of the 186 fewer part C points earned by women faculty, the shortfall appeared multifactorial, with first and last author research publications (−90 points) and other authorships (−56 points) being the largest contributors. In 2016 to 2017, women comprised 38% of faculty (37/97) and earned 37% of part C points (1004/2729, *P* = .75), and the distribution of points to women in major categories related to research was comparable to men. Density plot overlays for men and women faculty are superimposable (Figure 3B and 3C). In both years evaluated, female faculty were represented among the “outliers” for research publications and research funding.

Over both years, women were less likely than men to earn points in education (Figure 3D), and multiple subcategories contributed to gender differences in education points earned, including those recognizing: (1) high-ranking medical school lectures, (2) national and international teaching awards, and (3) textbook authorships.

Part C Points as a Function of Academic Rank

We also reviewed academic rank as a factor in part C point allocations, comparing point distributions among the assistant professors, associate professors, and professors (Figure 4A). Not surprisingly, more part C points are earned by senior faculty. In 2015 to 2016, assistant professors (*n* = 21, 23% of faculty) earned 412 (14%) part C points (average = 19.6). Associate professors (*n* = 30, 33% of faculty) earned 984 (34%) part C points (average = 32.8); professors (*n* = 40, 44% of faculty) earned 1499 (52%) part C points (average = 37.5). In 2016 to 2017, these proportions shifted, and assistant

professors (*n* = 29, 30% of faculty) earned a larger share of points, 634 (23%, +9%) with relative reductions for associate professors (32%, −2%) and professors (45%, −7%), but the change was not significant (*P* = .25 χ^2 test).

We next broke down the 2 largest research categories—first and senior authorships and grant funding—to see averages and point distributions for the 3 academic ranks. In both years, the average points earned for publications was 9 to 10 points, comparable for assistant (9.2 in 2016-2017) and associate (10.0) professors and higher for professors (14.0; Figure 4B). The standard deviation associated with these point distributions increased with academic rank, such that associate professors and professors are overrepresented among the “outliers.” Professors were also the most successful group garnering research funding (Figure 4C). A stepwise increase with academic rank was apparent in average points for funding. In 2016 to 2017, assistant professors, associate professors, and professors received averages of 2.6, 7.4, and 8.4 points, respectively. The upper boundary of the third quartile (Q3) also reflect this trend. Only 7/29 (24%) of assistant professors acquired points for research funding, and the Q3 upper boundary remains at zero. For associate professors, the Q3 upper boundary is 10 points (1 major grant award). For professors, the Q3 upper boundary is 17.5 points, showing a separation of 7.5 points in favor of professors over associate professors.

No consistent relationship was seen between academic rank and overall part C points earned in education. Professors tended to earn more points for high-ranking medical school lectures and for national and international teaching awards. These were balanced by points for invited presentations at national and international meetings, which are only awarded to assistant and associate professors.

Discussion

Here, we describe faculty compensation practices at Johns Hopkins' department of pathology in some detail. Our system includes 3 salary components: part A compensation (or base salary), which is determined by the type of appointment and affected by years at rank; part B salary, which is attached to defined administrative roles in the Department; and a part C BSI component. The (A + B + C) plan was developed 25 years ago by the Department's leadership with the approval of its faculty, and it continues to be in use today. We use this (A + B + C) structure to recognize all missions of the department and institution—patient care, teaching, and research. Here, we describe recent changes focused on enhancing transparent calculations of part C. Most recently, part C bonuses have amounted to 9.7% of total faculty compensation (A + B + C).

Routine clinical activities are rewarded monetarily, with higher based salary scales (part A) and opportunities to assume clinical leadership positions (part B). Clinical “outliers,” extraordinarily high-volume surgical pathology faculty with busy consult services, are compensated monetarily through part C as a percentage of clinical revenue through profit generated above a defined threshold. The part C point system, which

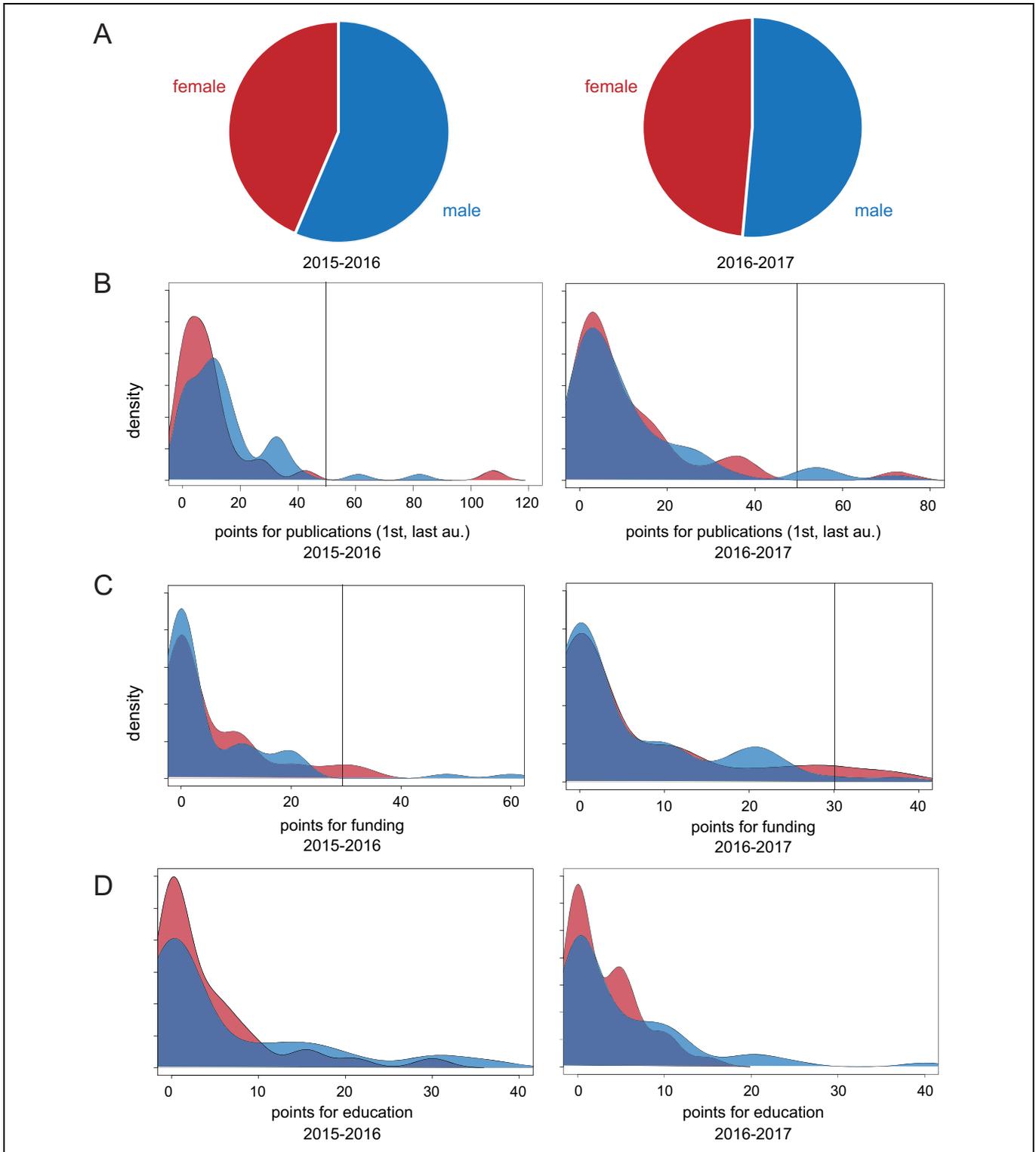


Figure 3. Bonus (part C) analysis by gender. A, Pie charts show part C point allocations for men (blue) and women (red) in 2015 to 2016 (left) and 2016 to 2017 (right). Total part C points were divided by numbers of faculty. Women made up 38% to 39% of faculty and earned 33% of part C points in 2015 to 2016 (943/2895) and 37% of part C points in 2016 to 2017 (1004/2729). B, Density plots showing the distribution of faculty receiving points for first and last author research publications (x-axis) each year by gender. In 2015 to 2016, the first and last author research publications subcategory contributed most to the gender difference. Both men and women are represented among “outliers” (>50 points, vertical line) for first and last author research publications in both years. C, Density plots showing the distribution of faculty receiving points for research funding (x-axis) each year by gender. Both men and women are represented among “outliers” (>30 points, vertical line) in both years. D, Density plots showing the distribution of points for education each year by gender.

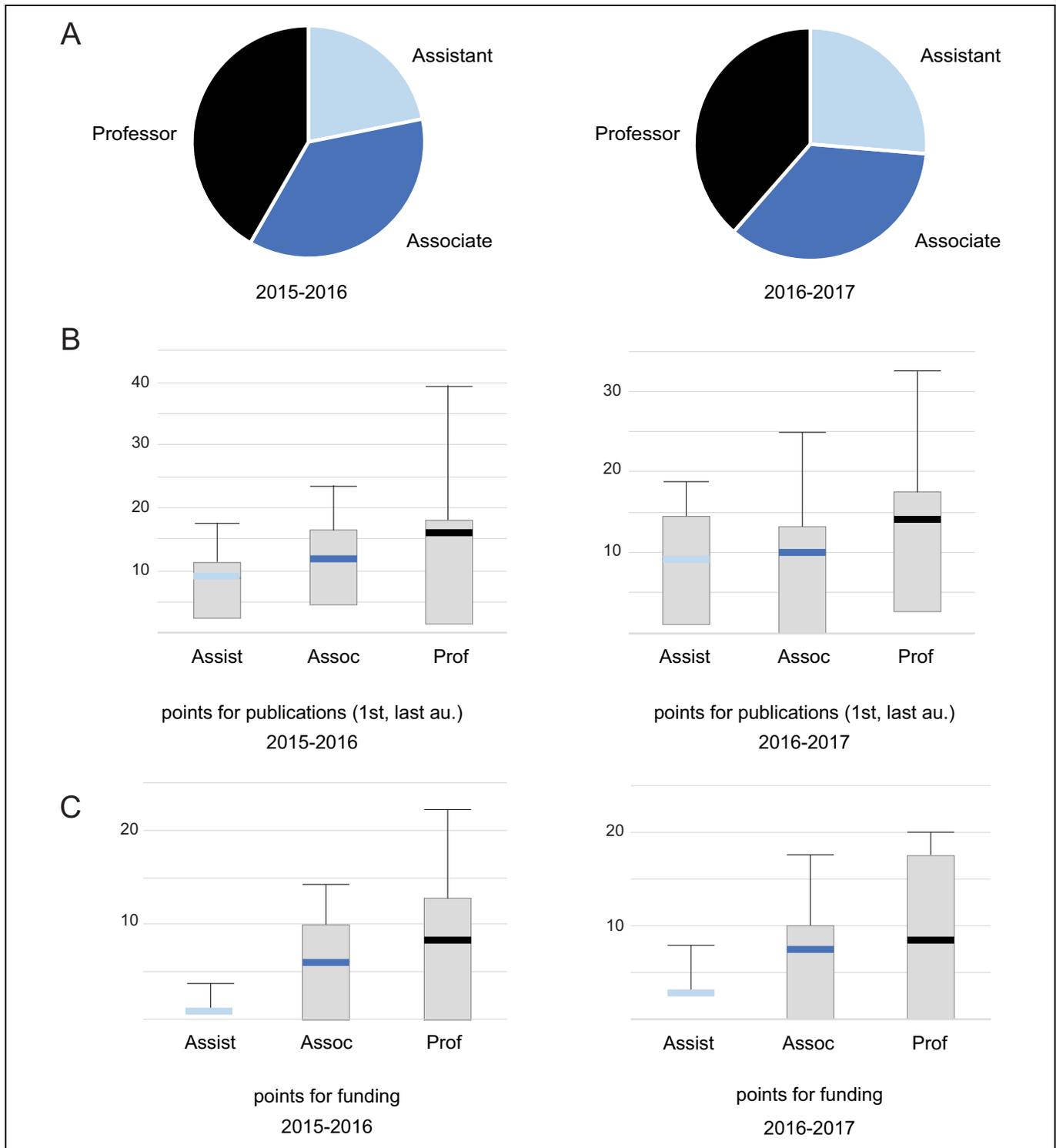


Figure 4. Bonus (part C) analysis by academic rank. A, Pie charts show part C point allocations for different academic ranks, assistant professors (light blue), associate professors (medium blue), and professors (dark blue) in 2015 to 2016 (left) and 2016 to 2017 (right). Total part C points were divided by numbers of faculty. In 2016 to 2017, assistant professors made up 30% of faculty and received 23.5% of total part C points (634/2694), associate professors made up 31% of faculty and received 32.5% of points (875), and professors made up 39% of faculty and received 44% of points (1185). B, Plots showing points for first and last author publications for faculty subdivided by academic rank. Data for 2015 to 2016 are plotted on the left; 2016 to 2017 on the right. Horizontal, colored lines show average (mean) points earned, and colors correspond to academic ranks; gray boxes demarcate boundaries of the first (lower) and third (upper) quartiles of faculty; vertical (T shape) bars extend upward to show the standard deviation. C, Plots showing points earned for research funding, as in B. More senior faculty tend to earn more points in both subcategories, and professors are overrepresented among high-earning “outliers” in both years.

awards points or “shares” in the department surplus, is used to recognize contributions in research, education, and clinical activities related to QI. Research achievements, along with education and clinical service, are also recognized through academic promotion, and thus indirectly through part A. Research activities received the majority of part C point system allocations (75% over 2015-2017). Both extraordinary or “outlier” accomplishments and more typical research achievements are recognized using the same scale of awarding points for publications and research funding. We view this emphasis on research as in keeping with our core values. Discovery is a key mission of medical schools and academic pathology; we want to foster this enterprise; and no aspect of the tripartite mission engages our faculty more universally. Education is rewarded using a hybrid approach, both fixed monetary teaching awards and part C points (16%). Although we view education as an important activity of all of our professors, its responsibilities tend to fall disproportionately on a few faculty, and annual bonuses for these most dedicated educators have increased significantly under the current plan.

Promoting diversity within our faculty was an important motivation of this policy. We continue a broad complement of efforts to attract and retain minority groups underrepresented in medicine. We now directly reward those faculty who dedicate time to recruit and support underrepresented minority trainees and faculty. In considering gender, our analysis showed no statistically significant discrepancy in part A salaries between men and women when type of appointment, academic rank, and years at rank are used to determine expected salary. We did not consider gender differences in the likelihood of academic promotion, however, which may be an important topic to consider in the future. It was gratifying to see that men and women earned nearly comparable part C points in 2016 to 2017 and that women matched the performance of their male colleagues in terms of authoring papers and winning research funding.

We have weighed several conflicts and trade-offs in developing our current part C plan:

- i. *Our interest to reward many types of faculty achievements versus the risk of creating an overly complicated, cumbersome system.* An important feature of our current part C plan is that it rewards many different types of faculty activities and that all types of points are accessible to all of our faculty. The downside is that the new policy relies on faculty reporting, and there is some effort required of faculty to learn the categories used and to complete the form annually. There is also an administrative burden in soliciting, collecting, and checking forms for accuracy; answering faculty questions; and making payroll entries. We estimate these tasks require 0.125 full time equivalents of staff time. For faculty experienced with the system, point values for most activities can be calculated within less than an hour, given that lists of research publications, research funding, and educational activities are already reported

formally during our annual review process. There are a few areas where documentation itself becomes time-consuming, most notably in QA/QI initiatives. Even this necessary documentation, however, has created opportunities for communicating how quality projects can be structured and the importance of measuring baselines and outcomes. This has opened more dialogue and encouraged consultation with the deputy director for quality at the outset of faculty and mentee QI projects.

- ii. *Our interest to implement a fully transparent, quantifiable scale versus the risk of stifling citizenship or industry in less tangible fields.* Transparent policies communicate by omission activities that are not rewarded. Thus, they run a real risk of devaluing activities that are not explicitly rewarded. Examples include participation on committees, mentoring trainees and junior faculty, and other types of volunteerism that are critical to the health of the department and institution. While extremely time-consuming roles, such as service on an institutional review board, are rewarded as part B compensation, the vast majority of meaningful and valued “citizenship” activities are not rewarded in the current plan. We are cognizant this may have unintended consequences. We are fortunate that our faculty are inherently generous with their time and value our broader work environment. However, we may want to consider more deliberately supporting this esprit de corps in the future.
- iii. *Our interest to use objective, measurable criteria versus the desire to reward innovative, unanticipated contributions.* Any system designed to reward a large, intelligent, and creative faculty with diverse clinical, research, and educational interests cannot predict their myriad contributions to the department and to the field of pathology. For example, after our part C bonus structure was implemented, several of our faculty began participating in a successful series on “PathCasts.”¹⁹ This novel form of education was not anticipated in the bonus structure and does not earn assigned points and yet has impact equivalent to other educational activities that are rewarded. In 2016, selected faculty in our clinical labs were called upon to spend significant effort on hospital Biocontainment Unit preparedness. The capacity for the department director, to occasionally add to faculty bonuses through part C provides flexibility to recognize one-time or first-in-kind endeavors. These are ad hoc decisions at the time that they are made but could be codified in future versions of the part C point system, which should adapt to reflect the ever-changing field of pathology.

We have several purposes in reviewing and publishing these data at this time. First is to enhance transparency, in keeping with a principal motivation behind our new part C policy.

Second is that 2 years after implementing a new part C policy, it was important to evaluate how surpluses were actually being allocated. Having these data available provides opportunity to consider the efficacy of the policy and encourage broader discussions of what we most value in how faculty spend their time and efforts.²⁰ Finally, we wanted to provide an example to other academic pathology departments. We anticipate that our experience may be of practical utility to others and that best practices can derive from interinstitutional comparisons. While our compensation plan reflects current institutional and departmental values, these are not unique to Johns Hopkins today.

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Supplementary Materials

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Development of Professionalism in Graduate Medical Education: A Case-Based Educational Approach From the College of American Pathologists' Graduate Medical Education Committee

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Abstract

Professionalism and physician well-being are important topics in academic medicine. Lapses in professional judgment may lead to disciplinary action and put patient's health at risk. Within medical education, students and trainees are exposed to professionalism in the institution's formal curriculum and hidden curriculum. Development of professionalism starts early in medical school. Trainees entering graduate medical education already have developed professional behavior. As a learned behavior, development of professional behavior is modifiable. In addition to role modeling by faculty, other modalities are needed. Use of case vignettes based on real-life issues encountered in trainee and faculty behavior can serve as a basis for continued development of professionalism in trainees. Based on the experience of program directors and pathology educators, case vignettes were developed in the domains of service, research, and education and subdivided into the areas of duty, integrity, and respect. General and specific questions pertaining to each case were generated to reinforce model behavior and overcome professionalism issues encountered

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in the hidden curriculum. To address physician burnout, cases were generated to provide trainees with the skills to deal with burnout and promote well-being.

Keywords

case vignettes, hidden curriculum, medical education, professionalism, physician well-being

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Introduction

Professionalism, defined as the aspiration “toward altruism, accountability, excellence, duty, service, honor, integrity, and respect for others,”¹ is undoubtedly an important component of medical education and the profession of medicine as a whole.²⁻⁴ Lapses in professionalism have led to disciplinary actions by state medical licensing boards and have affected board certification by various medical specialties.⁵⁻⁷ Unprofessional behavior is a cause for disciplinary action against medical students, residents, and fellows, and practicing physicians.⁵ Physician well-being and professional burnout have also become important health-care issues.⁸⁻¹⁰

The Accreditation Council on Graduate Medical Education (ACGME) recognizing the importance of professionalism in medicine adopted professionalism along with the American Board of Medical Specialties as 1 of their 6 core competencies in 1999.^{11,12} In 2013, the ACGME (Pathology Residency Review Committee [RRC]) and the American Board of Pathology in a joint initiative formulated its 27 residency training milestones that included 6 Milestones dedicated to professionalism (Table 1).¹³ The ACGME updated its professionalism common program requirements (VI.B) in March 2017 (Table 2) and is in the process of formulating new milestones.³ The proposed professionalism milestones include:

- professional behavior and ethical principles,
- accountability/conscientiousness, and
- self-awareness and help-seeking.¹⁴

Professional (physician) burnout and well-being are addressed in the self-awareness and help-seeking milestone and in the revised ACGME common program requirement VI.C.³ (Table 3)

Medical education proceeds through a continuum from undergraduate (UME, medical school) to graduate (GME, internship/residency/fellowship) education by which the novice student requiring supervision develops into a physician able to practice medicine without supervision. A well-defined curriculum is an accreditation standard in all UME and GME programs (*formal curriculum*). The formal curriculum represents the content (knowledge, skills, and attitudes) presented in lecture, small group, and clinical experiences with well-defined objectives linked to the institution’s objectives. By contrast, the behaviors and role modeling encountered during clinical rotations represent the so-called *hidden curriculum*. As its name

implies, the hidden curriculum is not formally taught. It is the more invisible, day-to-day experiences and interactions where learners emulate the behaviors they see. These learned behaviors can be positive or negative, so it is imperative that physicians and educators also model the professional behaviors they are trying to teach. Professionalism development is often a component of the formal curriculum but is always a component of the hidden curriculum. Student attitudes regarding professionalism develop in part from the formal curriculum but more important as part of the hidden curriculum, where students observe the interactions between faculty, staff, administrators, patients, and their peers.¹⁵⁻¹⁷

Trainees entering GME have already started development of their professionalism based on experiences prior to residency including their UME experience.¹⁸ The critical question is what modality or combination of modalities is most effective in continuing the development of professionalism in trainees. Role modeling by faculty is undoubtedly critical. Faculty responsible for development of trainees’ professionalism are aware that more is needed than just faculty role modeling in the health-care environment. Kirch and colleagues comment that “professionalism must be taught early, longitudinally, and deliberately using both targeted instruction and experiential learning.”¹⁹ (p. 1798) This article outlines a vehicle that can be used by programs to address professionalism in trainees.

A Case-Based Educational Approach

As one of its mandates, the College of American Pathologists’ (CAP) Graduate Medical Education Committee (GMEC) has addressed the issue of professionalism in pathology GME in prior publications.^{20,21} In Domen et al, we surveyed program directors (PDs) on how they would respond to lapses in professional behavior as depicted in case vignettes.²⁰ This publication was followed by Brissette et al,²¹ where PDs and residents rated the professionalism of various behaviors.²¹ In that survey, PDs and residents consistently identified 6 behaviors ranked from highest to lowest as being unprofessional (Table 4). In addition to the above mentioned behaviors, residents in contrast to program directors commonly rated the following behavior as unprofessional: did not promptly respond to pager or on-call responsibilities (including timely hand-offs).²¹

Brissette et al also surveyed residents on their participation in unprofessional behavior and observation of faculty participation in various behaviors. Program directors also reported

Table 1. Pathology Professionalism Milestones.¹³

PROF1: Licensing, certification, examinations, credentialing:
 Demonstrates attitudes and practices that ensures timely completion of required examinations and licensure (AP/CP)

PROF2: Professionalism: Demonstrates honesty, integrity, and ethical behavior (AP/CP)

PROF3: Professionalism: Demonstrates responsibility and follow-through on tasks (AP/CP)

PROF4: Professionalism: Gives and receives feedback (AP/CP)

PROF5: Professionalism: Demonstrates responsiveness to each patient's unique characteristics and needs (AP/CP)

PROF6: Professionalism: Demonstrates personal responsibility to maintain emotional, physical, and mental health (AP/CP)

Abbreviation: AP/CP, Anatomic and Clinical Pathology.

Table 2. ACGME Common Program Requirements for Professionalism (VI.B.)³

Programs, in partnership with their Sponsoring Institutions, must educate residents and faculty members concerning the professional responsibilities of physicians, including their obligation to be appropriately rested and fit to provide the care required by their patients.

The learning objectives of the program must:

- be accomplished through an appropriate blend of supervised patient care responsibilities, clinical teaching, and didactic educational events;
- be accomplished without excessive reliance on residents to fulfill nonphysician obligations; and,
- ensure manageable patient care responsibilities.

The program director, in partnership with the Sponsoring Institution, must provide a culture of professionalism that supports patient safety and personal responsibility.

Residents and faculty members must demonstrate an understanding of their personal role in the:

- provision of patient- and family-centered care;
- safety and welfare of patients entrusted to their care, including the ability to report unsafe conditions and adverse events;
- assurance of their fitness for work, including:
 - management of their time before, during, and after clinical assignments; and,
 - recognition of impairment, including from illness, fatigue, and substance use, in themselves, their peers, and other members of the health care team.
- commitment to lifelong learning;
- monitoring of their patient care performance improvement indicators; and,
- accurate reporting of clinical and educational work hours, patient outcomes, and clinical experience data.

All residents and faculty members must demonstrate responsiveness to patient needs that supersedes self-interest. This includes the recognition that under certain circumstances, the best interests of the patient may be served by transitioning that patient's care to another qualified and rested provider.

Programs must provide a professional, respectful, and civil environment that is free from mistreatment, abuse, or coercion of students, residents, faculty, and staff. Programs, in partnership with their Sponsoring Institutions, should have a process for education of residents and faculty regarding unprofessional behavior and a confidential process for reporting, investigating, and addressing such concerns.

Abbreviation: ACGME, Accreditation Council on Graduate Medical Education.

Table 3. ACGME Common Program Requirements for Well-Being (VI.C.)³

[Well-Being must include:]

- efforts to enhance the meaning that each resident finds in the experience of being a physician, including protecting time with patients, minimizing nonphysician obligations, providing administrative support, promoting progressive autonomy and flexibility, and enhancing professional relationships;
- attention to scheduling, work intensity, and work compression that impacts resident well-being;
- evaluating workplace safety data and addressing the safety of residents and faculty members;
- policies and programs that encourage optimal resident and faculty member well-being; and,

Residents must be given the opportunity to attend medical, mental health, and dental care appointments, including those scheduled during their working hours.

[Well-being must include:]

- attention to resident and faculty member burnout, depression, and substance abuse. The program, in partnership with its sponsoring institution, must educate faculty members and residents in identification of the symptoms of burnout, depression, and substance abuse, including means to assist those who experience these conditions. Residents and faculty members must also be educated to recognize those symptoms in themselves and how to seek appropriate care. The program, in partnership with its Sponsoring Institution, must:
 - encourage residents and faculty members to alert the program director or other designated personnel or programs when they are concerned that another resident, fellow, or faculty member may be displaying signs of burnout, depression, substance abuse, suicidal ideation, or potential for violence;
 - provide access to appropriate tools for self-screening; and,
 - provide access to confidential, affordable mental health assessment, counseling, and treatment, including access to urgent and emergent care 24 hours a day, 7 days a week.

There are circumstances in which residents may be unable to attend work, including but not limited to fatigue, illness, and family emergencies. Each program must have policies and procedures in place that ensure coverage of patient care in the event that a resident may be unable to perform their patient care responsibilities. These policies must be implemented without fear of negative consequences for the resident who is unable to provide the clinical work.

Abbreviation: ACGME, Accreditation Council on Graduate Medical Education.

their observation of resident and faculty behaviors. Residents and PDs most frequently observed the same unprofessional behaviors among faculty ranked from highest to lowest (Table 5). Program directors also observed these same behaviors among residents supporting the importance of the hidden curriculum in resident education.

Based on the cumulative experience and feedback from PDs and residents, the GMEC continues to discuss how to best incorporate professionalism development into the GME curriculum. A question that arose after reviewing the survey results from Brissette et al²¹ is what curricular changes or tools PDs could use to promote professional behavior: What would be

Table 4. Behaviors Most Consistently Rated Unprofessional by Program Directors and Residents.²¹

Posted patient information and/or case images with personally identifiable information to social media
Made a disparaging comment about a physician colleague on social media
Made a disparaging comment about a member of the support staff on social media
Made a disparaging comment about a physician colleague in a public hospital space (eg, elevator, cafeteria, parking lot)
Missed work but did not report the time off to the institution (ie, did not use one's sick/vacation days or paid time off)
Made a disparaging comment about a member of the support staff in a public hospital space (eg, elevator, cafeteria, parking lot)

Table 5. Unprofessional Faculty Behaviors Most Frequently Observed by Residents and Program Directors.²¹

Complained to a colleague about workload or hospital policies/procedures
Used a mobile device for work-related purposes during a lecture or sign out
Skipped a required lecture or rounds when no truly urgent clinical issue needed attention
Arrived late to a required lecture or rounds when no truly urgent clinical issue needed attention
Used a mobile device for nonwork-related purposes during a lecture or sign out

beneficial as part of the formal residency curriculum to address the ambiguities encountered by residents along with the biases they develop from the hidden curriculum? Equally important was asking how best to provide house staff with strategies to deal with the ambiguities encountered to minimize lapses in professional judgment and preclude resident burnout. Given the often situational and multifactorial nature of real-world professionalism challenges, the GMEC sees many benefits to the use of case vignettes focusing on specific themes of professionalism. Case vignettes provide subject matter and a structured format to:

- identify conflicts of interest,
- teach effective communication skills,
- deliver resilience skills,
- develop a sense of self awareness and a sense of one's limitations,
- teach skills to deal with lapses in professional behavior,
- remediate lapses in professional behavior,
- develop a team approach to augmenting professional development,
- minimize professionalism lapses and ameliorate burnout,
- review key ethical issues that underlie professional behavior, and
- use as a vehicle for formative assessment.

Creation of Case Vignettes

Themes drawn from elements of unprofessional behavior referenced in our prior publications and from the literature were condensed into 3 domains (service, research, and education) and serve as the basis for case vignettes. The service domain, known also as the competency domain, consists of both the academic requirements and the clinical responsibilities of residency. Within this domain, residents interact with students, peers, faculty, and other health-care professionals including clinical laboratory scientists, histotechnologists, and pathologists' assistants. The research domain deals with residents performing research with institutional requirements and federal regulations governing human and animal research. The education domain refers to residents delivering content based on curricular objectives to medical students, residents in other specialties, and other laboratory professionals including medical technologists. In this domain, a student-instructor relationship is implied.

Within each domain, the GMEC further clustered the professionalism scenarios into 4 areas: duty, integrity, respect, and resilience. Topics for the cases authored to date are included in Tables 6, 7, and 8. For each theme, cases (Table 9) were developed that could be utilized by PDs and department faculty to engage residents in a dialogue on what is appropriate professional behavior. A set of standard questions that apply to each case vignette were developed (Table 10) as were specific questions for each case (Table 9). The consensus among GMEC members suggested there was not a single correct answer but rather discussion points that need to be raised. The points include the PD's obligations, local institutional constraints, and accreditation requirements. A subset of the cases were piloted by GMEC members at the Association of Pathology Chairs' Program Directors Section annual meeting, CAP residency forums, and to house staff supervised by committee members to assess relevance and credibility.²⁰ Several were also presented at professionalism sessions at the CAP annual meeting. Themes identified as problem areas in the study by Brissette et al compose the majority of cases the GMEC authored.²¹

The selected GMEC case vignettes in Table 9 from the service, research, and education domains outline common scenarios encountered in pathology GME. The key issue addressed by each case is underlined. As outlined in Tables 9 and 10, the GMEC modeled the use of these scenarios in professionalism development through key questions and discussion of the underlying professional, ethical, and legal considerations. In building these case discussion, for example, the GMEC considered feedback from residents and PDs at different levels of experience and accreditation and legal standards. Resident well-being and skills to enhance resilience were also incorporated as a goal.

Case 1 deals with substance abuse while on duty. Although the outcome in case 1 is fixed,²⁰ given that many states have mandatory reporting requirements for substance abuse and PDs are required to request a "fitness for duty" evaluation, there is value in discussing the legal ramifications.

There is also value in discussing the responsibility of peers in reporting the problem and whether their intervention could

Table 6. Professionalism Themes and Topics Within the Service (Competency) Domain.

Themes	Topics	Examples
Duty	Maintain academic standards	Addresses poor attendance (no attendance) at required conferences, failure of in-service examinations or USMLE, Step 3, compliance with rotation objectives and time management
	Physician impairment	Includes drugs and alcohol abuse, as well as medical illness and burnout
	Know limitations	Includes declining skills and lack of or improper training
Respect	Dereliction of duty	Self-explanatory
	Patients	Includes privacy issues (proper use of PHI, informed consent, social media, and interpersonal relationships)
	Peers	Addresses interpersonal relationships (harassment, diversity, intimidation, control, romantic, anger management), assisting junior residents and social media issues
	Attendings/Staff	Addresses interpersonal relationships (romantic), abusive behavior, and lack of recognition
Integrity	Institution	Deals with proper use of social media, fiscal responsibility, theft and compliance with institutional policies
	Conflicts of interest	Self-explanatory
	Proper disclosure	Includes mandatory reporting
	Maintain confidentiality	Self-explanatory
	Dishonesty	Self-explanatory
Resilience	Falsification of records	Includes applications and mandatory reporting requirements
	Burnout	Self-explanatory

Abbreviations: PHI, Protected Health information; USMLE, United States Medical Licensing Exam.

have prevented the case outcome. For example, did the attending pathologist and residents who suspected potential substance abuse have a responsibility to notify the PD or should the PD have been more aware? If peers overlooked the problem and later in the resident’s career, there was a poor patient outcome as a result of a known substance abuse problem, would they feel responsible?²² Is there a team approach that could be utilized to remediate the resident? This case further allows PDs to address AMA Principles of Medical Ethics, sections 9.3.1 Physician Health and Wellness and 9.3.2 Physician Responsibilities to Impaired Colleagues.^{23,24}

Case 2 deals with unauthorized access to medical records. The case also raises the possibility of litigation and could be used to educate residents on the role of the institutional and hospital risk management offices and the elements of a negligence lawsuit.²⁵ This case further allows PDs to address

Table 7. Professionalism Themes and Topics Within the Research Domain.

Themes	Topics	Examples
Duty	Proper design of experiment with statistical analysis	Deals with maximizing research benefits and minimizing patient risk
	Know limitations	Includes lack of proper training in design, methodology, and interpretation.
Respect	Dereliction of duty	Self-explanatory
	Subjects (Patients)	Deals with maintaining privacy of PHI data, patient autonomy (informed consent), proper use of social media, and interpersonal relationships
	Peers, students, staff	Deals with interpersonal relationships and inadequate recognition of students and staff
Integrity	Institution	Deals with proper use of social media, fiscal responsibility (money and time), theft (fraud), and compliance with federal and institutional research requirements (IRB approval)
	Conflicts of interest	Includes sharing research findings and authorship
	Proper disclosure	Includes mandatory reporting
	Maintain confidentiality	Self-explanatory
Resilience	Dishonesty	Self-explanatory
	Falsification of records	Includes required reporting
Resilience	Burnout	Deals with not being funded and loss of laboratory and reassignment to new role

Abbreviations: IRB, institutional review board; PHI, Protected Health Information.

postmortem information (autopsy findings) and AMA Principles of Medical Ethics, section 3.2.2, Confidentiality, Postmortem.²⁶

Case 3 also deals with access to medical records. In contrast to a lapse in professional judgment, it demonstrates positive behavior. Comparing positive and negative behavior is important for professional development, and the 2 cases could be discussed in tandem. Residents should be encouraged to discuss the skill sets and actions that allowed for a good outcome.

Case 4 deals with posting patient information to social media. Proper use and improper use are discussed along with the institution’s policy and ramification to the individual and institution for improper use. The autopsy authorization form can also be discussed and accepted norms for using clinical material for educational purposes.

Case 5 deals with abusive behavior in the workplace. Ramifications of this behavior on patient care and workload are discussed. The case also allows for a discussion on what should be the department’s response if such an individual applies for a faculty or private practice position. What should be disclosed in

Table 8. Professionalism Themes and Topics Within the Education Domain.

Themes	Topics	Examples
Duty	Maintain academic standards	Incorporates designing course/ clerkship that meets institutional goals, designing appropriate assessments and complying with goals and objectives of course/ clerkship
	Education of peers and students	Includes outlining goals and objectives for faculty and students
	Instructor impairment	Includes impairment due to drugs, alcohol, and illness
	Know limitations	Includes declining skills and not properly trained
	Dereliction of duty	Self-explanatory
Respect	Students	Includes privacy of student information (FERPA), providing constructive assessments, proper use of social media, interpersonal relationships including abusive behavior, and lack of student recognition
	Staff	Addresses interpersonal relationships, abusive behavior, and inadequate recognition
	Institution	Addresses proper use of social media, fiscal responsibility (money and time), theft (fraud) and compliance with educational institution policies
Integrity	Conflicts of interest	Self-explanatory
	Proper disclosure	Deals with mandatory reporting (LCME and ACGME)
	Maintain confidentiality	Deals with grading, recommendations
	Dishonesty	Self-explanatory
	Falsification of records	Deals with required reporting
Resilience	Burnout	Self-explanatory

Abbreviations: ACGME, Accreditation Council on Graduate Medical Education; FERPA, Family Educational Rights and Privacy Act; LCME, Liaison Committee on Medical Education.

a recommendation letter? Are there legal repercussions to such disclosure?

Case 6 is in the research domain. Institutional policies and federal regulations can be discussed. The case also serves as a vehicle for addressing the Belmont report findings, respect for persons, beneficence, and justice. The concepts of informed consent, risk, and benefit assessment and selection of research participants are also part of the dialogue.^{27,28}

In the education domain, case 7 deals with sexual harassment. The case allows for discussion of the institution's policy and AMA Principles of Medical Ethics section 9.1.3, Sexual Harassment in the Practice of Medicine and ACGME professionalism standards.^{29,30}

Cases 8 and 9 focus on time management, physician burnout, and resilience. It is important that training programs address these issues. Resident burnout has a number of associated elements, including "emotional exhaustion", "depersonalization and cynicism," and "feelings of inefficacy".⁸ Emotional exhaustion and/or depersonalization were identified in 76% of US medical residents on the Maslach Burnout Inventory.⁸ Patient care errors have been associated with burnout. Residents should be aware of the signs of burnout and how to access appropriate interventions. Many of the cases raise these questions and provide a forum for a dialogue on the issue. The cases also allow for a discussion of AMA Principles of Medical Ethics, section 9.2.2, Resident and Fellow Physicians' Involvement in Patient Care.³¹

Case 10 deals with a resident with significant debt that lacks the skill on how to budget salary. Absent financial management skills may lead to excessive anxiety and burnout.^{32,33}

Discussion

"Professionalism" is a character trait medical students develop which manifests as behavioral change over the course of training.¹⁸ Students entering medical school tend to have a positive altruistic view and a sincere desire to help patients. They expect to be treated with "respect, honesty, and tolerance."¹⁸ Throughout UME, their view changes as they witness behaviors, positive and negative, in the health-care arena as part of the hidden curriculum.³⁴⁻³⁶ Market forces and societal pressures (eg, television programs such as *Grey's Anatomy*, *House, M.D.* and *Scrubs*) also influence their behavior.¹⁷ Medical students experience a disconnect between the formal curriculum and the personal interactions they witness leading to cynicism, loss of empathy and potentially burnout. As a learned behavior, professional behavior can be modified through positive experiences.

Students entering GME have already started their development of professionalism. The critical question is what methods or combination of methods can be deployed to continue the development of professionalism in residents. Residents observe behavior among clinicians, their peers and attendings, and other health-care workers while influencing medical students and other health-care personnel. The hidden curriculum is constantly at work. Recent literature indicates that modifying behavior is the best way to promote professionalism. Identifying positive behaviors while minimizing negative role models is important.¹⁷

The medical education literature deals with different modalities to deliver content, such as lectures and case-based instruction. Lectures tend to be passive and designed to cover a specific theme. Although cases may be incorporated into lectures, small groups with active discussion have a positive effect on learning. Small group teaching with well-defined goals and objectives, a proper attitude of the instructor, and development of rapport with the participants can be highly effective for teaching professionalism.³⁷ Most pathology

Table 9. Selected Cases From the Service (Competency), Education, and Research Domains and on Burnout and Resilience.

Case		Specific Questions to be Addressed
Service/Competency Domain		
Case 1. Resident with substance abuse problem compromising performance.	Dr F is a PGY2 pathology resident who is seeing you first thing on a Thursday morning for his semiannual evaluation. He has been noted to have difficulties during his most recent surgical pathology rotations, despite having done extremely well in his first year. Several attendings have informally commented that he seemed inattentive and “bleary eyed” during sign out and that he was missing important details in his gross descriptions. He recently cut himself in the frozen section laboratory during a frozen performed at night while on call. A few days ago, while walking through the resident’s room, you overheard one resident ask how his weekend was to which he replied, “Man, I got so wasted I barely made it into work today. I’ve got a wicked headache this morning.” His evaluations for other rotations have been satisfactory, but there has been a noticeable drop-off in performance across the board since the previous year. When he shows up for your meeting, he is 10 minutes late and looks disheveled. He states that his alarm clock didn’t go off and he had to roll out of bed to hurry into the hospital to meet with you. After beginning to go over his evaluations, he gets defensive and angry, blaming the attendings and other residents for making him look bad. When he leans over to point out something in his file, you detect alcohol on his breath.	<p>What is a fitness for duty statement?</p> <p>What are its consequences?</p> <p>What are the mandatory state reporting requirements for substance abuse?</p> <p>What is reported by the institution on job and fellowship applications?</p>
Case 2. Unauthorized access to EHR by resident	Dr S is a PGY-3 resident who has had positive evaluations throughout his residency. His spouse informs him that she heard from a neighbor that a mutual friend was diagnosed at his institution with metastatic malignant melanoma and asks him if he could verify the information. The next day Dr S searches the pathology database for the mutual friend’s pathology report to verify the diagnosis and passes the information on to his spouse who subsequently discusses it with their neighbor. You (the program director) are contacted by the Risk Management Office stating that the mutual friend contacted the health-care facility complaining that her confidential medical information had been disclosed by Dr S.	<p>What constitutes unauthorized access to the EHR?</p> <p>What is considered a HIPAA (Health Insurance Portability and Accountability Act of 1996) violation?</p> <p>What are the institutional guidelines related to EHRs?</p> <p>What are the consequences for the individual and the institution for unauthorized access?</p> <p>Is it a misdemeanor?</p> <p>Are ethical, institutional, or legal considerations different for postmortem data?</p>
Case 3. Positive action by resident for requested unauthorized EHR information	Dr. R is a PGY-2 resident. His wife wanted to know the laboratory results of a pregnancy test for their neighbor. Dr R tells his wife that he would want his medical information to be confidential and she would not want the results of her recent skin biopsy disclosed. Further he adds it would be a HIPAA violation and a possible misdemeanor and would put the hospital at risk. His wife accepted his response.	
Case 4. Posting patient information by resident and medical student to social media	Ms. D is a fourth-year medical student on an elective pathology rotation and is planning a career in pathology. Dr E is a PGY-3 resident on her third straight month of autopsy rotation and is supervising Ms. D on an autopsy on a 4-month old baby who died as a result of multiple congenital abnormalities. Before the autopsy they are both joking around and they both take multiple pictures of the baby with their cell phones and later post them on Facebook along with derogatory and insensitive comments about the baby, attendings in the hospital, and the department. Several other residents see the photos and also post comments.	<p>How does HIPAA apply to postmortem data?</p> <p>What content is appropriate for educational use?</p> <p>Does it need to be deidentified?</p> <p>What is the institution’s policy on social media?</p> <p>What are the repercussions for posting unauthorized material?</p> <p>Is the individual legally liable for posting the images?</p> <p>What is the institution’s liability?</p>

(continued)

Table 9. (continued)

Case		Specific Questions to be Addressed
Case 5. Abusive behavior by resident to peers regarding sexual orientation and IMG status	Dr. H is a PGY-6 Surgical Pathology Fellow. She is well-respected for her diagnostic skills, although she has a reputation for being “demanding” or perhaps “difficult” as an educator. During review of cases with residents and students she has been known to speak sharply when a resident misidentifies the tissue or takes too long to write up the day’s cases. Within a couple of months of the start of the new academic year, the pathology program director however begins to hear disturbing stories from both the residents and the faculty. Of late Dr. H has directed much of her vitriol and criticism toward Dr J and Dr M. Dr J a PGY-1 international medical graduate (IMG) is openly gay. Dr M, a PGY-3 USMG, however, has only come out of the closet after Dr J’s arrival in the program. One of the residents also reported that she overheard Dr. H’s loud phone conversation berating international medical graduates (IMG’s) as inferior to US-trained physicians in both skills and values and that this residency program had too many IMG’s. She has been overheard at lunch with her colleagues talking about the need to restore dignity to the profession and being careful about all these quote “non-traditional” trainees being accepted into the program.	<p>How can residents recognize their own and others’ bias toward different groups?</p> <p>What skills, structural factors, and institutional resources and policies can help maintain group cohesion and optimal patient care in a diverse group given differing experiences and expectations and unconscious bias?</p> <p>What are the responsibilities of faculty, PD and residents in dealing with reporting abusive behavior?</p> <p>What are Title 7 requirements? Title 9?</p> <p>What is the institution’s policy on discrimination?</p>
Research Domain		
Case 6. Failure by resident to comply with university’s research policies regarding IRB approval	A PGY3 resident approaches a faculty member, Dr R, about a research project proposal. The faculty member agrees, and the resident begins to develop and write an IRB protocol and develop a budget for the project. The resident is anxious to begin the project because of meeting abstract submission deadlines and submits the proposal for IRB approval. However, the faculty member fails to follow through on the required approvals, and the process of IRB languishes. The resident, however, begins to select and review cases and request the necessary stains as proposed. The faculty member is contacted by the resident, and the cases and necessary stains are reviewed. The resident then writes an abstract for submission to the scientific meeting and she submits it for faculty approval. After submission of the abstract, the resident is informed that an IRB protocol # is required for acceptance and finds that the faculty member never completed the IRB approval process.	<p>What is the role of an IRB?</p> <p>What regulations govern informed consent?</p> <p>What are the institutional and federal regulations for research and consequences of failing to comply with them?</p> <p>Can data collected in a non-IRB approved protocol be used?</p>
Education Domain		
Case 7. Sexual harassment by resident toward medical student	Although they were on call together, Dr. G, a PGY 2 resident, asked a medical student if she wanted a backrub. Although Dr. G apologized, the student filed a complaint with her supervisor. Dr. G was counseled by the PD stating there are professional boundaries that must be respected and gave him a copy of the institution’s sexual harassment policy. During his PGY 3 year, another female medical student filed a complaint against Dr G feeling that after initial conversations the conversations took on a sexual connotation. The student filed a complaint of having felt threatened and vulnerable with the Dean for Student Affairs. The PD counselled Dr G. During the session, it was found that Dr G had a history of repeated inappropriate overtures toward students. Dr. G was put on probation and informed that any future inappropriate behavior toward students or hospital personnel would be grounds for dismissal. Counselling was also recommended. Although his clinical performance was positive, another complaint was filed by a hospital employee for inappropriate comments in violation of the hospital’s sexual harassment policy. At no time was Dr G in a supervisory role with the students or found to be inappropriate with patients.	<p>What is the institution’s policy on sexual harassment?</p> <p>Is it appropriate for residents to have romantic relationships with patients, with faculty, with students or their own resident colleagues?</p> <p>Does the appropriateness of the relationship differ if one party supervises or is involved in evaluating others?</p>

(continued)

Table 9. (continued)

Case	Specific Questions to be Addressed
Burnout/Resilience	
Case 8. Resident with signs of burnout	Dr S is a PGY 2 resident. She has been a solid resident starting work at 6 AM and leaving after 6 PM. Her peers note she spends her evenings studying pathology and she comes in on weekends to review unknowns and work on projects. She has limited social interaction and no outside interests. Within the last month, laboratory personnel have commented she has become indifferent in contrast to when she first started the program. Faculty comments suggest she is cutting corners during grossing specimens and not taking the required sections. You also have just received a patient complaint from her last transfusion medicine rotation.
Case 9. Resident treated for burnout with improvement of performance	Dr P is a PGY 3 resident. Her performance had been solid. During her last performance review, however, she was noted to have signs of depersonalization (callous attitude toward patients and laboratory personnel accompanied by a cynical attitude). Therapy was recommended. As part of her therapeutic plan she developed outside interests with improvement in her attitude and performance. Recently, it was determined that prior to her last performance appraisal she had mislabeled specimens without informing anyone after she discovered the error; this led to a patient being misdiagnosed with cancer.
Case 10. Resident in Financial Trouble	Dr S. is a new PGY1. She and her husband graduated from medical school with significant tuition debt from both undergraduate and medical school. Prior to starting internship they purchased a new car and a condominium. They also found child care expenses manageable but more than they expected. Several months into her residency she started receiving phone calls from a collection agency. Although they generated a budget, they had not accounted for taxes and the high cost of living. The repeated phone calls led to significant anxiety and suboptimal performance in her clinical responsibilities. She came to see the program director for assistance when their car was repossessed.

Abbreviations: EHR, Electronic Health Record; HIPAA, Health Insurance Portability and Accountability Act; PD, program directors.

Table 10. General Discussion Points for All Cases.

- Was the resident's behavior unprofessional, professional or neither?
- What behavior in the case bothers you?
- Is there a breach of trust in the profession? Is there a potential for patient injury?
- How should the program director act? What if this was your coresident? What if it was you?
- Is there anything that could have been done to prevent it?
- Were there warning signs? Should they have been brought to the attention of the PD?
- What role do residents have in policing their peers?
- What are your institutional resources and policies?
- What are your State statutes and regulations regarding the issue?
- What are federal statutes and regulations?
- What message does this send to other residents?

residencies vary in size from 8 to 24 trainees, making small group faculty or senior resident-facilitated teaching ideal.

Case vignettes allow for self-reflection, assessment of peers, attendings, staff and patients, and allow residents to develop strategies and tools to deal with ambiguity and lapses in judgement.³⁸⁻⁴¹ Another benefit of this approach for PDs is to gain an

appreciation of the resident's perspectives (attitude, social norms, and cultural background). Program directors can take the opportunity to refresh their own knowledge of the program/ institutional background based on experience, regulatory, and legal standards and the consequences of the behavior in preparation for the discussion. Where appropriate, strategies can be incorporated into the discussion to modify behavior, promote resilience, and insure that trainees are familiar with institutional policies. Much of the professionalism curriculum in institutions focuses on lapses in judgment; we have furthered developed cases that highlight constructive responses highlighting the elements of professionalism. Another goal for utilizing case vignettes is to counter the hidden curriculum. Case vignettes can be instrumental in aligning the formal curriculum on professionalism with the hidden curriculum encountered in everyday practice. Our cases serve as a tool for program directors to make trainees aware of the hidden curriculum and develop strategies to overcome the negative biases they have encountered and promote positive behavior in their professional development.^{21,42,43}

The use of case vignettes with residents across medical specialties has demonstrated value in resident professional

development.^{38,39} Factors to consider in their use include personal attributes and characteristics including perceived identity, unconscious bias and inherent personality traits, interpersonal and interprofessional relationships including functioning in a group (group dynamics), and societal dimensions such as the political and economic framework within and external to the institution.³⁸ Case vignettes that are realistic and current address these factors. Reflection on case content is part of the experiential process as previously outlined.^{19,41}

Depending on institutional resources and the program's curriculum, case vignettes can be employed flexibly to create a meaningful experience and promote professional development. The simplest format is a group discussion led by the PD where residents review the case as a group and answer selected questions. The PD or other facilitator would then give their perspective, followed by a group discussion. Alternatively, residents could be given the cases ahead of time and asked to write answers to the specific questions, reflect on their answers prior to the session and then modify their answers if needed post session. As part of the exercise, PDs should alert trainees to the potential of unconscious bias. Another alternative is to have residents role-play the individuals in the case vignette or to use professional actors to role play in front of a camera. Residents could review the videotapes separately or as a group prior to the discussion. Videotaping allows residents performing away rotations to participate and ensure for accreditation purposes that each resident is exposed to the same curriculum. In many of these scenarios, it is worthwhile to retain the residents' comments and use the same cases year to year, with residents reflecting on their personal answers over all 4 years of the program to assess the change in their professional development. Based on our prior experience, it is worth seeing how residents would treat the resident who is unprofessional in each of the cases.²⁰ In several instances, residents felt the problem resident should be dismissed or their contract not renewed versus the PDs who advocated counseling; with repeated exposure to the scenario, residents could observe the evolution in their thinking and approach.

Assessment of resident behavior can be formative, summative, or diagnostic.⁴⁴ Norcini and McKinley outline 2 advantages of formative assessment. First, it provides feedback to residents and PDs to guide learning (professional development) and second, the act of assessment itself creates a learning environment.⁴⁴ As discussed earlier, residents should be able to perform a number of tasks by the end of training as outlined in the ACGME professionalism core competency.¹¹ Case vignettes have a role in formative assessment. Their role in summative assessment is open to debate.⁴⁵ Residents can be given the cases and generate a response to the general and specific questions for the cases. Although the GMEC position is that there is no single correct answer to many of the cases, there is consensus opinion and applicable guidelines or law for many of the broader issues that could be provided to the residents as formative feedback, for example, AMA Principles of Medical Ethics for service (competency) domain, and the Belmont

Report for research domain. All cases allow for self-reflection, which is critical in professional development.⁴⁴

Within the medical and pathology academic communities, professionalism is identified as one of the most important ethical issues.^{46,47} Employers rate areas of professionalism, including honesty, interpersonal interactions, knowing ones limitations, and knowing when to ask for help, as critical attributes in hiring recent trainees.^{21,48,49} Our experience is that professional development must provide residents with the knowledge, skills, attitudes, and strategies to minimize lapses in judgment and provide them resilience skills to prevent burn-out that may lead to compromised patient care.^{8,10,50,51} Although there is no substitute for real-world experience, we designed our case vignettes to realistically reflect current issues encountered in GME. Through these simulated cases, residents can role-play and practice positive behaviors while being coached and provided strategies to deal with conflict.

Role-modeling by faculty is undoubtedly also an important modality in professional development.^{18,21,46} Wagoner observed that when second-year students were asked what they considered as unprofessional behavior among faculty, the comments included 2 themes: dehumanization of students, colleagues, patients, and others by showing lack of respect, breach of confidentiality, displays of intolerance, or dishonesty and insensitivities based on gender, ethnicity, or cultural beliefs, particularly involving racist or sexist remarks.¹⁸ As discussed earlier, pathology residents have identified specific faculty behaviors as unprofessional.²¹

Residents need positive role models; they need to witness positive behavior in faculty to emulate. Negative behavior in role models is counterproductive. Faculty development has a role in developing positive role models and modifying behavior for residents and other laboratory personnel. The GMEC case vignettes can be utilized by institutions for faculty development and promoting faculty well-being as well.

Conclusion

Residents are diverse in their experiences and expectations, and their development of professionalism is based on multiple factors including "experiential learning."¹⁹ We have found case vignettes a useful vehicle to reinforce model behavior and counter the *hidden curriculum* that is part of the GME experience. Active participation using real-world experiences can be used for deliberate targeted instruction in a longitudinal manner starting during the first month of GME.

Authors' Note

For Dr Brissette: The views and opinions expressed in this manuscript are those of the author and do not reflect the official policy or position of the Department of Army/Navy/Air Force, Department of Defense or the United States Government.

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Quantification of the Effectiveness of a Residency Program Using the Resident In-Service Examination

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Abstract

This study describes a quantitative tool in the assessment of residency programs, in which national ranking of residents after the resident in-service examination in postgraduate year 4 is compared to that in postgraduate year 1. The relationship between training and changes in ranking, resident in-service examination results before and after training in specific areas are also compared. To illustrate the use of this novel approach, data from a large residency program were analyzed. The 70 residents were ranked as a postgraduate year 1 group at the 50th national percentile. As postgraduate year 4 residents, they were ranked at the 59th percentile, a significant ($P < .003$) improvement. There was moderate correlation between performance in postgraduate year 1 and that in postgraduate year 4 ($R^2 = 0.61$); however, initial ranking was no indication of the final ($R^2 = .34$), with the exception of high performers. Training in specific areas improved ranking, demonstrating association between training and performance. In conclusion, the effectiveness of training provided by a residency program can be quantified using the resident in-service examination. This should provide a quantitative tool in the assessment of postgraduate programs.

Keywords

RISE Exam, residency, effectiveness, education, measurement

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Introduction

The standards of the Accreditation Council for Graduate Medical Education (ACGME) and its accreditation system insure that most residency programs provide their trainees with the skills necessary to practice and to pass certification examinations.¹ However, in addition to personal or geographic preferences, there is significant variability in program size, curriculum, patient volume, faculty number, and so on, which makes assessing the effectiveness of residency programs difficult. To guide candidates and accreditation organizations, indices such as percentage of trainees passing specialty examinations,² employment placement, publications and even resident surveys have been used, but assessing a training program remains a challenge.

In contrast to the limited means to assess programs, there are multiple methods to monitor individual trainee

progression. Instituted by ACGME, the Milestones program³ guides and follows the professional development of trainees. Resident in-service examinations (RISEs) predate the Milestones and are standardized tests aiming to quantify the accumulation of theoretical and practical knowledge.⁴ For example, the RISE developed by the American Society for Clinical Pathology has been administered to pathology residents since 1993.⁵ The questions are generated by experts, are

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updated, and at least partially emulate the certification examination administered by the American Board of Pathology (ABP). The RISE results are reported both as absolute numbers and as percentiles ranking the test taker in his national postgraduate year (PGY) peer group.⁶ The consistent test format throughout training allows trainees and program directors to monitor the progression of individuals. The Milestones incorporate performance on standardized tests as a reliable (and recommended) method of assessment, especially as senior resident performance on the RISE correlates with outcomes of ABP examinations.^{6,7} However, the question remains: While almost all residents progress during training (in absolute scores on standardized tests,⁵ Milestones and from a subjective point of view), how to quantify the contribution of the program?

We use the RISE to measure the effectiveness of a specific residency program. This is a shift from its use in the assessment of individuals to providing quantitative information on the program. Professional growth requires an individual effort and effective training. Averaging the results of a large number of trainees reduces the variability induced by differences in drive, test-taking ability, and previous training. In consequence, comparing the national peer group ranking of a group of residents at the end of their training to that at the beginning should quantify the impact of the program. We apply this to a large residency program hoping to answer a few questions. First, can we detect changes in peer group ranking after training? Second, are changes an exclusive function of the initial ability of the resident? Third, is specific training associated with changes in ranking? To answer these questions, results of the RISE taken by 70 residents as PGY4 were compared to those in PGY1. Absolute numerical scores were ignored, focus was exclusively on the national peer group ranking of residents, with the idea that training in an ineffective program should lead to lower ranking as PGY4 than as PGY1 and the reverse, better ranking should be achieved in an effective training environment. To investigate the link between training and changes in ranking, we took advantage of a particularity of the program: training in transfusion medicine (TM) and in hematopathology (HP) was provided during PGY2. In consequence, ranking in these fields as PGY1 was used as baseline, while the changes in PGY2 were associated with training. This largely ruled out the possibility that the changes at the end of PGY4 were exclusively due to individual preparation, without a significant contribution of the training program. Overall, we illustrate the notion that changes in aggregate percentile ranking from PGY1 to PGY4 of all the residents as a group can measure the effectiveness of the program.

Methods

Participant Selection

After internal review board approval in 2017, 70 residents training in the same Anatomic and Clinical Pathology (AP/CP) program between 2006 and 2017 were identified. The

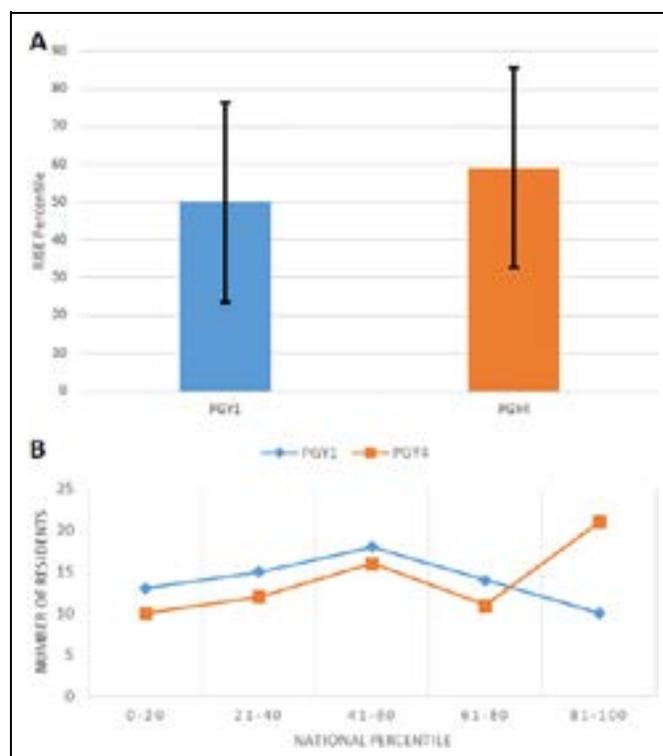


Figure 1. A, Average resident in-service examination (RISE) percentile. The increase of 9.3% in resident rank between postgraduate year (PGY1 and 4) is statistically significant ($P = .003$). B, Number of residents by quintile ranking. Postgraduate year 1 had a normal distribution, while PGY4 has a skew toward high performers.

AP- or CP-only trainees were not included. The results on the RISE were anonymized. Analyzed were the overall national percentile ranking on the tests taken during the PGY1 and 4 and the percentile ranking in TM and HP as PGY1 and PGY2, between 2006 and 2017.

Statistical Analysis

Anonymized data were stored, analyzed, and visually represented using Microsoft Excel (Microsoft, Seattle, Washington). Statistical tests used included average, standard deviation (SD), and paired t test. The difference in the performance on RISE for each resident was calculated by deducting the percentile ranking as PGY1 from the percentile as PGY4.

Results

National Ranking as Postgraduate Year 1

The mean national peer group percentile ranking of PGY1 residents was 50 (26.3; Figure 1A). With 70 individuals enrolled, it is not surprising that the performance of the group was no different from that of the national reference group of PGY1 residents. The SD is a reflection of the wide variation in performance, 13 residents ranking in the bottom 20%, while 16 in the top 80 (Figure 1B). The distribution of percentile

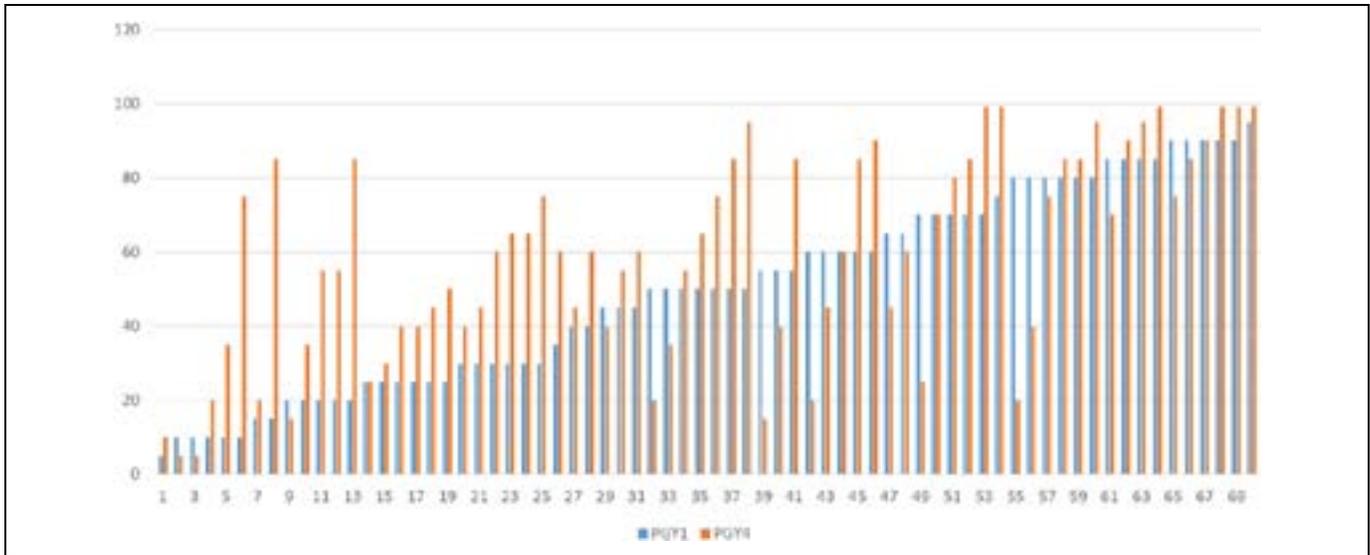


Figure 2. Individual resident in-service examination (RISE) percentile in postgraduate year (PGY) I and 4.

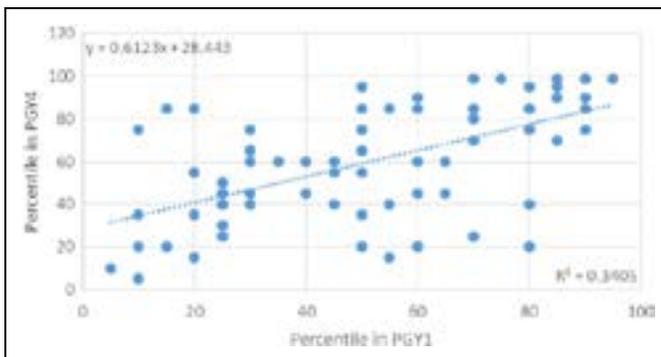


Figure 3. Correlation between ranking as postgraduate year (PGY) I and PGY4. There is a moderate correlation between ranking as PGY1 and PGY4 (slope 0.61); however, the coefficient of determination is low at 0.34. Dotted line = line of best fit.

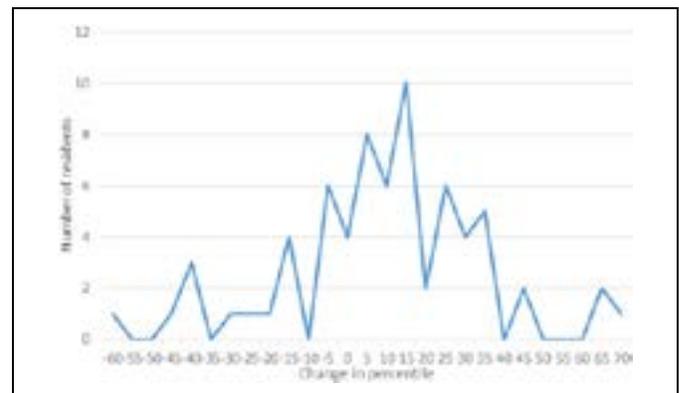


Figure 4. Changes in percentile ranking between postgraduate year (PGY) 4 and PGY1. Overall, a normal distribution “bell curve.”

rankings was normal, symmetrical, and roughly approximating that of a bell-shaped curve (Figure 1B).

National Ranking as Postgraduate Year 4

The mean percentile ranking of PGY4 residents was 59 (27.6; Figure 1A). Like for PGY1, ranking ranged from very low to very high, but the distribution curve was not symmetrical, this time there was a significant skew toward high performers (Figure 1B), defined as residents ranked in the upper national quintile (80%-100%).

Changes in Ranking

The individual percentile ranking as PGY1 and PGY4 of participants is displayed in Figures 2 and 3. The average change in ranking was 9.27 percentiles, but the SD was very large at 24.7, indicating variability in performance, even if the distribution of the values was normal, with a bell-shaped curve centered

around the value of 9 (Figure 4). The difference between the ranking as a PGY4 and that as a PGY1 was statistically significant ($P < .003$; Figure 1A). If any change in performance is taken into consideration, 48 residents improved their performance, 4 had a similar performance, while 18 performed worse as PGY4 than as PGY1, a resident was 2.7 times more likely to improve than to fall in ranking. If only changes larger than 5% are considered, the differences between improving and declining performance residents are more significant: 40 improved, 18 stayed the same while 12 declined in ranking, indicating that a resident was 3.3 times more likely to improve than to decline.

Correlation Between Performance as Postgraduate Year I and Postgraduate Year 4

Initial performance was not a strong predictor of final ranking, as shown in Figures 2 and 3, significant improvement in ranking being achieved across all quintiles. The lower quintile (0%-20%) had a significant number of PGY1 residents who

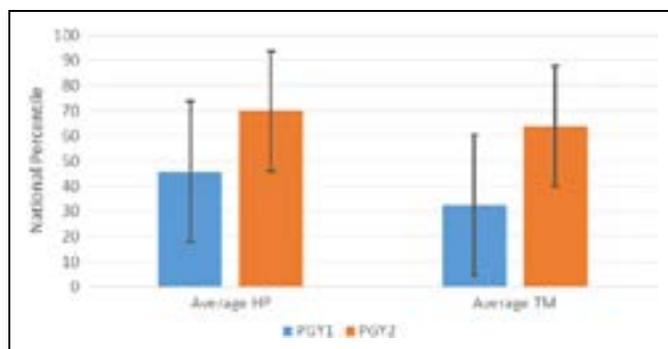


Figure 5. The impact of training in specific areas on national ranking. Training in these disciplines was offered at the beginning of post-graduate year (PGY) 2. Ranking was performed based on the performance on the resident in-service examination (RISE) administered in the second half of PGY2. The differences in ranking before and after training are significant in both disciplines ($P < .001$ for both). HP indicates hematopathology; TM, transfusion medicine.

improved as PGY4s, the proportion of improved-no change-declined being 10-0-3, with at least 2 residents becoming high performers. In fact, this quintile registered most significant gains, but performance was very heterogeneous, a few residents (6 of 13) remaining low performers even as PGY4, registering no or minimal improvements. Most impressive was the second quintile, with 14-1-0, no resident declining in performance, one staying the same, while 14 improved. The middle quintile (41%-60%) had a mixed performance, 10-1-7, while the worst performing fourth quintile (61%-80%) had an even number of improvers over nonchanging or worsening performers 7-1-6, with losses in ranking more severe than the gains registered (Figures 2 and 3). As expected, the high performers continued to be ranked highly and when losses in ranking were registered, they were not severe. Overall, the slope of the linear regression equation was 0.61, indicating a moderate correlation between the rankings as PGY1 and PGY4, but the coefficient of determination was low at 0.34, indicating that the performance as a PGY4 of a particular PGY1 resident was difficult to predict.

Impact of Specific Training

No experience in HP and TM was correlated with below average ranking in these disciplines (Figure 5) on the test administered in the second half of PGY1. Rotations at the beginning of PGY2 resulted in improvements in national ranking in HP (30 percentiles) and TM (25 percentiles) on the test administered at the end of PGY2 (Figure 5), clearly indicating the association between training and performance.

Discussion

To quantify the effectiveness of a program, we compared the national peer ranking of a group of PGY4 residents to that in PGY1. The idea was that residents in effective programs should improve their ranking, while those with ineffective training

should decline. In other words, differences in resident ranking as a group are at least partially dependent on program effectiveness. Individual differences in drive, test-taking ability, or personal histories were counterbalanced by the large number of residents involved (70).

We detected a difference of over 9 percentiles in ranking, but smaller changes may not be detectable in smaller programs. This could be circumvented by multigenerational data. Sure, programs change over the periods necessary to acquire data, but some changes may impact the residents at national level and certain parameters with a major impact on training may change very slowly: number of patients/cases/procedures, ratio faculty/trainee, location, patient population, affiliation, and so on. In addition, if differences are too small to detect with data from 20 to 30 residents, maybe the program has an average impact on resident training, neither beneficial nor detrimental.

We also investigated the correlation between individual ranking as PGY1 and as PGY4. The conclusions are mixed: Moderate correlation exists, but predicting individual PGY4 performance based on ranking as PGY1 is impossible, with the exception of very high performers. This is further argument for the role of the training program. An absent correlation would have been in direct contradiction with intuitive and statistical observations showing that individuals with strong performance tend to continue to perform well. A very strong correlation (basically preserved ranking from PGY1 to PGY4) would have shown unexpected uniformity in the effectiveness of training and total absence of individual factors, casting doubts over the accuracy of the data. Overall, the mixed results are not only realistic but also encouraging: Initial lackluster performance can be significantly enhanced, while strong performance can be maintained.

The possibility that progress was exclusively consequence of individual efforts (even when the cohort was sufficiently large to make this unlikely) was investigated. The impact of specific training was clearly demonstrated by the significant upgrade in ranking. These changes were more significant than those in overall ranking as PGY4, probably due to lack of standardization of the curriculum at national level: Some residents have HP or TM training in PGY1, some in PGY3, or maybe the time between training and testing allowed for information to be forgotten. Regardless, it is obvious that significant improvement in specific areas is linked to training, supporting the notion that changes in overall ranking after residency are impacted by program effectiveness.

The main limitation of the study is the possibility that the RISE may not cover relevant or current information and that important aspects of training are not addressed in this test. In the absence of an alternative method of standardized assessment of residents and with experience indicating that RISE performance correlates with that on the ABP certification examination,⁶ we feel that the data generated through the RISE should be taken into consideration.

The main finding is that candidates and regulatory agencies can obtain quantitative information on the effectiveness of a specific program. Residents gaining in national ranking (becoming better trained than their peers) is a good indicator that the program

has dedicated faculty and resources, regardless of the subjective impression of inspectors, faculty, or trainees. The opposite is also obvious: When trainees become less competitive in spite of the programs' stated goals, impressive appearances on paper, or high morale, alarm bells should sound. A search of the literature shows that this type of quantitative assessment has not been used before by residency programs in any specialty, a somewhat surprising finding, as in-service examinations of varying types are widespread and as data are easily analyzed and interpreted. Implementation of this type of analysis in a consistent and transparent manner could have a significant impact on how residency programs are accredited and funded. One could imagine accreditation agencies withdrawing support for programs who repeatedly fail to quantitatively demonstrate their effectiveness and consistently lag behind the other programs in that specialty. Hospitals may choose to divert scant resources across specialties, encouraging effective programs, and decreasing the resources allocated to ineffective ones. For candidates, ranking programs on the match rank order list would become a more objective endeavor with the quantitative knowledge described earlier. These data should allow effective programs to answer the question every recruit should ask: Why would I train in this program and not in a competing one?

Conclusion

Changes from PGY1 to PGY4 in aggregate national percentile ranking of residents as a group can measure the effectiveness of the training.

Authors' Note

C.V.C. and K.S.T. contributed equally to this work.

Declaration of Conflicting Interests

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Impact of Daylight Saving Time on the Clinical Laboratory

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Abstract

Daylight saving time is a practice in some countries and local regions to set clocks forward (typically 1 hour) during the longer days of summer and back again in autumn. Time changes resulting from daylight saving time have the potential to impact clinical laboratory instruments, computer interfaces, and information systems. We analyzed turnaround time data for an academic medical center clinical laboratories (chemistry, hematology, blood gas analyzer, and transfusion medicine), examining how turnaround time was impacted by the daylight saving time shifts in 2017. We also determined whether the daylight saving time shift on November 5, 2017 (“fall back” by 1 hour) resulted in any “absurd” time combinations such as a receipt time occurring “before” a normally later time such as final result. We also describe challenges resulting from daylight saving time changes over a 5-year period. The only significant impact on turnaround time was for clinical chemistry samples during the autumn daylight saving time change, but the overall impact was low. Four instances of absurd time combinations occurred in the autumn time change with only a transfusion medicine example resulting in an interface error (a Type and Screen resulted “before” receipt in laboratory). Over a 5-year period, other daylight saving time impacts included problems of reestablishing interface to instruments, inadvertent discrepancies in manual time changes at different points of the core laboratory automation line, and time change errors in instruments with older operating systems lacking patches that updated daylight saving time rules after 2007. Clinical laboratories should be aware that rare problems may occur due to issues with daylight saving time changes.

Keywords

clinical chemistry tests, clinical laboratory information system, electronic health record, hematology, software, transfusion medicine

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Introduction

Daylight saving time (DST) is a practice in some countries and local regions to set clocks forward (typically 1 hour) during the longer days of summer and back again in autumn. DST has a long and complicated history worldwide, including regions where DST was adopted and then later repealed.^{1–4} In the United States, the majority of states and territories have adopted DST, with the major federal legislation being the Uniform Time Act of 1966.^{1,2,5,6} Current exceptions in the United States include Arizona (except for the Navajo on tribal lands), Hawaii, and the overseas territories of American Samoa, Guam, Puerto Rico, Northern Mariana Islands, and the US

Virgin Islands. Arizona observed DST starting in 1967 as part of the Uniform Time Act but then exerted an exemption statute and opted out of DST in 1968. Most of the state of Indiana did

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not observe DST until 2006. In the United States, DST starts on the second Sunday in March (spring forward) and ends on the first Sunday in November (fall back), with the time changes at 2:00 AM local time. This means that the time officially jumps from 2:00 AM to 3:00 AM on the spring date and back from 2:00 AM to 1:00 AM on the autumn date.

There is relatively little published literature on the impact of DST changes in health care, with the major focus being on accidents,⁷⁻¹² myocardial infarction risk,^{13,14} mood disorders,¹⁵ and sleep disruption.¹⁶ Two studies have shown a small but transient impact of DST shifts on the incidence and timing of myocardial infarction, with elevated risk during the spring shift and lower risk in the autumn change.^{13,14} Multiple studies have shown increases in motor vehicle and/or other accidents following the spring shift, also with elevated risk in the spring.^{7-9,11} However, other studies have not seen a significant effect.^{10,12} The DST impact on myocardial infarction and accidents may be related to the loss of sleep during the spring shift and an extra hour of sleep during the autumn shift. Impacts of DST changes on mood disorders have also been reported.¹⁵

There has been little investigation on DST impact on instrumentation and devices used in health care. A review article on technical issues that may affect insulin pumps covered potential glitches associated with DST changes.¹⁷ These include lack of automatic adjustment and global positioning system capability of some devices. Manual changing of time on insulin pumps carries risks such as inadvertent confusion between AM and PM (for devices not using military or 24-hour time) or adjustment of time in the wrong direction for a DST shift. In the case of insulin pumps, erroneous time could lead to improper timing of insulin delivery. The risks with insulin pumps could equally well impact a variety of medical devices and instrumentation that depend on accurate time for their function yet have varying capabilities for the DST adjustment.

Within clinical laboratories, DST changes can have a number of impacts. First, depending on instrument and computer capabilities, performing the time change itself may require shutdowns or pauses that impact specimen processing and analysis, potentially requiring additional manual staff effort and delaying turnaround times (TATs). Second, times associated with specimens (eg, order time, collection time, receipt time, and result time) will be affected if the DST change occurs somewhere in the specimen history. This may have negligible impact for most specimens but can potentially result in problems such as “absurd” times (eg, result time occurring “before” receipt time in the autumn change) or complicate the interpretation of laboratory tests where timing may be especially important (eg, therapeutic drug levels and associated medication administration times; or Type and Screen results relative to blood product release). Lastly, the DST change may inadvertently be adjusted in the wrong direction, either due to manual error or software glitch.

In this report, we evaluate the impact of DST changes on the operations of clinical laboratories within an academic medical center. This analysis was originally prompted by DST-related technical problems within the core laboratories that ultimately led to a more detailed protocol for handling the DST shifts. Our

analysis included assessment of the number and type of specimens impacted by the spring and autumn time changes and of problems resulting from the DST changes.

Material and Methods

Institutional Setting

The institution of this study, University of Iowa Hospitals and Clinics (UIHC), is a 761 bed state academic medical center that serves as a regional tertiary/quaternary care center with a full range of pediatric and adult inpatient and outpatient services, including intensive care units. The electronic health record (EHR) for UIHC has been Epic (EpicCare Ambulatory and EpicCare Inpatient version Hyperspace 2017, Madison, Wisconsin) since May 2009. The laboratory information system (LIS) for all UIHC clinical laboratories is Epic Beaker (version Hyperspace 2017), with Beaker Clinical Pathology and Anatomic Pathology (AP) implemented in 2014 and 2015, respectively.^{18,19} Interfacing of laboratory instruments to the LIS is mostly via middleware software (Instrument Manager, Data Innovations, Burlington, Vermont).^{19,20} The core laboratory has a Roche Diagnostics (Indianapolis, Indiana) automated line (8100) that connects to 10 cobas 8000 chemistry analyzers and 2 Sysmex XN series hematology analyzers. The Roche chemistry analyzers were upgraded from modular P (photometric and ion-selective electrode) and E170 (immunoassay) analyzers to the cobas 8000 series of analyzers in February 2013. The 8100 automated line replaced the MPA-7 preanalytical line in January 2017. The introduction of the 8100 line also included the hematology (Sysmex, Lincolnshire, Illinois) analyzers, which were formerly separate from the process of the chemistry analyzers. The transfusion medicine LIS for the UIHC DeGowin Blood Center utilizes software from Haemonetics (Braintree, Massachusetts).

The core laboratory (chemistry and hematology) runs approximately 3 500 000 tests annually. The DeGowin Blood Center issues approximately 1300 packed red blood cell, 4200 plasma, and 4100 platelet units per year. The Blood Center also includes pheresis and tissue bank services.

Analysis

Data in this report were collected as part of a retrospective study approved by the University of Iowa Institutional Review Board (protocol # 201801719) covering the time period from January 1, 2012, to December 31, 2017. This study was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). As previously described,^{21,22} Epic Reporting Workbench was used to retrieve order descriptions, order and result date/times, patient demographics, patient location, and results for clinical laboratory testing. The analysis also utilized preexisting TAT and specimen tracking reports from Healthcare Enterprise Decision Intelligence, a data warehouse managed by UIHC hospital information technology (Health Care Information Systems).²³

Table 1. UIHC Core Laboratory and Transfusion Medicine Instruments and Interfaces.

Manufacturer	Model	Quantity	Method of Time Change	Comments
Advanced Instruments	A2O Osmometer	1	Manual	
Bio-Rad	BioPlex 2200	2	Automatic	
CellaVision	DM96	2	Automatic	<ul style="list-style-type: none"> Nearly 5-hour downtime in 2017 autumn DST change due to loss of connectivity with middleware
Data Innovations	Instrument Manager version 8.13	1	Manual	<ul style="list-style-type: none"> Cache database requiring manual time change and then restart Instruments may have difficulty regaining conductivity
Immucor	Echo	2	Manual	<ul style="list-style-type: none"> Uses Windows XP without patches and updated DST dates post-2007 (vendor restriction)
Radiometer	ABL 90	4	Automatic	<ul style="list-style-type: none"> If auto-update fails, troubleshooting deferred until dayshift
Roche	Cobas c502, c602, c702	3, 4, 2	Manual	<ul style="list-style-type: none"> Analyzers must be in standby mode with samples cleared out
Roche	Cobas p701 post-analytical storage	1	Automatic	
Roche	8100	1	Manual	<ul style="list-style-type: none"> Must be cleared out prior to time change Samples remaining in system will error out
Siemens	BCS XP	2	Manual	<ul style="list-style-type: none"> Extended downtime in previous years following time change
Sysmex	XN series	1	Automatic	<ul style="list-style-type: none"> Manual process for time change is quite involved if auto-update fails

Abbreviations: UIHC, University of Iowa Hospitals and Clinics; DST, daylight saving time.

With regard to issues that occurred during DST changes, e-mails and variance reports were reviewed for DST changes in 2012–2017. The analysis focused on core laboratory (chemistry, hematology, blood gas analyzers) and transfusion medicine. AP was not included, since the AP laboratory is not open during the hours spanning the time change. Microbiology and molecular pathology were also not included due to very light volume of test resulting during the hours spanning the time change. The analyzers and interfaces potentially most impacted by DST changes are listed in Table 1, which also includes comments on DST-related issues. Table 2 summarizes the overview of the core laboratory staff protocol for the DST changes. The current protocol has been adapted multiple times over the past 5 years to address challenges during previous DST changes.

Detailed analysis on TAT and time stamps (eg, receipt time, result time) covered in this report cover the DST shifts in 2017 only, when these times could be reliably extracted. For automated instrument analysis, tests potentially most affected by DST changes were defined as those with receipt times in the laboratory within 2 hours before and 2 hours after the time changes (4 hours total). The TAT analysis examined this 4-hour period compared to the entire day. For the autumn time change, “absurd” time combinations were those where a normally later time appeared “before” a normally earlier time (eg, result time before receipt time). The March 12 and November 5 DST change dates in 2017 were compared to the other Sundays in March and November of that year. For the non-DST Sundays in March and November, 0:00 to 04:00 was the time period that was used to correspond with the DST Sundays. Statistical analysis was conducted using Student *t* test.

Table 2. Timeline for Time Change Tasks at UIHC.

Approximate Time (Unadjusted for DST Change)	Tasks
01:30-01:45	Hospital IT contacts laboratory
01:45	Stop loading 8100 automation line and clear out specimens
	Log off middleware terminals
02:00-02:30	Cycle middleware to adjust times (typically takes less than 10 minutes)
	Change time on data manager and then control units for chemistry analyzers; verify that times are synced
	Change time on other instruments requiring manual adjustment
02:30-02:45	Check instrument connections
	May need to reset middleware interfaces
	Contact technical support for any problems
	Touch base with hospital IT
02:45	Troubleshoot problems

Abbreviations: UIHC, University of Iowa Hospitals and Clinics; DST, daylight saving time.

Results

Impact of Daylight Saving Time on Automated Testing Turnaround Time and Time Stamps

We focused detailed TAT analysis on the potential impact of DST shifts using data from 2017. The core laboratory has an automation line that links to the main chemistry and hematology analyzers and performs preanalytical functions, such as centrifugation and aliquoting. The core laboratory also includes a Critical Care Laboratory section that performs analysis on

blood gas analyzers for whole blood specimens. This is not connected to the automated line.

The TATs for clinical chemistry, hematology, and blood gas analyzer analysis are presented in Figure 1. The data include all Sundays in March 2017 and in November 2017, with TAT separated into 2 categories: specimens with receipt times within the 4 hours bracketing the time change (0:00-04:00 in non-DST Sundays) and for the entire day for each Sunday. Table 3 summarizes the number of tests during the days of analysis. As can be seen in Figure 1, the only significant impact on TAT was for clinical chemistry samples during the autumn time change (November 5, 2017). Both hematology and blood gas analyzer analysis had slightly higher average TAT during the 0:00 to 04:00 time period compared to other Sundays but did not reach statistical significance. The standard deviation of the TAT for the hematology and blood gas analyzer analysis was wider than in corresponding Sundays, driven by a small number of samples with extended TAT related to interface resulting issues following the DST change. Manual differentials were used as a backup for samples whose automated differential could not cross the interface. Overall, the impact of DST was only evident in the early morning times and did not impact average TAT for the entire day.

We also analyzed whether the DST changes resulted in any “absurd” time combinations. The only absurd combinations were noted during the autumn DST change (November 5, 2017), with 2 chemistry and 1 hematology test result each having a result time “before” receipt time in the laboratory. None of the 3 results ended up with the result time being before the specimen collect or provider order time in the EHR. There appeared to be no clinical impact for these 3 results.

The spring 2017 DST change causes no reported issues in transfusion medicine. The November 2017 DST change resulted in a single absurd case of a Type and Screen result occurring “before” receipt in laboratory. This situation caused an interface error from the Haemonetics SafeTrace Tx (transfusion medicine LIS) to the EHR and required manual intervention to post the result in the EHR. The only blood products issued by the UIHC Blood Center in the immediate time around the autumn 2017 DST change were 2 packed red blood cell units released at 01:12 after the fall back in time. These were released without incident.

Daylight Saving Time -Related Issues in Earlier Years

Review of data from 2012 to 2016 revealed some other issues associated with DST changes. In general, it was the autumn shift (fall back) that created more issues. In 2016, the core laboratory coagulation analyzers (Siemens BCS, Lincolnshire, Illinois) had difficulty interfacing back with the middleware system following the manual instrument time change, even after multiple restarts. The analyzers were operational after the manual time change, but interface took several hours to be reestablished. This caused TAT delays in coagulation test resulting.

In earlier years, more challenging DST issues have arisen at various points in the middleware interface and automated line.

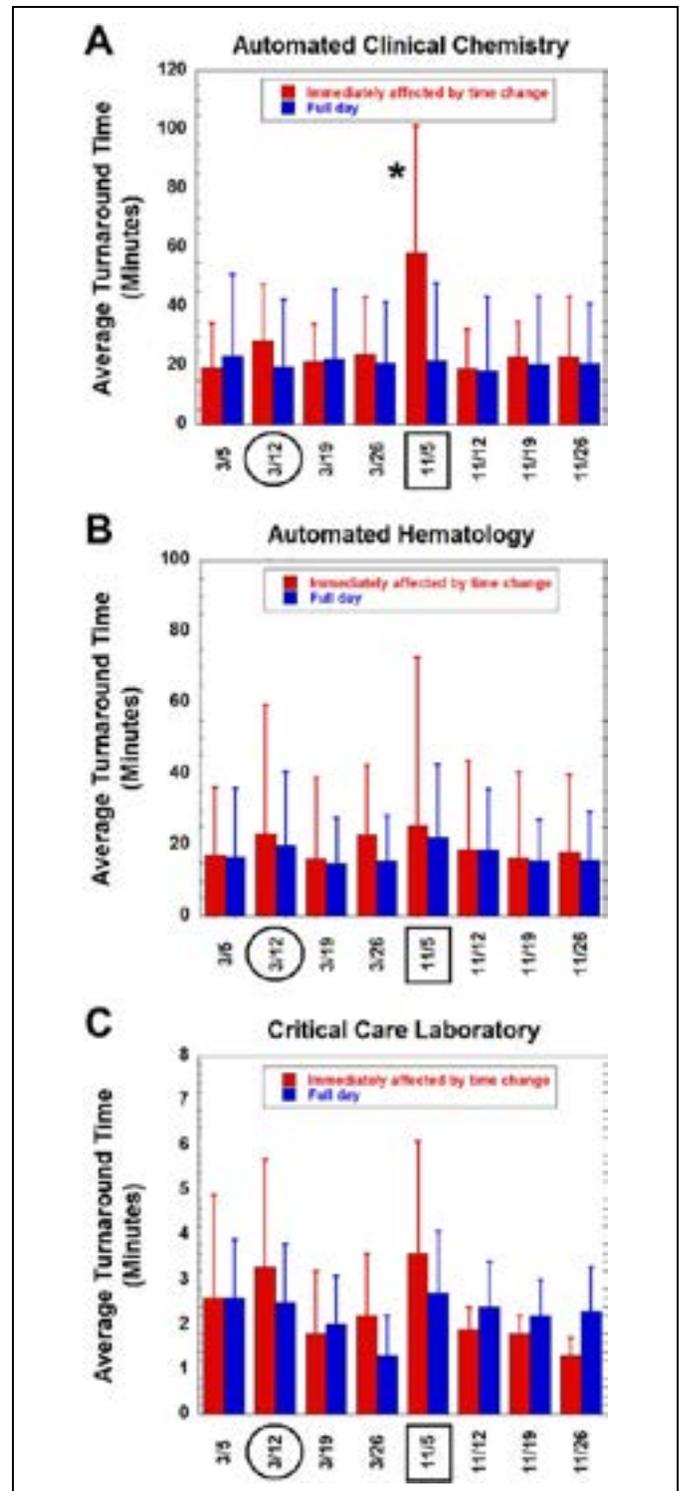


Figure 1. Turnaround time (TAT) for clinical chemistry (A), hematology (B), and critical care laboratory (C) testing during Sundays in March and November 2017. TAT was calculated as from receipt in laboratory to final result. For each date, the first bar (in red) is for the 2 hours before and 2 hours after DST shift and for 0:00 to 04:00 for the other 6 Sundays. For each date, the second bar (in blue) is for the entire day. The only significant difference in TAT is on November 5 for clinical chemistry tests for the hours immediately bracketing the DST change (labeled with *, $P < .01$). DST indicates daylight saving time.

Table 3. Automated Testing Volumes for Sundays in March and November 2017.

Date	Clinical Chemistry*		Hematology*		Critical Care Laboratory*	
	0:00-04:00	All Day	0:00-04:00	All Day	0:00-04:00	All Day
March 5	96 (4.2%)	2276	59 (5.0%)	1173	21 (5.6%)	376
March 12 [†]	102 (3.9%)	2634	55 (4.4%)	1248	15 (4.2%)	355
March 19	79 (3.1%)	2517	53 (4.4%)	1198	14 (3.8%)	364
March 26	69 (3.3%)	2088	47 (4.2%)	1132	19 (5.0%)	378
November 5 [†]	107 (4.5%) [‡]	2357	65 (5.0%) [‡]	1295	23 (6.4%)	362
November 12	92 (3.7%)	2470	51 (3.6%)	1417	16 (4.2%)	377
November 19	82 (3.5%)	2321	54 (4.6%)	1172	14 (4.0%)	348
November 26	60 (2.9%)	2055	46 (3.8%)	1198	12 (4.0%)	300

*Values indicate number of tests in the specified time periods, either 0:00 to 04:00 for non-DST Sundays (or the 2 hours before and after DST change for March 12 and November 5) or all day. The percentage for the 0:00 to 04:00 data column is the percent of total samples in that time window to the volume for the entire day. Clinical chemistry includes automated serologies. Hematology includes blood counts and nonbatched coagulation testing (eg, prothrombin and partial thromboplastin times). Critical Care Laboratory includes analysis of whole blood specimens on blood gas analyzers.

[†]In 2017, March 12 and November 5 were the DST dates in the United States.

[‡]Two chemistry tests and 1 hematology test had “absurd” combination of result time before receipt time.

In 1 case, a staff member attempting a time change on a control unit for the automated line entered an incorrect password too many times, causing system lockout. This caused extended delay in bringing the full automated system back online as resolution required vendor technical support by telephone. In another case, the spring DST change for the automated line front-end (Roche MPA-7 at that time) was inadvertently overlooked, causing time discrepancies between the preanalytical times and those on the downstream chemistry analyzers. The end effect was that the analyzers showed the correct time that was an hour discordant with the (unchanged) preanalytical receipt time, causing a large number of tests to show up erroneously on the overdue list for TAT. Fortunately, the issues encountered still allowed for manual resulting of testing, if needed.

A recurring challenge at UIHC has been analyzers connected to computers with older operating systems, such as Windows XP. Due to vendor restrictions on operating system updates and patches, some computers have out-of-date rules for DST in United States, not incorporating changes to dates put into law 2007. This can lead to an incorrect time change (on the wrong date based on pre-2007 DST dates) or erroneous change back of a valid time change driven by an external standard such as Atomic Clock, examples of which were encountered during the past 5 years. This issue will fade as operating systems get updated with current DST rules.

Table 4 summarizes the types of issues encountered with DST shifts.

Discussion

There is very little literature on the impact of DST on operations within health care. Most focus has been on the impact of DST shifts on accidents, mood disorders, and sleep.⁷⁻¹⁶ A review article on technical issues potentially affecting insulin pumps did discuss glitches associated with DST changes that could similarly affect other devices and instrumentation within health care.¹⁷

Clinical laboratories are a setting where DST changes in time can create problems, with the most obvious impact being on clinical laboratories that operate during the night shift. As illustrated in our own analysis at an academic medical center core clinical laboratory, the methods of changing time for DST shifts vary between analyzers, automation line, and interface software. Some systems change date automatically, while others require manual intervention, in some cases requiring instrument pause or reset prior to time change. Manual time changes may require staff to interact with computer logins or menus on control units or analyzers that they would otherwise not routinely deal with. In addition, problems can occur even for analyzers that change date automatically if there is a discrepancy between the analyzer time and that of the automation line or interface software. Laboratory computers with unpatched older operating systems due to vendor restrictions (eg, the now unsupported Windows XP operating system) may have out-of-date DST rules in addition to their other security risk (sometimes necessitating measures such as strict firewalls). As we outlined above, we have encountered DST issues arising from all of these factors at various times.

Interfaces between the EHR and LIS present an additional complexity in DST changes. The institution in this report (UIHC) utilizes an integrated EHR-LIS system (Epic Beaker Version Hyperspace 2017) that has a common method for time change for the EHR and LIS software. Other institutions with separate EHR and LIS can encounter time change issues related to EHR-LIS interface(s).

One broad issue raised by the challenges in DST changes is the role of manufacturers and regulatory bodies in defining standardized practices and protocols for management of time for clinical laboratory analyzers, interfaces, and information systems. In theory, automated time switches following a consistent standard could streamline the process of managing DST shifts. However, as seen in our retrospective review, some of the most challenging problems resulted when automated DST shifts did not go as planned, in some cases resulting in troubleshooting deferred until dayshift because of cumbersome

Table 4. Types of Issues Encountered.

Issue	Challenges and Considerations
Analyzers/ computers with older operating systems	<ul style="list-style-type: none"> Operating system such as Windows XP unable to be patched due to vendor restrictions may lack current DST change roles (eg, 2007 change in US law) Inaccurate time change can occur with conflict between external time standards (eg, Atomic clocks) that sync system time but then erroneously corrected by out-of-date operating systems perceiving time is incorrect
Cache databases “Fall back” issues	<ul style="list-style-type: none"> Require instrument/computer pause, manual time change, and then restart Possible for “absurd” timing (eg, “result” time to be before “received” time) that may cause errors Extra hour of time needs to be covered by laboratory personnel One additional hour to prepare for workload from inpatient phlebotomy
“Spring forward” issues	<ul style="list-style-type: none"> Generally fewer issues and without risk for absurd timing (unless time change done in incorrect direction) Jump in time means 1 less hour to prepare for morning inpatient phlebotomy rush Staff works 1 fewer hour (does this affect pay for that shift?)
Staffing	<ul style="list-style-type: none"> Time change occurs on third shift with low staffing May encounter unexpected challenges (eg, unfamiliar with how to access systems normally perpetually logged in; inadvertent lockout to software access) Manual time updates compete with other tasks
Syncing issues	<ul style="list-style-type: none"> Failure to sync analyzer and automation line times can lead to wrong turnaround times (eg, samples showing up erroneously as overdue)
Transfusion medicine	<ul style="list-style-type: none"> Errors in timings of compatibility testing (eg, Type and Screen result before specimen receipt resulting in interface error) Confusion in blood product distribution and administration time if time change intervenes

manual backup processes (Table 1). The variability in computer operating systems described above adds an additional layer of complexity.

In addition to time discrepancies between instruments and interface software, the autumn DST change (fall back) has the additional risk of absurd time combinations, such as a result time being “before” receipt time. In 2017, we documented 4 occurrences of this (3 in core laboratory, 1 in blood bank), with only the blood bank Type and Screen time discrepancy resulting in an interface error blocking result transmission to the EHR. In our laboratory, the number of absurd time combinations is limited by holding some specimens that arrive just prior to the DST change (especially since the automation line and analyzer are already in pause mode and not able to load new specimens).

In the United States, DST shifts occur on early Sunday mornings (02:00) in March and November. For clinical

laboratories associated with hospitals or medical centers, the DST changes would generally fall within the third shift for personnel and also at a time of low specimen volume, being after most late evening inpatient draws and typically before routine morning phlebotomy draws start. For transfusion medicine, the DST changes also typically occur when there is low activity for blood products, being well outside routine surgery hours.

Although the autumn DST change may cause unique problems such as absurd time combinations and an extra hour of work, the fall back in time does allow the staff an additional hour before heavier specimen load arrives (eg, morning inpatient phlebotomy). In contrast, the spring DST change results in a lost hour, with less time to resolve problems before daytime. Human resource issues also arise with the DST changes. For example, does the extra hour during the autumn DST shift garner overtime pay for that additional hour or the regular hourly rate? Conversely, how is compensation handled for the spring DST change which results in 1 less hour of actual work?

Overall, low activity in early Sunday morning hours in the clinical laboratories and blood bank mitigate the impact of DST changes on clinical laboratory service. In the present study, the impacts on TAT for core laboratory were either negligible or apparent for only the hours immediately bracketing the DST change. The occurrence of DST changes on the third shift does raise some potential challenges when problems occur. For most clinical laboratories, early Sunday mornings may be a time of light staffing, possibly without supervisory staff being routinely present or covering multiple laboratory sections. Exceptions may include regional or national reference laboratories that encounter higher specimen volumes from courier deliveries in the evening or intentionally balance high test volumes across all 3 shifts and thus have a greater depth of personnel during the third shift. Early Sunday morning may also be a time when it can be difficult to get through to vendor support for problems that occur. At our institution, a hospital IT representative checks in with the laboratory prior to the time change and is available to coordinate if any problems occur. We have strengthened our protocol for DST changes over the years to account for previous issues.

In summary, DST can affect clinical laboratories, especially with the November fall back in time, but with a generally small impact due to low volumes of specimen testing on early Sunday mornings. Clinical laboratories should be aware that rare problems may occur due to issues with DST changes.

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When Pathology and Laboratory Medicine Becomes a Commodity and Health Care Becomes Both Its Customer and Owner

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Keywords

Alberta, Calgary Laboratory Service, health-care regionalization, merger, model

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The purpose of this Op-Ed is to provide readers with an update on the provision of academic pathology and laboratory services in Alberta and across Canada. It builds on an article “Calgary Laboratory Services: a unique Canadian academic model following provincial integration of public, private, and academic laboratories” that was published by *Academic Pathology* in 2015.¹ This Op-Ed documents that the Calgary Laboratory Services’ (CLS) model is presently expanding across Canada, updates and analyzes recent changes in Alberta, and suggests lessons learned from the model’s evolution.

Background Pertaining to the 2015 Publication

The previous paper reported that “regionalization” of health care² was highly disruptive in the mid-1990s after it was initiated by a newly elected provincial government in Alberta committed to balancing the provincial budget at all costs. One result was a 40% province-wide budget cut for laboratory service provision and the exodus of about 40% of the province’s pathologists, all in about 1 year.¹ This turmoil instigated a precipitous merger of all public (hospital-based) and private laboratories in Calgary, including the University of Calgary Department of Pathology and Laboratory Medicine in 1996. This public–private partnership was called CLS with industry holding a 50.1% share and the Calgary Regional Health Authority (CRHA; ie, the provincial health-care service covering Calgary and surrounding towns) owning a 49.9% share. In 2006, CLS became a wholly owned subsidiary of CRHA when the public side bought out the private side. After the 2008 amalgamation of 9 regional health authorities into a single

authority, Alberta Health Services (AHS), CLS became a wholly owned subsidiary of AHS (ie, the government-owned provincial health-care service). Despite the tumultuous 20-year period, academics eventually prevailed—but only after the shock and awe had worn off.¹

The paper also described how the “CLS model” had begun to be implemented elsewhere in Canada, citing 2 locations: Eastern Ontario Regional Laboratory Association (a merger of all hospital laboratories in our nation’s capital and the University of Ottawa’s Pathology Department) and Diagnostic Services Manitoba (a merger of lab services for the Province of Manitoba and the University of Manitoba Pathology Department), which is currently undergoing additional changes of an unknown magnitude as well as a name change to Manitoba Shared Health Services.

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Table 1. Elements of CLS and CLS-Like Models.

- Merger of academic and nonacademic hospital pathology and laboratory medicine services.
- Combined service assumes academic duties for a Canadian medical school.
- Merger was either precipitated by provincial government action or was initiated by the provincial government.
- Merger results in upgraded and harmonized quality assurance programs.
- Merger saves provincial health-care dollars through increased efficiency.
- Enlarged service base and larger test volumes can facilitate research, enhance teaching opportunities, and promote clinical trials.
- Comprehensiveness of an expanded testing menu results in lessened need to refer out testing.
- Merger may or may not include community laboratory service provision; if not included, these are likely provided by private laboratories.
- Merger may or may not result in the provincial health-care service becoming both the owner and customer of the merged laboratory service. If government-owned, the system is at risk for undercapitalization which can stifle innovation.
- Seamless movement of research and innovation is possible because of inclusion of the academic mandate and the capacity for knowledge translation within the system.
- Capital planning can be more deliberative and reduce redundancy.
- Some aspects of the CLS/CLS-like model are variable depending upon how and where it is being implemented.

Abbreviation: CLS, Calgary Laboratory Services.

Continued Expansion of the Calgary Laboratory Services Model Across Canada

Now, in 2018, 6 more Canadian medical school pathology departments are being assimilated into CLS-like merged laboratory structures, specifically at the University of Alberta (discussed in detail below), the University of Saskatchewan, McGill University, University of Montreal, Sherbrooke University, and Laval University. With roughly half of Canada's medical schools patterning their academic pathology departments to some extent after CLS, the "CLS-like model" (Table 1) is clearly becoming a dominant academic laboratory service model in Canada.

It makes sense that the CLS model is expanding across Canada as such mergers permit simultaneous widespread implementation of quality assurance/improvement initiatives at multiple sites as well as achieving significant cost savings for laboratory service provision. When CLS formed in 1996, immediate efficiencies were gained and annual laboratory operating expenses decreased from Can\$110 million to Can\$60 million at the time of the transition; however, because of the abrupt nature of the merger, there were big-ticket 1-time transition costs which had not been planned for, such as switching to common testing platforms to achieve single reference ranges for the city and implementing a system-wide laboratory information system (personal communication, Fred Swaine, MD,

former CLS Chief Operating Officer, September 28, 2017). While operational savings of this magnitude would be specific to Calgary in 1996-1997, implementation of CLS-like models almost certainly generates real cost savings elsewhere in Canada. Calgary Laboratory Services currently accessions >30 million tests, >160 000 surgical cases, and >210 000 cytology cases per year.

As CLS-like models expand across Canada, the degree of similarity, will of course, vary widely from school to school. Even the approach at the University of Alberta will differ from in Calgary because the CLS model is now poised to become province-wide, and the medical school departments in Calgary and Edmonton, combined with their respective associated zone clinical departments, will become hubs for clinical service provision across all of Alberta.

It is a fascinating time for academic pathology in Canada! It is also timely that the Alberta story be brought up to date and learnings discussed that might benefit transitioning academic pathology and laboratory medicine departments and their clinical laboratory services partners.

An Alberta Review and Update

From the time of health-care regionalization in Alberta in the mid-1990s, the Capital Regional Health Authority (Edmonton)/the University of Alberta took a very different approach than the CRHA/University of Calgary.³ This was likely in large part because merging all hospitals in Edmonton was not politically feasible as 2 of the larger hospitals were under Covenant Health, the largest Catholic health-care provider in Canada. Therefore, true regionalization occurred in Calgary but not in Edmonton. As a result, Edmonton continued with multiple pathology and laboratory service providers including large and small commercial laboratories and laboratories operated by Covenant, the Health Authority, a cancer hospital, and the University of Alberta. A large commercial laboratory was awarded a 15-year contract to provide community laboratory services.

In the early 2010s, it was necessary to develop plans for when this 15-year contract ended, and AHS decided it would contract with a private company to provide a new CLS-like laboratory in Edmonton which would encompass the University of Alberta Department of Laboratory Medicine and Pathology, meet its academic mandates, and would also provide global hospital and community laboratory services for Edmonton and the northern part of the province (geographically 75% of a province which has roughly the same surface area of the state of Texas); the contract was to be for Can\$3 billion over 15 years. A request for proposals (RFP) was issued. Many assumed the current community provider would eventually be hired, but the RFP process would force them to offer competitive pricing. Eventually, 3 multinational laboratory corporations were short-listed. Prior to the 2015 provincial election, Sonic Healthcare of Australia was selected to go forward with a full proposal (<http://www.cbc.ca/news/canada/edmonton/alberta-health-services-privatizing-edmonton-labs-1.2460544>;

<http://www.cbc.ca/news/canada/edmonton/australia-s-sonic-healthcare-nets-3b-contract-for-edmonton-labs-1.2802270>). This unexpected result prompted the current community provider, which was in part owned by one of the 2 multinational corporations which had been unsuccessful in the RFP, to put forward a legal challenge based upon alleged flaws in the bidding process and this prevented further negotiations with Sonic for over 6 months.

In mid-2015, a new provincial party was elected to govern Alberta after a 44-year-long reign of a single political party. On August 14, 2015, the new government of Alberta cancelled the RFP stating that additional privatization was not in the public interest and the whole project was placed on hold. The government announced that it would study laboratory services and then develop a plan to restructure these provincially (<http://www.cbc.ca/news/canada/edmonton/health-minister-cancels-3b-contract-will-not-expand-private-services-in-alberta-1.3190004>). As an interim measure, the contract for the community provider was extended “as a stop-gap measure to March 31, 2017” to assure continued lab services (<http://edmontonjournal.com/news/local-news/alberta-health-services-extends-contract-with-lab-company>). Interestingly, immediately prior to the cancellation, there had been a ruling that AHS had breached its duty of procedural fairness (<http://globalnews.ca/news/2163916/watch-live-albertas-health-minister-discusses-lab-services-in-edmonton/>; https://www.huffingtonpost.ca/2015/08/13/alberta-health-minister-cancels-contract-with-private-lab-company-from-australia_n_7985202.html) and that the bidding process had been compromised which led to additional legal wrangling and Sonic sought to recover its RFP costs; this was settled out of court. Because the original timeline to replace the current community provider was no longer feasible, the contract for the current community provider was extended by 5 years to March 31, 2022, with an agreement that AHS would pay the provider Can\$15 million over the life of the contract to “ensure equipment is upgraded,” as well as Can\$50 million at the end of the contract (<http://www.cbc.ca/news/canada/edmonton/alberta-health-services-to-extend-dynalife-contract-five-more-years-1.3735622>; <http://www.cbc.ca/news/canada/edmonton/alberta-health-services-to-buy-out-dynalife-transfer-services-back-to-province-1.3785100>). In addition to these payments, Dynalife’s parent company (Laboratory Corporation of America Holdings), reported in its 2016 Form 10-K filing with the United States Securities and Exchange Commission that it would amortize the value of Dynalife’s license in Alberta (US\$34.9 million) by 2022 (http://www.annualreports.com/HostedData/AnnualReportArchive/l/NYSE_LH_2016.pdf).

In retrospect, the initial plan would almost certainly have had disastrous consequences for CLS. Although CLS would have continued and would have provided laboratory services for the southern portion of the province in the short term, there were grave concerns that this scenario would not be sustainable as the playing field could not have been more uneven. One of the advantages that existed when CLS was part of a public-private partnership was that the private partner understood the importance of capital expenditures to provide state of the art

services and to remain competitive; unfortunately, this ceased to be a priority once CLS was publicly owned. Specifically, after becoming a wholly owned subsidiary of AHS, the CLS capital budget eventually decreased to 10% of what it had been a decade earlier. If Edmonton had private enterprise funding (with deep pockets) and CLS only public funding, the long-term outcome almost certainly would have resulted in CLS failing to be competitive and being absorbed into Sonic.

Curiously, it never made sense why 3 multinational commercial laboratories would fight over the opportunity to provide laboratory services for a population of less than 2 million people of which roughly three-quarters were residing in the Edmonton area and the rest being spread throughout the remainder of northern Alberta (with a land surface area larger than that of the State of California); furthermore, the contract would have required the successful company to create laboratory infrastructure from scratch, hire the current technical staff and pathologists, provide global academic services for the medical school, and meet many other highly specific conditions. Since this did not appear to be a recipe for profit, most at the time speculated that the business model was a loss leader approach, allowing a foothold in Canada from which Sonic could seek new business all across the country. In addition, with a potential monopoly on all regional clinical, genetic, and laboratory data, they would have had a unique and exploitable informatics asset as well as distinct advantages when competing for pharmaceutical industry dollars and clinical trial business. This model is now defunct with the change in government.

The New and Evolving Plan for Laboratory Services in Alberta

Early signals suggested that the new government planned to reorganize laboratory services for the entire province resulting in a single laboratory service entity as an AHS department, with its workforce under a common union; under this structure, laboratory decisions would have been almost entirely under the control of government health-care providers, and academic pathology leadership would have been largely disenfranchised.

In May 2016, the Health Quality Council of Alberta (<http://www.hqca.ca/>) at the request of the Minister of Health presented a report entitled *Moving Ahead on the Transformation of Laboratory Services in Alberta* (https://d10k7k7mywg42z.cloudfront.net/assets/5728f685d4c961739d073381/HQCA_Moving_ahead_on_transformation_of_laboratory_services_in_Alberta_January_18_2016_FINAL.pdf; <http://edmontonjournal.com/news/local-news/report-recommends-new-public-agency-be-responsible-for-medical-tests-in-the-edmonton-region>) which prompted the government to hire an external consultant, Dr Penny Ballem from Vancouver, who initiated a province-wide consultation. This eventually culminated in a report *Provincial Plan for Integrated Laboratory Services in Alberta* (https://d10k7k7mywg42z.cloudfront.net/assets/59121626a0b5dd209e020b9f/Provincial_Plan_for_Integrated_Laboratory_Services_in_Alberta_FINAL_.pdf) posted online

in May 2017. The report proposed “two conceptual options for a public sector stand-alone organization with the mandate to deliver laboratory services.” One possibility was to dissolve CLS and merge all provincial laboratory services into a single public agency and the other was to have all provincial laboratory services provided by an AHS subsidiary health corporation. Functionally, the second model would keep CLS intact as a wholly owned subsidiary of AHS and as a southern Alberta laboratory hub, form a similar laboratory service in Edmonton to function as the northern Alberta laboratory hub, and then have them share a single board of directors. Because the government recognized the success of CLS, it decided to pursue the latter approach. Technical workforces will share a single union province-wide, but the 2 hubs will maintain some degree of regional and academic autonomy; however, both will report to a single board. If implemented with strong board leadership that is arm’s length from AHS, this could be an ideal model that serves patients and academics alike, resolves current chronic issues on how to implement innovative new tests and rationalize provision of more esoteric laboratory services, and creates economic opportunities for the province. Fortuitously, the province has a once in a lifetime opportunity to get it right. The conditionality of a strong arm’s length board is critical (see below).

What Can Canada Learn From Calgary Laboratory Services and Alberta?

The CLS experience has shown that large city-wide laboratory mergers can work. Calgary Laboratory Services has provided strong, yet economical, high-quality clinical service provision and robust academic support for the University of Calgary; to accomplish the latter, a carefully constructed academic affiliation agreement, as previously described,¹ was necessary. Going forward, AHS is in the process of harmonizing clinical information and laboratory information systems province-wide. With a new merged entity with a monopoly on all laboratory services linked to population data for the entire province, Alberta could become a powerhouse for informatics research and a magnet for pharmaceutical company investment and clinical trial dollars. The merger, which also brings together expertise from 2 medical school departments, creates huge opportunities, which now far exceed those envisioned by the multinational corporations who were vying to serve only 43% of Alberta’s population. This merger creates the right set of circumstances for entrepreneurial opportunities that could never happen in the United States because of its highly fragmented health-care system. The distributed business models of hospitals in large American cities is not conducive to genetic or laboratory-based research attempting to encompass entire populations, as its fragmentation essentially precludes any chance of centralized access to population data and bio-banked patient samples. A visionary board, that is not risk adverse, could spin this merger into gold.

However, the main risk for any CLS-like entity arises when the provincial government health-care service becomes both

the owner (ie, provider) and the customer (purchaser) of laboratory services. While intuitively, a close provider–purchaser relationship should allow the provider to fine-tune their services to meet the needs of the customer, this is only a good thing for patients if the customer fully understands the nuances of its needs, knows what laboratory services best meet these needs, and hopefully wants the state of the art services that the provider naturally wants to provide. While pathology and laboratory medicine are viewed by laboratory physicians and many clinicians as a consultative medical specialty practice, many health-care administrators simply view “lab services” as commodities that are not much different than housekeeping and laundry services, a conundrum that is almost 100 years old.^{4,5}

Realistically, laboratory services are special as they have some elements of both medical practice and commodities. Good, fast, and cheap have been likened to the quest for the Holy Grail in business (also sometime called the “quality triad”). Conventional wisdom suggests that only 2 of the 3 are possible (<https://www.forbes.com/sites/joshlinkner/2015/01/15/pick-only-two-cheaper-faster-or-better/#68a95cc963a3>; <https://www.business.com/articles/fast-good-cheap-pick-three/>); however, for laboratory services, none of the 3 are absolute, all can be viewed as continuums, and the relationship is more of a complex equilibrium state. As such, normally, the “market” determines “good versus fast versus cheap” for any given laboratory service. However, this kind of simplistic analysis does not take into account that sometime efficiencies can be gained through lean processes and that, in high-tech fields like laboratory medicine, implementing newer and more innovative technologies can result in methodologies that are actually better, faster, and cheaper. However, to improve services and achieve operational savings, there may be one-time upfront infrastructure costs. While current laboratory services in Alberta are good and, because of robust quality assurance and a highly skilled and dedicated workforce, will undoubtedly remain so, further progress will require a mechanism for funding for innovation and implementation of newer testing platforms that could make the overall service better but the context, unfortunately, may inhibit such improvements.

Under normal conditions, academic laboratories based on new research should try to drive “good” to be the best, but the market ultimately determines whether better, for any given test, is more valuable than good. Academic commercial laboratories often focus on development of esoteric or niche testing. However, when the government health-care service, which pays globally for laboratory services, owns the provider, is the sole customer of the provider, and naturally wants to minimize the overall costs of providing health-care, incentives can become perverse, and the normal delicate good versus fast versus cheap equilibrium can easily be upset. Cheap can become the primary driving force for government-funded health services, with only lip service paid to making good better. In other words, “competent” laboratory services becomes good enough, and fast becomes defined as fast enough that clinicians ordering tests do not complain very much. When the government owns the provider, nonlaboratory physician administrators with little

content expertise can directly or indirectly play a role in determining whether new and innovative tests will be funded and the public can miss out on opportunities to have better, faster, and cheaper tests. For these reasons, decision-making by providers should be at arm's length from the purchaser.

In Alberta, where there are 2 medical schools competing to provide new and innovative forms of testing, the current service model (soon to become the past service model) has effectively contained costs by slowing the implementation of innovative testing by referring decision-making on implementation of new testing to one or more of 12 laboratory networks (<http://albertahealthservices.ca/lab/Page3285.aspx>), subspecialty-based committees with geographic representation covering the entire province, to adjudicate each proposed new test and make a recommendation to a province-wide committee charged with granting final budgetary approval. Essentially, this form of central decision-making in Alberta was highly political and stifled innovation—especially when one academic laboratory was often able to prevent the other from developing a new test. The new board will need to be able to judge proposals from either hub on merit and avoid regional politics; it should also be possible to retire the 12 laboratory networks, freeing up valuable time for the many laboratory physicians serving on these committees. The new proposed merged structure, with an arm's length board possessing content expertise, could essentially rectify these problems, resulting in esoteric tests being developed and then provided by one of the 2 academic laboratory hubs. Adding advanced modes of testing also creates research, educational, and economic opportunities.

Unfortunately, government agencies are naturally risk averse. And without content expertise and business experience, a board composed of nonlaboratory health-care administrators and government administrators may not be able to recognize unique opportunities that were obvious to multinational corporations and may not be able to correctly assess risk-benefit ratios. For them, it is simpler and much less risky to settle for competent laboratory services.

Success in this new venture will be dependent on a board of directors with vision to support enhanced capital budgets sufficient to facilitate innovation in both hubs. As the centerpiece of the new plan is a state of the art Can\$325 million "super lab" being planned and built from scratch in Edmonton to support northern Alberta (<http://edmontonjournal.com/news/local-news/province-to-announce-new-edmonton-super-lab-for-health-tests>), it is critical not to forget to budget for upgrading equipment and infrastructure in Calgary to support the laboratory needs for the southern and central more populous regions of the province. As a result of decimation of its capital funding for almost a decade, recent press coverage highlighted that 60% of CLS laboratory equipment is considered to be at the end of its life (<http://edmontonjournal.com/news/local-news/report-calls-for-one-lab-services-agency>).

Previous experience has shown that government overseers of the health-care mandate, often insist on direct oversight of decision-making related to laboratory services, providing only a "short leash" to laboratory medical leadership. For example,

in the past, there was resistance to going big and competing for third-party revenue as it was deemed unfair to use publicly funded infrastructure to compete against private laboratories in Alberta. With the new model in which all lab services will be public, this policy, which was previously an anchor preventing CLS from aggressively pursuing entrepreneurial opportunities which could have been used to fund new infrastructure, should no longer be a concern. Hence, the province's new model can be viewed as a grand new experiment which could create economic dividends.

The context has recently moved from hugely promising to worrisome. Several months ago, a new interim board of directors of the new yet-to-be-named provincial laboratory entity was appointed which did not include any medical school representatives, academic pathologists, industry experts, business persons, or academicians with expertise in laboratory medicine. In fact, the only pathologist on the interim board is from a community hospital in Red Deer, Alberta (strategically located exactly halfway between Edmonton and Calgary). The government is approaching a big crossroad as the interim board is to be replaced by a definitive board this fall. These appointments will predict the future of the new Alberta model and the future will be dim if the board is populated primarily by AHS health-care leadership and government administrators. Since at least 70% of important medical decisions are believed to be based upon laboratory results, Albertans could reap huge health benefits from the appointment of a knowledgeable board that recognizes and rewards innovation. Surely, the people of Alberta deserve the best that the combined pathology and laboratory medicine expertise at the University of Alberta and the University of Calgary can provide. Clearly, decisions made in Alberta, since CLS is now a Canadian prototype, will be studied and some will eventually be implemented elsewhere in Canada. What Alberta does next will affect academic pathology one way or the other across the country.

Knowledgeable laboratory physicians need to be inextricably linked to the decision-making process about what laboratory testing should be offered in the province, not health-care administrators focused on cost. Costs can be better controlled by providing the 2 hubs with global annual budgets and holding laboratory medical leadership accountable for these budget targets, rather than by micromanaging individual test implementation. Furthermore, learning from the multinational companies that were formerly vying to provide services to northern Alberta so that they could seize economic opportunities by providing testing outside of Alberta, the new board should reward innovation and allow the 2 hubs to defray some of their operating costs by aggressively seeking third-party revenue.

When CLS was formed in 1996, important decisions were made without considering their effects on academics and, as a result, it took the better part of a decade for research and teaching to fully recover and then thrive under the new system.¹ To the government's credit, academics have not been entirely forgotten in this merger of 2 CLS-like entities, each supporting a different medical school. So what should be the metrics to measure academic success for this new Alberta model? Some

Table 2. Recipes for Success When Implementing a New CLS-Like Laboratory Service.

- Advanced planning—do not implement change precipitously like when CLS formed.¹
- Engagement with “buy in” from laboratory physicians on:
 - Vision and mission statements.
 - Governance structure.
 - Importance of supporting the academic mandate.
- Clinical faculty appointments provided for any medical scientific staff at nonacademic hospitals who are expected to teach.¹
- Leadership must understand and manage town-gown dynamics.¹
- A remunerative structure that values both clinical and academic work.¹
- Explicit academic affiliation agreement outlining responsibilities of all parties.¹
- A mechanism to assure continued capital investment in infrastructure.
- If the potential of owner versus customer conflict of interest exists, a strong arm’s length board of directors is critical.
- If applicable, find a mechanism to avoid regional politics

Abbreviation: CLS, Calgary Laboratory Services.

of the metrics such as departmental publication output, citations, research funding, and growth in the number, scope, and quality of training programs should be the same as those used when evaluating CLS in 2015.¹ However, the 2 academic departments will need to be less competitive and to work together. While a substantial degree of duplication will be necessary so that both departments can provide core academic competencies to their respective medical schools, both will need to accept that sometimes one and other times the other will excel in different research or educational arenas based upon a myriad of factors, including the availability of certain skill sets or infrastructure in one local versus the other. If there is a need to decide upon a single location for an academic program, decisions should be made based upon excellence rather than politics.

The new Alberta model should be extremely well suited for clinical, translational, population-based genetic, and informatics research. Clearly, high clinical test volumes will also create opportunities for test development and validation as well as beta testing with industrial partners. However, the model will also need to support excellent fundamental research into mechanisms of disease, as classic experimental pathology research and discovery-based basic research are the foundations on which translational research is built.

In closing, the prospects for improved academic laboratory services and economic advancement in Alberta look promising if the definitive board has broad arm’s length representation that includes the academy and industry and if there is some distance between the provider and customer interests. For Canadian pathologists engaged in CLS-like reorganizations, vigilance and principled engagement are crucial. The CLS academic model can work exceedingly well in a Canadian environment, but success is dependent upon a workable system of governance and other factors (Table 2). For our American colleagues, perhaps you will find the erratic way decisions are made about our profession in Canada instructive, but, like you, we strive to provide excellent and innovative academic laboratory services.

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Evidence-Based Alignment of Pathology Residency With Practice: Methodology and General Consideration of Results

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Abstract

Few medical specialties engage in ongoing, organized data collection to assess how graduate medical education in their disciplines align with practice. Pathology educators, the American Board of Pathology, and major pathology organizations undertook an evidence-based, empirical assessment of what all pathologists need to learn in categorical residency. Two challenges were known when we commenced and we encountered 2 others during the project; all were ultimately satisfactorily addressed. Initial challenges were (1) ensuring broad representation of the new-in-practice pathologist experience and (2) adjusting for the effect on this experience of subspecialty fellowship(s) occurring between residency and practice. Additional challenges were (3) needing to assess and quantify degree and extent of subspecialization in different practice settings and (4) measuring changing practice responsibilities with increasing time in practice. We instituted annual surveys of pathologists who are relatively new (<10 years) in practice and a survey of physician employers of new pathologists. The purpose of these surveys was to inform (1) the American Board of Pathology certification process, which needs to assess the most critical knowledge, judgment, and skills required by newly practicing pathologists, and (2) pathology graduate medical education training requirements, which need to be both efficient and effective in graduating competent practitioners. This article presents a survey methodology to evaluate alignment of graduate medical education training with the skills needed for new-in-practice physicians, illustrates an easily interpreted graphical format for assessing survey data, and provides high-level results showing consistency of findings between similar populations of respondents, and between new-in-practice physicians and physician-employers.

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Introduction

In today's environment of rapidly advancing biomedical science and continually evolving health-care organization, clinical disciplines must adapt to emerging modes of practice and new methods of care. Yet incorporation of change into established practices is slow, sometimes approximating the rate of turnover of the practitioners themselves. In particular, practice habits acquired in the course of graduate medical education (GME) may last a practice lifetime, making GME a prime educational locus for any adaptation to change.^{1,2}

Such slow change highlights the importance of ongoing alignment of GME with the actual skills that physicians need to practice. GME however takes place at the interface between the established, didactic environment characteristic of undergraduate medical education and the evolving, experiential environment in which practice-based learning and improvement occurs. As a result, GME tends to reflect current practice within the training department rather than focus on future practice needs of the trainees. Justifying and enabling educational change in these circumstances requires explicit and specific information on the actual effectiveness of GME in preparing trainees for practice.³ In many disciplines, this information is not available because the experiences of recent trainees are not routinely assessed to see how effective the training they received was in efficiently preparing them for the demands they subsequently encountered in practice.

Educational and organizational leaders in one discipline (pathology) perceived an urgent and increasing need to develop an evidence-based assessment of how well current training in their discipline was meeting the needs of their trainees recently in practice.⁴⁻⁶ Pathology is faced with recent changes in both training and practice, as well as a longer term decrease in numbers of pathologists being trained.⁷ Combined, these called for systematic consideration of the effectiveness and efficiency of GME in our discipline, toward which a necessary first step was an evidence-based understanding of the alignment of the content of our training with that of our practice. This article sets forth how this was accomplished for pathology, and illustrates generally how such processes may be developed to contribute to discipline-specific, evidence-based paradigms more broadly in GME.

Specifically, this article describes the development of a system for the methodical, ongoing assessment of effectiveness and efficiency of training in a clinical discipline (pathology). Although there are particular features specific to residency training in each discipline, the general concepts needing to be addressed are similar: First, a practical categorization of areas of clinical activity, encompassing in common both training and practice; next, an individual determination of each

recently trained practitioner, of the importance to his or her practice of each of those areas, and of the usefulness of his or her training in that area in preparing him or her for practice; and finally, a demographic characterization of that individual's practice and other training (fellowships), to contextualize the practice importance and preparation information. This article describes our methodology and explains the role of each of the foregoing elements.

To understand the relationship of practice requirements to GME experience for each individual trainee's transition into practice, we collected information on multiple parameters of both the training and the practice experience of each individual respondent. We assessed by comprehensive survey, on an individual basis (1) the characteristics of the practice responsibilities into which that recent trainee had entered, together with (2) his or her residency preparation for practice, and (3) his or her other training and demographic characteristics. Each individual's transition from training to practice was then analyzed, by practice area, for alignment of training with practice. Data collected for each individual included the importance of practice and preparation in training for each practice area, fellowship(s) taken, practice setting and size, and number of years in practice. These and other parameters were assessed against different combinations of training and practice circumstances. As a check on the validity of these new-in-practice physicians' perceptions of the importance of these areas of practice, and their preparation for practice, we also similarly surveyed physician employers/supervisors of new-in-practice physicians in the discipline.

In this article, we focus on our methodological approach and an illustrative overview of results. Forthcoming companion articles will provide details of the pathology-specific results and their possible significance as a guide for change in content and/or organization of pathology GME.

Methods***Practice Area Categorization***

We had to develop a categorization of practice areas that could apply to both training programs and practice circumstances, so that we could simultaneously assess each area for (1) that area's empirical importance in the actual practices of our recent trainees and (2) the utility of the preparation for practice in that area these trainees had experienced in residency. This categorization was developed by consulting source material from the 2 primary agencies that set the existing specifications for training in pathology—the Accreditation Council for Graduate Medical Education (ACGME)⁸ and the American Board of Pathology (ABPath).⁹ The ACGME sets the requirements for accreditation

Table 1. Practice Areas Queried in New-in-Practice Pathologist Survey.

Autopsy pathology	Hematopathology
Medical autopsy	Hematopathology (lymph nodes, spleen, etc)
Forensic autopsy	Laboratory hematology (bone marrows, peripheral blood)
Surgical pathology	Bone marrow procedures
General surgical/oncologic pathology	Flow cytometry
Bone and soft tissue pathology	Coagulation
Breast pathology	Microbiology
Cardiovascular pathology	Medical microbiology
Dermatopathology	Molecular microbiology
Endocrine pathology	Molecular pathology
Gastrointestinal pathology (including liver, gallbladder, and pancreas)	Molecular diagnostics
Genitourinary pathology	Whole-genome sequencing
Gynecologic pathology	Cytogenetics
Head and neck pathology	Tissue typing (including human leukocyte antigens)
Medical renal pathology	General pathology
Neuropathology	Clinical consultation
Pediatric pathology	Laboratory administration
Placental/perinatal pathology	Medical coding and billing
Pulmonary/mediastinal pathology	Pathology informatics
Transplant pathology	Research methods/grant writing
Frozen section procedure	Special laboratory techniques (eg, immunohistochemistry, fluorescent in situ hybridization, polymerase chain reaction, mass spectrometry)
Gross description/dissection	Laboratory administration
Cytopathology	Lab leadership (eg, Lab medical director)
Cytopathology—gynecologic	Lab personnel management
Cytopathology—nongynecologic	Lab operations (eg, organization, quality control and quality improvement, workflow, test utilization)
Cytopathology—fine needle aspiration	Financial Management of Lab
Blood banking/transfusion medicine	Lab compliance issues
Blood banking/transfusion medicine	Pathology informatics
Blood center donor services	Basic hardware and software for general-purpose applications
Apheresis	Project management (data management, computational statistics)
Clinical chemistry	Laboratory management (ie, aggregating data sources and analyses)
Clinical chemistry	Oversight or management of the laboratory information system
Electrophoresis	Understanding lab-specific software, workflow, and automation systems
Immunology/serology	
Toxicology	
Urinalysis	
Molecular pathology*	
Molecular—Inherited diseases	
Molecular—hematopathology	
Molecular—pharmacogenomics	
Molecular—infectious disease	
Molecular—identity and/or histocompatibility testing	
Next-generation sequencing and/or genome-wide association studies	

* Subspecified “drill-down” areas.

of pathology training programs, and the ABPath sets the requirements for certification of individual pathology practitioners. Although both entities address structural and content aspects of training, the ACGME requirements are mainly programmatic and structural, whereas those of the ABPath are mainly individual and content focused. Starting from the training content areas in these requirements, a survey design taskforce comprised of experienced pathology practitioners, new-in-practice pathologists, pathology trainees, and pathology residency program directors developed a list of practice areas covering the spectrum of pathology practice activities that would recognizably be applicable both to pathology training and to practice. The practice area list we developed is shown in Table 1.

Survey Development

With these areas in hand, we developed 2 surveys—one for new-in-practice physicians (in practice for 10 years or less) and one for physician-employers/supervisors who had in the past 5 years hired new physicians for their first job. (We collected information from pathologists 10 or fewer years in practice because this was the time when they were comprehensively covered by the ABPath Maintenance of Certification [MOC] program, within which we could sort responses by length of time in practice. We chose 5 years for the employer survey based on our perception that employers would not likely be able to recall and report on the initial readiness for practice

of pathologists who had joined their practice more than 5 years ago.) The surveys were designed to answer 3 questions: (1) directly, how well does residency training align with the most critical knowledge and skills required for actual practice; (2) indirectly, to what extent does the certification examination (of the ABPath, which sets an implicit standard for pathology GME program content) assess the most critical knowledge and skills required for practice; and (3) by way of validation, do the physician-employers/supervisors agree with the new-in-practice physicians' self-assessments?

Since October 2014, the ABPath has administered the new-in-practice physician surveys in conjunction with the biennial MOC reporting required of its recent diplomates, in which approximately half of all diplomats certified since 2006 participate each year. The ABPath MOC reporting cycle runs each year from October 1 through the following January 31. To date, these MOC-associated survey data have been collected over 4 MOC cycles: the MOC surveys in the 2014 to 2015 and 2016 to 2017 cycles given to ABPath diplomates from even-numbered years; the MOC surveys in the 2015 to 2016 and 2017 to 2018 cycles given to diplomates from odd-numbered years (see Supplemental Table 1 for a description of the survey parameters.).

The physician-employer survey was fielded by the College of American Pathologists (CAP) in 2015. This survey was designed as validation for the MOC diplomate surveys rather than as a free-standing assessment tool. In contrast to the MOC surveys (fielded to all board-certified new-in-practice physicians in pathology as described above), we lacked a reliable general mechanism to identify all pathologist employers of new-in-practice pathologists. No entity had comprehensive data on pathology practices, practice leaders, or employers of pathologists. Also, although diplomates may be predisposed to respond to the survey because of its association with the MOC process, respondents to the physician-employer survey have no incentive to participate beyond a general interest in contributing to the potential improvement in GME, so we did not anticipate a comparably robust response to the survey.

As a proxy for identifying employers who supervise new-in-practice physicians in pathology, we sent an online survey to all CAP fellows (members) who had been in practice for at least 5 years. (Although pathologists in practice for at least 5 years may not have supervisory responsibilities for new-in-practice pathologists, previous research by the CAP has shown that surveys sent to this population provide relatively high response rates on information about new pathologists.) Respondents who neither hired nor supervised a new-in-practice pathologist within the last 5 years were screened out of the survey. The remaining self-identified pathologist-employers/supervisors were asked practice-area questions about the most recent new-in-practice pathologist they hired/supervised. These questions, analogous to those asked of the new-in-practice pathologists, were: (1) How important is the new pathologist's knowledge/skill in each practice area to his or her performance of his or her job, and (2) To what extent was this new pathologist prepared for his or her responsibilities in that practice area? Respondents were also given the opportunity to answer

the same questions about the next to most recent new-in-practice pathologist they had hired/supervised.

Survey methodology. In both the MOC (new-in-practice) and the employer (employer/supervisor) surveys, our methodology in large part parallels the methodology of the American Board of Pediatrics, which regularly assesses the relative importance of various training areas to practice and the frequency with which this knowledge is called for practice.¹⁰ The assessment process we developed for pathology differs in that:

- we survey physician-employers/supervisors and new-in-practice physicians;
- we explicitly assess both the positive and negative usefulness for practice (utility) of residency training received in each practice area; and
- we assess both practice importance and training utility by individual, by practice area, and in conjunction with information on fellowship training.

Survey of New-in-Practice Pathologists (ABPath Diplomates). We asked new-in-practice pathologists to evaluate each pathology practice area on 2 scales: (1) the importance of that practice area to the performance of their current role and (2) the usefulness (utility) of their training in that practice area relative to the performance of their current role (Table 2). To avoid potential bias in how respondents ranked the 65 practice areas assessed, these areas were presented in random order to each survey recipient (48 distinct practice areas were assessed in the initial 2 surveys, 8 of which were replaced by 17 "drill-down" areas in the third and fourth surveys, for a total of 65 practice areas surveyed).

Possible responses for practice area importance ranged from "critically important" (ie, deep knowledge and skill in the area is absolutely essential for the respondent's success in practice) through "unimportant" (ie, knowledge and skill in the area is only minimally needed) to "NA/No knowledge needed." For practice area utility of training received, response options ranged from "Much Less than Practically Useful" through "About Right" to "Much More than Practically Useful"; respondents could alternatively select "NA/No Training" (received).

To be included in this survey process, MOC participants were asked 3 screening questions:

- Completed the last year of pathology residency within the prior 10 years?
- Practiced Anatomic or Clinical Pathology (or both) during the past 2 years?
- Received primary certification in Pathology?

Only if all 3 questions were answered affirmatively was the survey continued.

Survey participant response rates are shown in Table 3. All pathologists who reported for MOC were asked to complete the survey. During the first 2 years during which the survey was

Table 2. Survey Questions Asked in ABPath Survey of Diplomates.

1. Rate the *amount of training* you received in [*practice area*] during residency training relative to what is needed for performance in your current role.
(If you did not complete any residency training in this area, select No Training.)
 - Much more than practically useful
 - Somewhat more than practically useful
 - About right
 - Somewhat less than practically useful
 - Much less than practically useful
 - No training
2. Indicate how *important* [*practice area*] is to performance in your current role.
(Select Critically Important if deep knowledge and skill in the area is absolutely necessary for success in your current role. Select Unimportant if only minimal knowledge and skill in the area is needed for your role. If you do not need any knowledge of this area to fulfill your responsibilities, select NA/No Knowledge Needed.)
 - Critically important
 - Very important
 - Important
 - Slightly important
 - Unimportant
 - NA/No knowledge needed

Abbreviation: ABPath, American Board of Pathology.

fielded, slightly over one-third opened the survey link, of whom at least 80% met the survey eligibility requirements. Of those eligible, about 85% completed the core survey questions concerning importance and utility of training received by practice area, resulting in 629 respondents in 2014 to 2015 and 699 respondents in 2015 to 2016. Participation rose substantially in the most recent years of the survey. Overall, over 50% of MOC participants opened the survey in both 2016 to 2017 and 2017 to 2018, and about 75% met the eligibility requirements. In total of 1153 pathologists completed the core survey questions in 2016 to 2017, and 893 completed it in 2017 to 2018. The lower number of respondents in 2017 to 2018 is partially attributable to there being over 500 fewer MOC participants than in the previous year.

The surveys queried the 65 practice areas listed in Table 1, which were grouped into categories that could be related to ACGME program requirements and ABPath examination specifications. To isolate the impact of intervening fellowship training from that of residency training, we excluded from the analysis responses for areas in which the respondent had done a directly-related subspecialty fellowship (Supplemental Table 2 lists subspecialty fellowship(s) directly related to each practice area). The impact of fellowship training on preparation for the various areas of practice is a matter for separate analysis, because it relates more directly to the overall structure of training for pathology practice (residency plus fellowship) than to the content of residency training per se. The complementary analysis (training and performance in practice areas preponderantly reported as important only by those with directly-related

subspecialty fellowship training) is ongoing and will be reported separately.

In addition to subspecialty fellowship training received, participants also answered demographic questions on residency size (number of residents), current practice role, primary practice setting, practice size (number of pathologists), primary areas of practice responsibility, number of autopsies personally performed per year, and number of non-fellowship employed positions held since completing training.

Survey of Pathologist-Employers. Employers of new-in-practice pathologists were necessarily asked slightly different although parallel questions (Table 4). To assess importance of practice areas, we asked the employer to rate (1) the importance of the new pathologist's knowledge and skill in each practice area to the performance of his or her job and (2) the extent to which the new pathologist was prepared for his or her responsibilities in that practice area. (Note that, in contrast to the new-in-practice physician survey, we did not ask employers to assess whether their new-in-practice pathologist-employee had the "right" amount of training in each practice area: Instead, we simply asked employers to assess the adequacy of their pathologist-employee's preparation for his or her responsibilities; although employers could certainly tell if their employee's training had been inadequate, if it was adequate, they could not distinguish their employee's training having been "about right" from having been more than practically useful).

To shorten the employer/supervisor survey as much as possible, we restricted questions to practice areas within which the recently hired pathologist had job responsibilities. For example, we asked about specific clinical chemistry practice areas (electrophoresis, immunology/serology, toxicology, and urinalysis) only if the employer first indicated their pathologist-employee had responsibilities in clinical chemistry. In addition to these practice-area questions, employer/supervisor respondents were asked to provide an overall rating of satisfaction with the new-in-practice pathologist; identify what changes, if any, had been made in the new-in-practice pathologist's job responsibilities since being hired; and state whether the new-in-practice pathologist was still working in their practice and, if not, give reasons for their departure.

Possible responses for Importance to Practice ranged from "critically important" (ie, deep knowledge and skill in the area is absolutely essential for the employee's success in their practice) through "unimportant" (ie, knowledge and skill in the area is only minimally needed by the employee) to "NA/No knowledge needed." For Preparation for Practice, response options ranged from Not At All (prepared) through Very Much So; respondents could alternatively select NA (to the employee's practice).

To reduce employer/supervisor bias toward reporting on the most "memorable" new hire (whether because a new hire was particularly able or particularly unable), we asked respondents to complete the survey only after answering 2 screening questions to determine their appropriateness for the survey:

Table 3. MOC Participant Survey Response Rates, 2014 to 2015 Through 2017 to 2018.

Number of Diplomates	2017-18 Survey	2016-17 Survey	2015-16 Survey	2014-15 Survey
Reported for MOC	2639	3176	2952	2434
Opened the survey	1361 (52%)	1710 (54%)	1017 (34%)	901 (37%)
Met survey eligibility requirements	1034 (75% of those opening survey)	1272 (74% of those opening survey)	814 (80% of those opening survey)	746 (83% of those opening survey)
Completed all core survey questions	893 (86% of those eligible)	1153 (91% of those eligible)	699 (86% of those eligible)	629 (84% of those eligible)

Abbreviation: MOC, Maintenance of Certification.

Table 4. Survey Questions Asked in CAP Survey of Employers of New-in-Practice Pathologists.

Think about the *MOST RECENT* new-in-practice pathologist you hired and/or supervised. Answer the following questions about this pathologist regardless of his or her current employment status.

For the purposes of this survey, a new-in-practice pathologist is defined as a pathologist in his or her first job after residency/fellowship training.

- How important is the pathologist's knowledge/skill in [practice area] to his or her performance in this job?
 - Critically important
 - Very important
 - Important
 - Slightly important
 - Unimportant
 - NA/No knowledge needed
- To what extent was this pathologist prepared for his or her responsibilities in [practice area]?
 - Very much so
 - For the most part
 - Somewhat
 - Only slightly
 - Not at all
 - NA

Abbreviation: CAP, College of American Pathologists.

- The number of years since the practice most recently hired a new-in-practice pathologist and, if within the previous 5 years;
- Whether the respondent was responsible for hiring/supervising at least 1 new-in-practice pathologist hired within those previous 5 years.

Respondents whose practice had not hired a new-in-practice pathologist in the last 5 years, or who had not been responsible for hiring/supervising at least 1 new-in-practice pathologist in that time, were screened out from taking the survey.

Analytical Methods

Each of the MOC surveys and the employer survey were conducted with specific aims in mind. The first 2 MOC surveys presented a unique opportunity to compare 2 functionally identical but individually distinct populations of new-in-practice pathologists; this constituted our principal consistency check, and our interest was to ascertain to what extent these

populations (the first being those who received initial board certification in odd-numbered years, and the second being those who received initial certification in even-numbered years) would report their practice experience in relation to their training similarly—both overall and by practice characteristics subgroups. The employer survey, whose target group was the population that supervised new-in-practice pathologists, was designed to validate and/or challenge the perspective of those new-in-practice pathologists. Due to the very high degree of consistency that emerged between the first 2 MOC survey cycles, we were able to introduce small but important changes in our subsequent MOC surveys, to “drill down” into aspects of training or practice areas which appeared to show important findings, about which more detailed and specific reporting would help us make educational sense.

In order to compare the responses from different practice areas for both the MOC surveys of new-in-practice pathologists and the employer survey, we developed a weighted average of the responses based on (1) importance of skill/knowledge in that area to practice and (2) utility of training received in that area to practice. For each practice area, the responses on each scale were weighted to distribute over a potential range from –100% to +100% (Tables 5 and 6), noting that practice importance was rated by respondents on a 6-point scale (Table 5), whereas training utility was rated on a 5-point scale (Table 6).

Averaged over all respondents in each analysis, each practice area thus had a weighted average of between –100% and +100% in its importance to practice, and a weighted average of between –100% and +100% in its usefulness of training to practice. This allows us to display the weighted ratings of these 2 parameters on a 2-dimensional graph, showing reported need for less to more training on the vertical axis, and reported practice importance from less to more on the horizontal axis. Doing so places practice areas into quadrants as shown schematically in Figure 1.

Graphical data such as that schematically illustrated by Figure 1 can also be represented numerically to show the indicated need/opportunity for change (The formula for the numerical combination of importance for practice and need for training to yield need for change is: Change Needed Index = Training Needed Index × [1 + SIGN(Training Needed Index) × Practice Importance Index]/2.). Figure 2 shows the calculated indication for change as a function of low to high practice importance and of more to less need for training developed

Table 5. Weights Assigned to Individual Responses for Calculation of Aggregate Importance to Practice of Each Practice Area.

Importance of Area to Practice	
Rating	Weighting
NA/No knowledge needed	−100%
Unimportant	−60%
Slightly important	−20%
Important	+20%
Very important	+60%
Critically important	+100%

Table 6. Weights Assigned to Individual Responses for Calculation of Aggregate Usefulness of Training Received to Practice of Each Practice Area.

Amount (Utility) of Training Received	
Rating	Weighting
Much more than practically useful	−100%
More than practically useful	−50%
About right	0%
Less than practically useful	+50%
Much less than practically useful	+100%

from the survey responses. In Figure 2, a practice area of high importance and in need of much more training is in the “red zone,” denoting need for increased training. By contrast, a practice area of low importance in need of much less training is in the “blue zone,” denoting the opportunity for decreased training. Practice areas in which less training is needed, but which are important in practice, provide a smaller opportunity for negative change (“lighter blue”).

Reassuringly, the range of reported practice importance and training needed ratings on MOC surveys clustered in the mid-portion of the potential vertical range (the green parallelogram in Figure 2), corresponding to a broad range in reported practice importance with a tighter clustering of most practice areas around “about right” in terms of residency training for most new-in-practice pathologists. The parallelogram shape reflects greater allowance for overtraining, and lower tolerance for undertraining, in categorical residency of practice areas that are of greater importance practice and the corresponding converse for practice areas that are of lesser importance in practice.

Comparisons were made among the MOC surveys and between the MOC surveys and the employer survey. For the MOC surveys, the distributions by practice area of both practice importance and training utility were compared among surveys for all respondents as well as for subsets (by practice setting, practice size, and length of time from training) of respondents. The individual MOC surveys and the aggregate of the MOC surveys were also compared to the employer survey for both practice importance and training utility, although structural differences intrinsic to the survey types (MOC vs employer, described below) limited exact matching. Also

compared were the results from the MOC surveys by individual year for “No Training Received” versus “No Training Needed” as well as several subsidiary analyses within the “drilldown” areas surveyed in more granular and specific detail in the 2016 to 2017 MOC survey.

Initial data review was by direct visualization to enable us to see similarities and/or disparities among the abovementioned comparison population survey findings. The basic format for visualization was to display the putatively parallel results as distributions of reported rankings of practice importance and/or training utility in Excel (Microsoft Excel for Mac 2011 version 14.7.7) line charts to emphasize any deviations from parallelism. Visible similarities (and dissimilarities) were then quantified by calculating the Pearson correlation coefficient r using the Microsoft Excel CORREL function and, from this, 2-tailed Student t distribution P values were calculated using the Microsoft Excel TDIST (Student t -distribution probability) function.

Results

The general results are presented to illustrate the efficacy and limitations of the above-described methods; detailed presentation of the pathology-specific results and their significance as a possible guide for change in content and/or structure of pathology training will be provided in separate publications.

Intersurvey consistency

The MOC survey responses on practice area importance and usefulness of training showed a striking degree of consistency, providing a credible basis on which to assess the alignment of residency training with practice. Table 7 shows the Pearson r statistics and P values for overall survey findings.

Evaluations of training needs

Specifically to answer the questions originally posed, these data enabled us to sort by importance to new-in-practice physicians the practice areas that comprise our discipline and simultaneously how these physicians’ training in residency had prepared them for practice in each area. We combined these ratings to assess the indications and opportunities for change in residency training implicit in the data.

Graphically displayed, the green parallelogram in Figure 3 shows MOC survey respondents reported their training in most practice areas to have been “about right,” taking into account as described above both practice area importance and need for “more” or “less” training to align with their job requirements. The complementary practice areas in which training was reported as *not* having been substantially “about right” can also be seen in Figure 3: Practice areas above the parallelogram were reported to be undertaught and important in practice; those below the parallelogram were reported to be overtaught and less important in practice.

Finally, we “reality tested” these assessments, which were based on the perceptions of the new-in-practice physicians, by

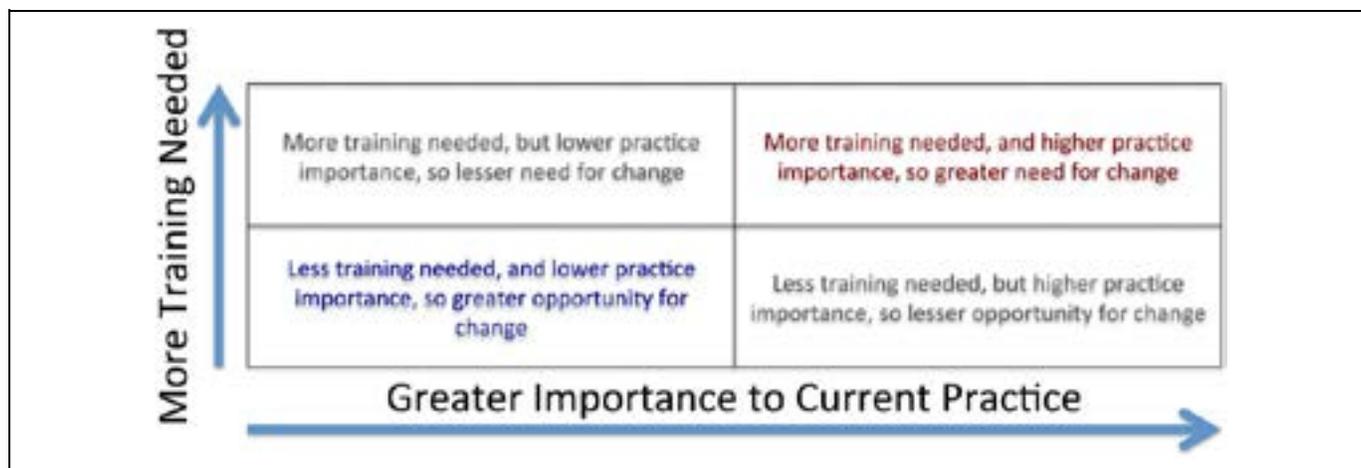


Figure 1. Schematic assessing weighted ratings of training and importance: This figure shows quadrants that verbally describe how to interpret weighted ratings of training and practice importance on a 2-dimensional graph. It shows reported need for less to more training on the vertical axis and reported practice importance from less to more on the horizontal axis.

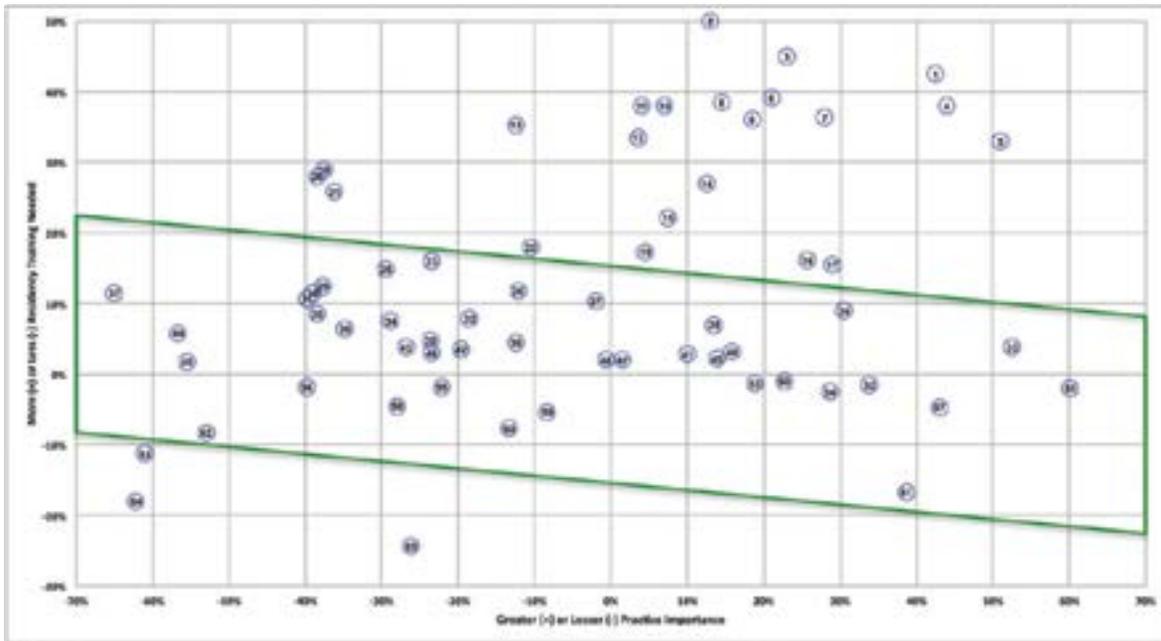
		Practice Importance (+/-)										
		-100%	-80%	-60%	-40%	-20%	0%	20%	40%	60%	80%	100%
Training Needed (+/-)	100%	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
	80%	0%	8%	16%	24%	32%	40%	48%	56%	64%	72%	80%
	60%	0%	6%	12%	18%	24%	30%	36%	42%	48%	54%	60%
	40%	0%	4%	8%	12%	16%	20%	24%	28%	32%	36%	40%
	20%	0%	2%	4%	6%	8%	10%	12%	14%	16%	18%	20%
	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	-20%	-20%	-18%	-16%	-14%	-12%	-10%	-8%	-6%	-4%	-2%	0%
	-40%	-40%	-36%	-32%	-28%	-24%	-20%	-16%	-12%	-8%	-4%	0%
	-60%	-60%	-54%	-48%	-42%	-36%	-30%	-24%	-18%	-12%	-6%	0%
	-80%	-80%	-72%	-64%	-56%	-48%	-40%	-32%	-24%	-16%	-8%	0%
	-100%	-100%	-90%	-80%	-70%	-60%	-50%	-40%	-30%	-20%	-10%	0%

Figure 2. Alignment of indication for change with reported experience in practice: This figure shows the calculated indication for change as a function of low to high practice importance and of more to less need for training developed from the survey responses. In this figure, a practice area of high importance and in need of much more training is in the “red zone,” denoting need for increased training. A practice area of low importance in need of much less training is in the “blue zone,” denoting the opportunity for decreased training. Practice areas in which less training is needed, but which are important in practice, provide a smaller opportunity for negative change (“lighter blue”). The green parallelogram in this figure corresponds to a broad range in practice importance considered “about right” in terms of residency training.

Table 7. MOC Surveys—Intersurvey Correlation (*r*) and Significance (*P*) Values.

	14-15 MOC Practice Importance (+/-)	15-16 MOC Training Needed (+/-)	14-15 MOC Change Needed (+/-)	15-16 MOC Practice Importance (+/-)	16-17 MOC Training Needed (+/-)	15-16 MOC Change Needed (+/-)	16-17 MOC Practice Importance (+/-)	14-15 MOC Training Needed (+/-)	16-17 MOC Change Needed (+/-)	14-15 MOC Practice Importance (+/-)	16-17 MOC Training Needed (+/-)
Pearson <i>r</i>	0.99	0.97	0.98	0.99	0.98	0.99	0.99	0.99	0.94	0.95	
<i>P</i> value	<.00001	<.00001	<.00001	<.00001	<.00001	<.00001	<.00001	<.00001	<.00001	<.00001	

Abbreviation: MOC, Maintenance of Certification.



Key	Practice Area	Key	Practice Area	Key	Practice Area
1	Lab Admin - Leadership*	23	Molecular - Inherited Diseases*	45	Cytopathology - Non-Gynecologic
2	Lab Admin - Financial Management*	24	Molecular - Hematopathology*	46	Flow Cytometry
3	Lab Admin - Personnel Management*	25	Molecular Microbiology	47	Endocrine Pathology
4	Lab Admin - Operations*	26	Cytogenetics	48	Laboratory Hematology
5	Lab Admin - Compliance Issues*	27	Bone and Soft Tissue Pathology	49	Bone Marrow Procedure
6	Medical Coding and Billing	28	Pulmonary/Mediastinal Pathology	50	Gynecologic Pathology
7	Laboratory Administration	29	Transplant Pathology	51	General Surgical/ Oncologic Pathology
8	Path Info - Information Management*	30	Molecular - Identity / Histocompatibility*	52	Gastrointestinal Pathology
9	Path Info - Laboratory Specific IS*	31	Toxicology	53	Genitourinary Pathology
10	Path Info - Project Management*	32	Neuropathology	54	Breast Pathology
11	Path Info - LIS Oversight / Management*	33	Clinical Consultation	55	Medical Microbiology
12	Molecular - NGS and/or GWAS*	34	Pediatric Pathology	56	FNA Procedure
13	Pathology Informatics	35	Cardiovascular Pathology	57	Frozen Section Procedure
14	Path Info - General Purpose IT*	36	Urinalysis	58	Electrophoresis
15	Molecular Diagnostics	37	Tissue Typing (HLA)	59	Cytopathology - Gynecologic
16	Special Laboratory Techniques	38	Placental/Perinatal Pathology	60	Blood Banking/Transfusion Medicine
17	Molecular - Solid Tumors*	39	Immunology/Serology	61	Gross Description/Dissection
18	Whole Genome Sequencing	40	Head and Neck Pathology	62	Blood Center Donor Services
19	Dermatopathology	41	Hematopathology	63	Apheresis
20	Molecular - Pharmacogenomics*	42	Clinical Chemistry	64	Forensic Autopsy
21	Research Methods/Grant Writing	43	Coagulation	65	Medical Autopsy
22	Molecular - Infectious Disease*	44	Medical Renal Pathology		

Figure 3. Combined Maintenance of Certification (MOC) surveys showing net residency training need versus relative practice importance: This figure provides a graphical representation of the average rating of each practice area. The practice areas are represented as numbers, and the key below the graph shows the practice area associated with each number. The green parallelogram in this figure shows MOC survey respondents reported their training in most practice areas to have been “about right,” taking into account as described above both practice area importance and need for “more” or “less” training to align with their job requirements. The complementary practice areas in which training was reported as *not* having been substantially “about right” can also be seen in this figure: practice areas above the parallelogram were reported to be undertaught and important in practice; those below the parallelogram were reported to be overtaught and less important in practice.

comparing them to analogous assessments from the separate survey sample of physician employers/supervisors of new-in-practice physicians. Table 8 shows a high correlation between employers and new-in-practice pathologists in ratings of the *importance* of each practice area to current responsibilities. By contrast, Table 9 shows the significant though distinctly lower correlation of employers’ and new pathologists’ rankings of needs for more training in each practice area. This lower level of correlation is not surprising, because it involves comparing the employers’ “one-tailed” (ie, ranging from inadequate to adequate) perception of the new-in-practice

pathologists’ training with the new-in-practice pathologists’ own “2-tailed” (ranging from inadequate through adequate to excessive) perceptions. This issue will be discussed in more detail in a pathology-specific companion article.

Discussion

For all the attention that is now placed on evidence-based medical practice, there is surprisingly little emphasis on evidence-based medical education. We contend that rapidly changing biomedical technologies and evolving health-care

Table 8. Statistical Comparison of MOC and Employer Ratings of Practice Area Importance.*

Practice Importance	14-15 MOC	15-16 MOC	16-17 MOC
Employer	$r = 0.87$	$r = 0.87$	$r = 0.83$
14-15 MOC	-	$r = 0.99$	$r = 0.98$
15-16 MOC	-	-	$r = 0.98$

* P values for all correlations $<.00001$.

Table 9. Statistical Comparison of MOC and Employer Practice Area Training Need Ratings.

Training Needed	14-15 MOC	15-16 MOC	16-17 MOC
Employer	$r = 0.29$; $P = .04450$	$r = 0.40$; $P = .00487$	$r = 0.51$; $P = .00066$
14-15 MOC	-	$r = 0.97$; $P < .00001$	$r = 0.96$; $P < .00001$
15-16 MOC	-	-	$r = 0.99$; $P < .00001$

Abbreviation: MOC, Maintenance of Certification.

delivery systems make continuing evidence-based assessment of physician training equally essential. To that end, we developed a framework to acquire regular feedback from new-in-practice pathologists on practice areas in which they perceive they needed more (or required less) training in residency and on their important in actual practice. These assessments were supplemented with assessments by physician-supervisors of new-in-practice pathologists to provide validation and perspective. This article describes our general approach. Our next articles, still in development, will present detailed pathology-specific results from the annual surveys of new-in-practice pathologists and the survey of pathologist-supervisors, as well as our recommendations for how these results can be used to assess the curricular requirements for pathology residency.

A major challenge we encountered and addressed was the need to adjust for the now nearly ubiquitous phenomenon, whereby fellowship training intervenes between residency and practice (In a 2017 survey of pathology residents, 96% reported that they plan to complete at least one fellowship post residency; 46% planned to complete at least 2 fellowships.¹¹). Acknowledging and addressing the potentially confounding effect of fellowship training on preparation for initial practice was both essential and complex. Categorical specialty training in residency necessarily includes core training in all essential specialty practice areas, while fellowship training in a subspecialty area involves advanced training in a subset of the specialty's practice areas. To assess how residency training per se prepares graduates for practice, each respondent's survey responses needed to be segregated, by practice area, into (1) practice areas in which that respondent was residency-only trained and (2) practice areas in which that respondent was both residency and fellowship trained. Each response type was separately and distinctly important to analyze.

The residency-only trained practice area responses directly reflect, area by area, how effectively and efficiently categorical residency training is currently preparing pathologists for initial practice. With this being our primary focus, we therefore segregated our data to include in this analysis only those practice area responses not directly related to fellowship training received by the respondent (Supplemental Table 2 shows practice areas directly related to fellowships).

However, although the residency-plus-fellowship-trained practice area responses do not directly relate to the effectiveness and efficiency of residency training per se as preparation for entry into practice, they do provide important information: on a Practice Area by Practice Area basis, comparison of fellowship-plus-residency trained responses to residency-only trained responses shows how practice responsibilities of those with specific fellowship training differ from those without that same fellowship training. These differences show both the extent to which (1) specific fellowships are followed by substantially subspecialized practice and (2) specific practice areas have become effectively restricted to fellowship-trained practitioners. Assessment of the relationship between fellowship training and practice is ongoing and will be reported subsequently.

Our ability to measure the relationship between particular areas of practice importance and fellowship training, and how practice importance and utility of training can be combined to indicate the need for change in training, was dependent on maintaining throughout a relational data structure that allowed us to parse these anonymous responses on an individual basis, both by practice area and by all the potentially related demographic information on training, both residency and fellowship, and practice characteristics.

In particular, while our MOC survey data were anonymous as to individual respondent, each individual's demographic and practice characteristics, as well as their quantitative rating responses to practice area questions and their comments, remained linked. This was essential not only to excluding potentially confounding effects of intervening fellowship training addressed above, but also to enabling us to identify areas in which high practice importance ratings were essentially restricted to fellowship-trained individuals and, for all respondents, to analyzing and quantifying post-training subspecialty practice in non-fellowship-trained areas. We could therefore meaningfully characterize the relationship between practice importance and utility of training by practice type and demographic subgroups within each survey, and also develop a novel quantitative measure for the highly variable extent and degree of subspecialization of practice across different practice settings. Quantification of subspecialization was needed because, in large practices, narrow subspecialization results in low reporting of practice importance in the non-practiced subspecialties. This is distinct from the distribution of reported practice importance by area among less subspecialized, typically smaller practices.

Our data collection and analysis was generally reassuring in that it showed that, in most areas, residency preparation for practice in pathology was "about right," based both on our

recent trainees' reported employment experience and on the report of their employers. Also, those areas in which training was reported as excessive or inadequate largely coincided at least directionally with our expectations based on anecdotal discussion at national meetings of educationally interested pathology organizations. It was in the quantitative comparisons among the under- and overtaught areas, and analyses at the level of respondent subsets by practice setting, practice size, and years in practice that new and potentially important findings emerged.

In examining these subset analyses, it became apparent that in addition to the relatively small number of practice areas generally over- and undertaught in residency, more flexibility was needed in our approach to GME in pathology. We have both excessive residency training in practice areas predominantly performed by fellowship-trained individuals and inadequate preparation for practice in other areas in which, for many practitioner subsets, residency training must suffice. Although residency content area adjustments are certainly possible and desirable, our current rigid GME formulation of 3 or 4 years of general residency plus 1 or 2 years of subspecialty fellowship(s) is not well suited to the broad range of actual practice. Additionally, some areas of practice consistently became important only 5 or more years after entry into practice, raising a question of whether either residency or fellowship is an optimal setting for training in those areas. This process has for the first time provided quantitative, evidence-based information on the content of categorical training in residency, which has heretofore been largely a matter of eminence-based opinion.

Although the detailed findings of our process are necessarily specific to pathology, our general approach to designing and conducting these surveys, and subsequent analysis of the results, is not in any way particular to pathology. Also, while the perceived need to assess the content and structure of our training at this time was triggered by demographic circumstances and scientific advances particular to pathology, the concept of developing and maintaining an evidentiary basis for education in any clinical discipline ought to be of general interest in an era of advancing science, growing population, and (particularly for education) constrained resources.

The importance of this work, beyond the discipline-specific qualitative and quantitative findings to be presented in companion articles, lies in the general approach, methodologies developed, and potential to generate evidence to guide the ongoing direction of GME.

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Report and Recommendations of the Association of Pathology Chairs' Autopsy Working Group

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Abstract

Autopsy has been a foundation of pathology training for many years, but hospital autopsy rates are notoriously low. At the 2014 meeting of the Association of Pathology Chairs, some pathologists suggested removing autopsy from the training curriculum of pathology residents to provide additional months for training in newer disciplines, such as molecular genetics and informatics. At the same time, the American Board of Pathology received complaints that newly hired pathologists recently certified in anatomic pathology are unable to perform an autopsy when called upon to do so. In response to a call to abolish autopsy from pathology training on the one hand and for more rigorous autopsy training on the other, the Association of Pathology Chairs formed the Autopsy Working Group to examine the role of autopsy in pathology residency training. After 2 years of research and deliberation, the Autopsy Working Group recommends the following:

1. Autopsy should remain a component of anatomic pathology training.
2. A training program must have an autopsy service director with defined responsibilities, including accountability to the program director to record every autopsy performed by every resident.

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3. Specific entrustable activities should be defined that a resident must master in order to be deemed competent in autopsy practice, as well as criteria for gaining the trust to perform the tasks without direct supervision.
4. Technical standardization of autopsy performance and reporting must be improved.
5. The current minimum number of 50 autopsies should not be reduced until the changes recommended above have been implemented.

Keywords

autopsy, pathology training, residency, anatomic pathology, autopsy service director, entrustable activities, rapid autopsy

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Introduction

The autopsy has been the foundation of pathology training for generations, but since 1971, when The Joint Commission no longer required autopsy utilization for hospital accreditation, the number of hospital autopsies in the United States has steadily declined.¹ At the 2014 meeting of the Association of Pathology Chairs (APC), some pathologists suggested that it was time to remove autopsy from the training curriculum of pathology residents. The rationale given for this recommendation was 2-fold. Firstly, fewer autopsies are performed by resident and attending pathologists, which has challenged some training programs to provide residents the number of autopsies required by the American Board of Pathology (ABP) to sit for the basic qualifying examination in anatomic pathology (currently 50 autopsies).² Secondly, removal of autopsy from the residency curriculum would provide several additional months for resident training in newer disciplines in pathology, such as molecular genetics and informatics. At the same time, the ABP has received complaints from some established pathologists that newly hired pathologists recently certified in anatomic pathology by the ABP are unable to perform an autopsy when called upon to do so as a professional component of their new position.

In response to the call to abolish autopsy from pathology training on the one hand and the call for more rigorous autopsy training on the other, the APC formed the Autopsy Working Group to examine the role of autopsy in pathology residency training. The APC wanted this work to be a joint effort between experts in pathology training and in autopsy practice, and so the group had 2 co chairs—Gayle L. Winters representing the Pathology Program Directors (PRODS) and Gregory G. Davis representing the National Association of Medical Examiners (NAME). The members of the Autopsy Working Group represented various organizations concerned with resident training, resident evaluation, and autopsy practice, including the Accreditation Council for Graduate Medical Education (ACGME) and its Review Committee for Pathology, the ABP, the APC with its Residency Program Directors Section (PRODS), the College of American Pathologists (CAP), and the NAME. By virtue of their appointments, various members were able to communicate the insights and concerns of the

ACGME, ABP, APC, PRODS, CAP, and NAME. Following is the list of the scope of tasks that the APC envisioned for the Group.

1. Assess what systems are used to determine that autopsy training is adequate or inadequate.
2. Collect data on how autopsy training is accomplished by the programs doing it most effectively.
3. Identify more specifically what the limiting factors are where training is not effective.
4. Evaluate whether the requirement of 50 autopsies consumes a disproportionate amount of resident training time.
5. Review whether and how programs can continue to comply with the 50 autopsy requirement while autopsy numbers are declining.
6. Explore whether new paradigms of training could be deployed to support the weaker training programs.
7. Develop tools to assist programs in addressing relevant issues (live workshops, online resources, webinars).

The Autopsy Working Group addressed these tasks during its existence from 2014 to 2016. In 2016, the Autopsy Working Group submitted its final report to the APC. The members of the Autopsy Working Group have now revised their 2016 report into a format suitable for publication as an article in *Academic Pathology*, with the members of the Autopsy Working Group listed as authors of this article.

Materials and Methods

The Autopsy Working Group met 14 times in person or by conference call during its 2-year existence. Much of the information that the Autopsy Working Group had to work with was anecdotal in nature, as formal studies of efficacious pathology training are lacking. The members of the Autopsy Working Group agreed on the following points.

Background

1. Performing an autopsy is the practice of medicine. As such, autopsy has been central to the development of the

science of medicine for centuries. Autopsy has been similarly central to the development of pathology as a discipline and to pathology training for over a century.

2. An ABP survey indicates few practicing pathologists perform autopsies at a rate sufficient to maintain skills in autopsy practice. (Specifically, 46% perform no autopsies, and another 30% of all responders to the survey perform 1-5 autopsies per year.)³
3. Autopsy is unsurpassed as a method of quality assurance for assessing sensitivity and specificity of clinical diagnoses.
4. Autopsy is an essential component of competent medico-legal death investigation.
5. With a proper autopsy permit, an autopsy can allow training in aspects of pathology beyond autopsy alone, such as performing a bone marrow biopsy or a fine needle aspirate.
6. After peaking in the mid-20th century at approximately 50%, hospital autopsy rates have been decreasing since then, in part related to the decision by The Joint Commission to remove the requirement of a minimum number of autopsies for hospital accreditation.⁴
7. Hospital autopsy has no direct method for reimbursement from the Centers for Medicare & Medicaid Services or third-party payers because it is “medically unnecessary.”

Residency Training

1. Pathology is becoming more complex and more diverse. Subspecialties within pathology may have little or no relationship to other subspecialties with respect to daily practice.
2. Assuming combined training in anatomic and clinical pathology, residents have 48 months to train. More diversity means fiercer competition for training time during the 48 months. In one study, 16 programs (21% of all survey respondents) no longer have a dedicated autopsy rotation, but combine autopsy with other rotations.⁵
3. Currently, 50 autopsies are required to qualify for ABP certification in anatomic pathology/clinical pathology (AP/CP), anatomic pathology/neuropathology (AP/NP), or AP only.
4. Fifty autopsies can require months of assigned rotations in some institutions, limiting months spent training in newer, developing fields.
5. Forensic pathology performs a vital function in an ordered society. Resident training in hospital and forensic autopsy pathology is vital to maintain an influx of interested and qualified trainees into the currently critically short-staffed field of forensic pathology.

In attempting to address its charge, the Autopsy Working Group sensed the need to better understand the present state of autopsy training in US residency programs. Not only was

there no current information about how autopsy training is accomplished in US programs, but also there was no available list of autopsy service directors who would be the parties with the most direct knowledge of how such autopsy training is performed. To address these needs, the Autopsy Working Group contacted 142 program directors of pathology residency training programs in April 2016 using a SurveyMonkey poll from the APC to collect the names of persons serving the role of autopsy service director for their program. These 142 requests led to 120 responses and 113 named autopsy service directors. In June 2016, the named autopsy service directors were asked to complete a second SurveyMonkey poll about autopsy training in their programs. The 113 requests yielded 66 at least partial responses (58% of requests). Of the nonresponders, 4 opened the survey but did not respond, 42 did not open the survey, and 1 request could not be delivered through e-mail. The autopsy service director survey was conducted with the identity of the programs known, but not to be individually disclosed. Publically available statistics about the numbers of trainees in the programs were obtained from the web site of the ACGME and were used to interpret the survey results. Of the responding autopsy service directors, 28% also served in the capacity of residency program director.

The Autopsy Service Director Survey addressed several key features of autopsy training, including annual case volumes and distribution of special autopsy types (fetal, pediatric, or forensic—not intended to be mutually exclusive) on the main service. Case volumes were combined with numbers of residents in the program to estimate the number of autopsies available per resident on the main autopsy service ($4 \times$ annual autopsy volume/total number of residents in the program on the ACGME roster). No correction was made for the number of residents in a clinical pathology-only track who do not have an autopsy requirement, for residents in an anatomic pathology-only track (who may progress through training in only 3 years), for residents in an anatomic–neuropathology (who may progress through anatomic pathology in only 2 years), or for programs covering more than 1 autopsy service. The percentage of cases shared by 2 residents on the main service was solicited and was then used to extend the estimated number of autopsies available per resident, multiplying the above estimate by $(1 + \% \text{ of autopsies shared})$.

The survey collected specific data about who usually performs evisceration procedures and the most frequent dissection method used on the main service. For autopsy service directors who were not also the residency program director, the autopsy service director was asked whether a list of autopsy cases completed by each resident was transmitted to the residency program director. Autopsy service directors were also asked about the fraction of autopsies on their services where they serve as the attending pathologist of record. Autopsy service directors were asked questions about the roles of board-certified forensic pathologists and neuropathologists on the main autopsy service.

The sharing of teaching responsibilities on the autopsy service among various parties (autopsy service director, other

faculty, fellow, other residents, pathologist assistant, or other staff) was solicited for a list of entrustable activities that comprise the performance of a complete autopsy. For each entrustable activity, the autopsy service director was asked to respond which party most often teaches how to perform the entrustable activity, with an additional option for each activity to respond that the activity is not taught.

Autopsy service directors were asked about their opinions about the current requirement that residents perform or share at least 50 autopsies, whether the number 50 is too many, too few, or about right, and then whether residents in their department have trouble completing the required 50 autopsies. The results of these opinion questions were further stratified by the number of residents in the program, either fewer than 18 total residents or 18 or more residents.

All members of the Autopsy Working Group agreed that autopsy training is an essential component in transforming a newly graduated physician into a competent anatomical pathologist. The various members of the Autopsy Working Group differed in their opinions of how many autopsies were necessary to achieve competency in autopsy, so much time was spent discussing methods of documenting competency in performing an autopsy. The current model requires 50 autopsies for all residents, which includes a limited number of fetal and single-organ autopsy examinations. This one number ignores the truth that some residents are more naturally gifted at autopsy techniques and assimilating data to enable a sound diagnosis, but the number has the advantage of being a discrete measure that is easily assessed. Some members of the Autopsy Working Group strongly advocate developing a competency model for assessing residents, so that a resident needs to perform no more autopsies than are necessary for the resident to demonstrate competence in autopsy procedures and diagnosis. No one could offer a satisfying model for a competency-based training system, however.

Results

Soliciting responses about autopsy training from autopsy service directors provided the Autopsy Working Group with important perspectives from which to make its recommendations. The 66 responding programs ranged from over 35 residents to as few as 7 residents and showed good geographic distribution (data not shown).

There was an enormous difference in the available number of autopsies for resident education, with a range from 900 to 14 cases per year (Figure 1). Normalizing the available number of autopsies per resident, without accounting for sharing, showed a range from 3 to 275 cases per resident. Only 18 of the 59 programs responding to this question attained 50 available autopsies on the main service without sharing (Figure 2).

Sharing of autopsies at rates ranging from 1% to 100% was reported by 42 of the 60 program respondents (data not shown). Eighteen programs explicitly stated that there was no sharing of autopsies by residents. Extending the number of available

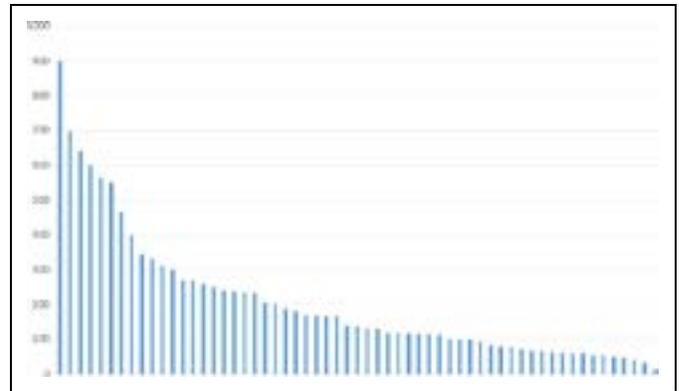


Figure 1. What was the total autopsy case volume of the service you direct for calendar year 2015? Each bar on x-axis represents 1 of the 59 programs that responded to this question.

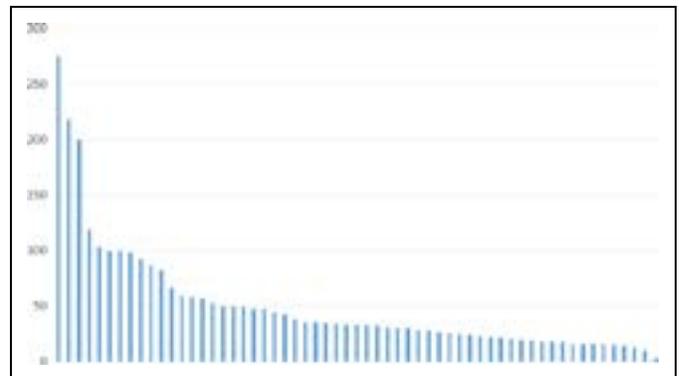


Figure 2. Number of available autopsies in main service per resident. $4 \times$ total autopsies on main service/residents on Accreditation Council for Graduate Medical Education (ACGME) roster. Each bar on x-axis represents 1 of the 59 programs that responded to this question.

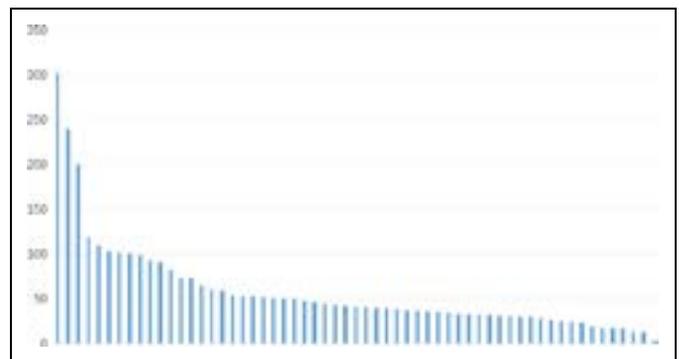


Figure 3. Available autopsies on main service per resident, extended by sharing. $\text{Resident} \times (1 + \% \text{ shared})$. Each bar on x-axis represents 1 of the 59 programs that responded to this question.

autopsies per resident using the reported rate of sharing allowed 24 of 59 programs to attain 50 autopsies per resident on the main service (Figure 3). It is clear that in order to reach the required 50 autopsies per resident, many programs depend upon residents sharing autopsies.

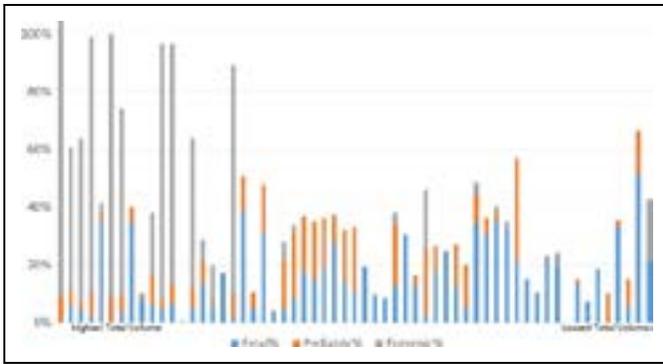


Figure 4. Distribution of fetal, pediatric, and forensic cases, percent of total. The order of the programs is identical to that in Figure 1. Because the categories are not mutually exclusive, some totals exceed 100%. Each bar on x-axis represents 1 of the 59 programs that responded to this question, including the space.

Special autopsies (fetal, pediatric, and forensic) showed striking variation in distribution (Figure 4). Although it is clear that forensic autopsies predominate in most of the programs with the highest case volumes, several programs with fewer total autopsies have relatively high numbers of fetal cases and few pediatric or forensic autopsies.

Questioning autopsy service directors about usual practices on their services showed remarkable heterogeneity. Of 60 respondents, only 15 indicated that residents performed the majority of eviscerations, with 45 indicating that the task is usually performed by the assistant and 5 indicating that evisceration is usually performed by the attending. The most common dissection technique was en bloc evisceration followed by dissection for 42 of 60 respondents, organ-by-organ removal for 17, and in situ examination of organs for 1 respondent. Of the 46 responding autopsy service directors who were not also the residency program director, 28 (60.8%) stated that they do not provide the residency program director a list of autopsies completed by each resident.

The distribution of teaching activities on autopsy services showed interesting trends. Autopsy service directors reported that they were the main teachers for many of the entrustable activities comprising a complete autopsy, with the exception of sampling the brain, removal of the brain and spinal cord, and restoration of the body for disposition (Figure 5). Other faculty played important roles teaching neuropathology, histologic diagnosis, and interpretation of laboratory results (Figure 6). Other trainees in the program were most involved in teaching how to review the medical record and to perform organ dissection and sampling (Figure 7). Support staff were instrumental in teaching restoration of the body as well as opening and evisceration techniques (Figure 8). The most common entrustable activities that were noted as not taught to residents were those of interviewing caregivers, restoring the body, removing the brain and spinal cord, and reviewing the medical record (Figure 9).

The role of forensic autopsies on the main teaching services showed considerable variation. Only 25 of 60 respondents

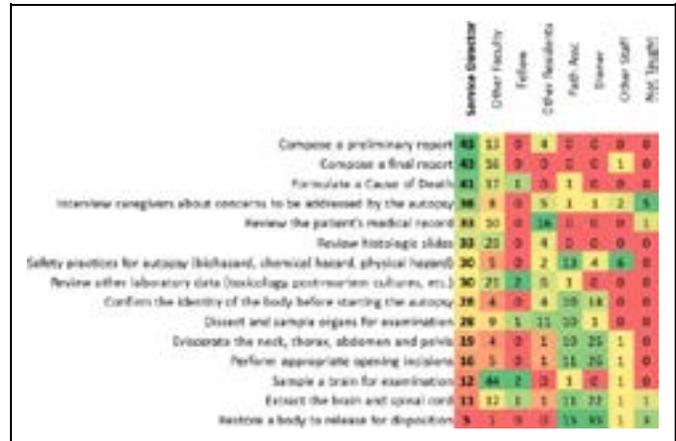


Figure 5. Entrustable tasks most often taught by the autopsy service director. Numbers shown in bold text under bold text heading.

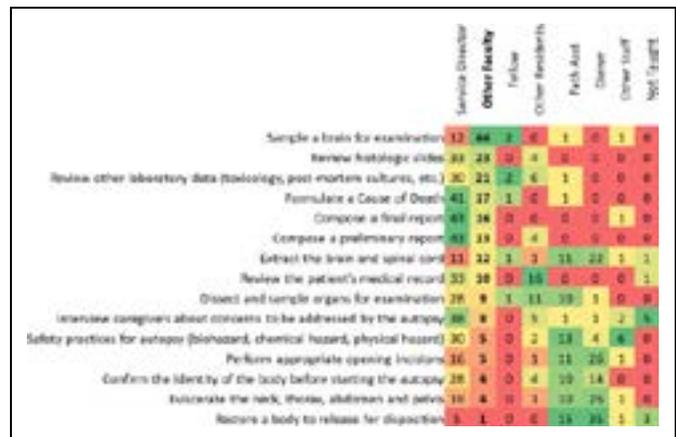


Figure 6. Entrustable tasks most often taught by the other faculty. Numbers shown in bold text under bold text heading.



Figure 7. Entrustable tasks most often taught by other trainees. Numbers shown in bold text under bold text heading.

indicated that forensic autopsies were a part of the experience on the main teaching service. Of the services performing forensic autopsies, 12 indicated that a board-certified forensic

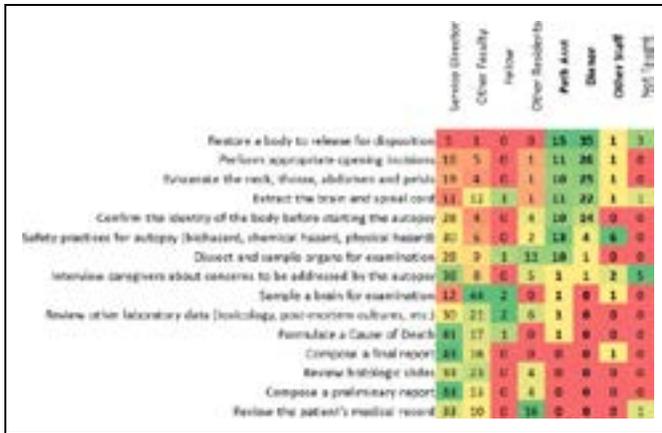


Figure 8. Entrustable tasks most often taught by support staff. Numbers shown in bold text under bold text heading.



Figure 9. Entrustable tasks most often not taught. Numbers shown in bold text under bold text heading.

pathologist always supervised forensic autopsies, while 7 stated that a forensic pathologist never supervised the forensic autopsies. The resident was responsible for completion of the forensic autopsy report in 16% of responding programs, had a variable role for reporting in 37%, and had no role for reporting in 54%, with 6% indicating that the forensic experience was purely observational.

The role of neuropathologists in teaching autopsy was more uniform, with 92% of respondents either having a board-certified neuropathologist on-site or visiting to support the autopsy service.

The opinions of autopsy service directors about the current rule requiring residents to complete 50 autopsies indicated that most (41 of 58 responding) felt that 50 autopsies were about right, with 12 indicating that 50 cases were too few and 7 that 50 autopsies were too many. The responses to these questions did not show significant differences between autopsy service directors from small programs (fewer than 18 residents) or large programs (18 or more residents; Figure 10). Although most autopsy service directors did not feel that their residents

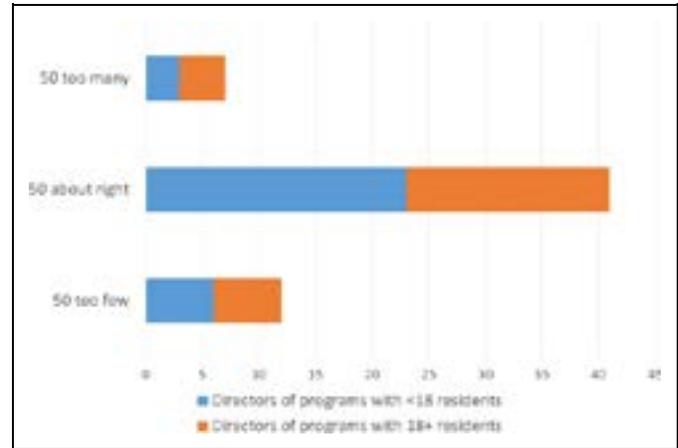


Figure 10. What is your view of the American Board of Pathology (ABP) requirement that residents perform 50 autopsies? 58 responses; 8 skipped this question.

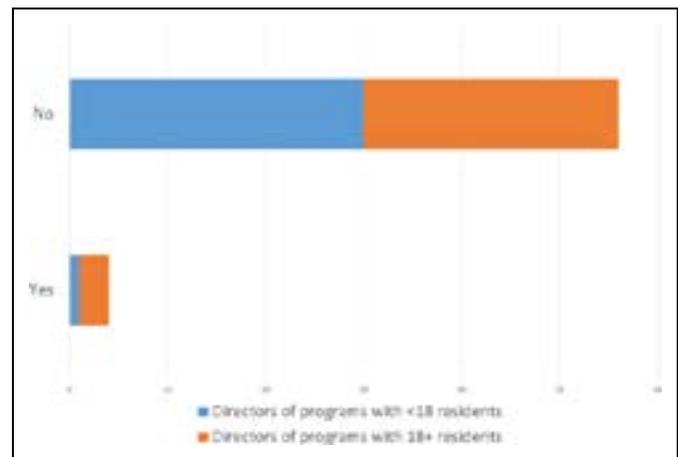


Figure 11. Do your residents have trouble getting the required 50 cases? 60 responses; 6 skipped this question.

had trouble reaching the required 50 autopsies (56 of 60 respondents), 3 of the 4 responses indicating that residents had trouble performing 50 autopsies came from larger programs (Figure 11).

Discussion

In surveying autopsy service directors, the Autopsy Working Group has gathered the most complete information to date about the current state of pathology resident autopsy education in the United States. Although the rate of response was favorable, there are important limitations that must be considered in interpreting the data. First, the fact that the identity of respondents was used in order to include program size statistics in calculations and comparisons may create a bias in the responses, dissuading responses from struggling programs or eliciting more positive responses in cases where the respondent may have doubts. The survey therefore reflects a reality that is most likely not better than is reflected by the data presented.

Second, in surveying autopsy service directors, we understand fully that the respondents in many cases have a vested career interest in the role of the autopsy in graduate medical education in particular, as well as in the practice of medicine in general. The Autopsy Working Group itself shares the same bias because of its members. Any recommendations that are put forward should consider carefully the needs of other stakeholders, including those of our trainees, the body of employers of newly trained pathologists, clinical colleagues who from time to time request autopsy services with a reasonable expectation that a satisfactory examination will be conducted, and the public, who ultimately benefit from understanding advances in medicine through postmortem surveillance. Third, for the sake of simplicity, it was assumed in performing calculations and making comparisons based on the total numbers of residents that all residents were in 4-year anatomic and clinical pathology programs. Even though the great majority of residents do train in both anatomic and clinical pathology, the residents in straight clinical pathology, who are not required to train in autopsy, have the effect of making more autopsies available for their colleagues. Residents in straight anatomic pathology programs or in anatomic–neuropathology programs, who are exposed to the incoming volume of autopsies for 3 or 2 years, respectively, rather than 4, have a slight opposite effect on the availability of cases for their colleagues.

With the limitations of the survey understood, the Autopsy Working Group was able to draw several important conclusions:

There is Great Variation Among Programs in the Availability of Autopsies for Training Residents

Our results indicate that not only do total numbers of autopsies on the main service under the direction of an autopsy service director vary by orders of magnitude, there is also considerable variation in the mix of cases available for this training. Both of these factors may affect the training of residents on service. Even extending the numbers of autopsies available per resident by the reported rates of sharing autopsies, most responding programs could not achieve the required 50 autopsy quota on their main services alone. In many cases, residents are sent offsite to perform forensic autopsies, which do complement the hospital autopsy experience, but should not replace it.

Autopsy Training is a Team Sport

In learning to perform autopsies, pathology residents should learn to master many component entrustable activities. Although much of the teaching comes from faculty (whether a service director and others), very significant teaching contributions are made by other trainees, as well as by participating support staff.

The sharing of responsibility for autopsy, instituted to prolong the number-based criterion, has created a dialogue between residents working together to complete their complex task, which is a valuable team experience to be gained in residency.

Because, as noted above, it is likely that residents learn to perform autopsies in more than one setting, they may be exposed to a variety of procedures and philosophies.

Resident Education in Autopsy is Not Conducted in a Standardized Fashion

One predicate of a number-based criterion for assessing competency in autopsy is that each counted autopsy should have a similar instructive value from resident to resident and from program to program. In addition to the previously noted differences in available cases and in the mixture of specialized cases on different services, the very act of sharing cases fundamentally changes the unit value of every case for an individual resident. Sharing of cases has allowed for the number-based criterion of 50 cases to last for a few more years on the basis that all residents are required to participate in 8 broadly defined component parts of the autopsy.⁶ The reality is that cases cannot be completely shared at the most basic level. Only one person in a team will remove the brain, only one will run the bowel, and only one person will draft the report for the first time. On the other hand, as noted above, sharing autopsies does permit for a positive social interaction among residents, who might otherwise be left alone to complete the complex task.

Perhaps more importantly, our results show great variation in the technical aspects of autopsy training among programs. It is true that there is more than one way to perform an autopsy, but familiarity with in situ examination only will ill serve a resident hired by a pathology group that practices en bloc dissections. A number-based criterion that admits as equivalents en bloc dissection as the standard protocol in one program, organ-by-organ dissection as the standard protocol in a second program, and in situ examination as the standard protocol in a third program seems to have missed its mark.

There is Need for Accountability for Autopsy Training to the Residency Program Director

A relative minority of autopsy service directors are also residency program directors (28%). As a part of the present application to sit for credentialing by the ABP, the resident must represent, and the program director must attest to the Board, that a stated number-based training requirement has been met. It is concerning that the majority of autopsy service directors who are not concurrently the residency program director do not provide a list of cases completed by each resident to the program director. More concerning still is that in trying to collect the list of autopsy service directors, it became apparent that no such person existed in some programs.

Recommendations

On the basis of the foregoing, the Autopsy Working Group makes the following recommendations:

1. Autopsy Should Remain a Component of Anatomic Pathology Training

Although the numbers of autopsies have decreased in hospital settings, and many new-in-practice pathologists perform few autopsies, if any, the ability to review a medical record, interview clinical colleagues, perform a thorough examination, and make a meaningful report add value to the education of residents. This is their main contact with common entities in cardiovascular pathology, neuropathology, and renal pathology that are less frequently seen in surgical pathology. The autopsy provides excellent opportunity to review anatomy and gain skills handling tissues of every type.

The Autopsy Working Group endorses the practice of autopsy as relevant to the practice of medicine and as an essential component of pathology training, now and in the future. Autopsy integrates medical knowledge with clinical history, scientific observation, and pathological test results more thoroughly than any other procedure in pathology. A solid foundation in autopsy practice catalyzes the transformation of a medical student into a practicing pathologist able to assess data in a given case and synthesize this information so that the appropriate analyses are performed to provide the correct diagnosis. Autopsy remains essential for pathology training because autopsy practice makes one a better pathologist in any aspect of anatomical pathology practice and informs clinical pathology practice too, for those pathologists with combined training in AP and CP. For those individuals focused on molecular genetics, remember that rapid autopsy allows pathologists to procure tumor samples for research in molecular genetics. Without autopsy training and an active autopsy service, this important component of molecular genetic research becomes impossible.

2. A Training Program Must Have an Autopsy Service Director With Defined Responsibilities, Including Accountability to the Program Director to Record Every Autopsy Performed by Every Resident

Proper autopsy training requires the participation of a team, and setting standards for the performance of autopsies and the education of residents requires oversight to prevent progressive cutting of corners.

An autopsy service director manages the autopsy service in a teaching hospital with a residency training program. The successful autopsy service director is active in teaching, service work, and research and is also the primary liaison for internal and external questions and problems that must be resolved for the continuing function of the autopsy service. The successful autopsy service director recognizes and acts upon appropriate opportunities for improvement in the autopsy service. At a minimum, an autopsy service director should have the following qualifications:

- Be certified by the ABP in anatomic pathology
- Possess experience in practicing anatomic pathology, preferably with recent experience in autopsy practice.

- Demonstrate an ability to resolve disputes fairly with diplomacy and tact.
- Believe in and advocate for value of the hospital autopsy to medical practice and public health.

A competent autopsy service director will provide hands-on teaching of residents in autopsy performance, from gathering information prior to autopsy, to examination and evisceration of the body, to the interpretation of findings, autopsy reporting, including composition of the report, and communication of findings to treating physicians and at conferences. The director will encourage research by the residents in training; manage quality assurance, staff, and supplies (ultimately); participate in maintaining laboratory and residency training accreditation; and keep abreast of the future direction of the autopsy, both scientifically and socially. A more complete description of the ideal autopsy service director is presented in Supplemental Appendix 1. Some of the qualities listed in Supplemental Appendix 1 are aspirational—it is unlikely that any one person would embody all these traits as an autopsy service director, but these are the traits that a pathologist appointed as autopsy service director should work to embody.

To the extent that any number-based criterion exists in the future, the numbers of cases performed by each resident on each service where residents rotate should be independently verifiable by the program director.

The residency program director is accountable to the ABP for resident training in autopsy pathology, including performance of at least 50 autopsies currently and ensuring that the resident has appropriately participated in all aspects of the autopsy. Because the residency program director (unless also the autopsy director) may not have first-hand knowledge of residents' autopsy experiences, enhanced communication between an attending pathologist who has been involved with the resident on the autopsy service and the program director is necessary. Ideally, this role should fall to the director of the autopsy service. It is in this specific way that the Autopsy Working Group recommends that an autopsy service director be accountable to the program director.

The Autopsy Working Group recommends the form in Supplemental Appendix 2 as a means of enhancing communication between the residency program director and the autopsy director or the director's designee. This form was derived from program requirements of the ABP and ACGME and is taken from a program that has been using it successfully to succinctly document resident competence in autopsy performance.

3. Specific Entrustable Activities Should be Defined That a Resident Must Master in Order to be Deemed Competent in Autopsy Practice, as Well as Criteria for Gaining the Trust to Perform the Activities Without Direct Supervision

Entrustable Professional Activities in pathology training have recently been put forward as a more acceptable model for defining and evaluating the progress of residents in pathology residencies. Unlike many other clinical residencies, pathology

training comprises a number of mini-residencies with knowledge, skills, and attitudes that residents acquire in different orders based upon their program and rotation schedule. The autopsy experience is only one of those areas where residents gain the trust of their teachers. We have broadly defined several such skills in conducting and interpreting our survey (Figures 5-9). Other sets of entrustable Professional Activities have been proposed (McCloskey et al and Supplemental Appendix 3.)⁷

4. Technical Standardization of Autopsy Performance and Reporting Must be Improved

There is a great need to define the expectations of what it means to perform and report an autopsy as a resident. The standards may be incorporated in definition of Entrustable Professional Activities, or in a procedure manual that can be agreed upon by key stakeholders. Being able to compare the autopsies performed in one program with those performed in another program is mandatory for any number-based criterion that may be adopted in the future.

A degree of standardization in the teaching and performance of autopsies throughout the nation would help ensure adequate training of pathologists. The Autopsy Working Group recommends communicating the expectations for autopsy training in America in a white paper concerning the role of autopsy in pathology training, including discussion of technical standards of autopsy.

Online learning modules can supplement resident training and experience in autopsy practice, provide a means for self-assessment, and offer standard training education that would be available to all pathology residents. Finally, incorporating some questions that test knowledge of autopsy technique into the anatomic pathology examinations, such as the Resident In-Service Examination or the examination by the ABP, will reinforce the importance of learning autopsy techniques.

5. The Current Minimum Number of 50 Autopsies Should Not be Reduced Until the Changes Recommended Above have Been Implemented

Whatever its shortcomings, the current minimum number of 50 autopsies was endorsed as appropriate for residency training by the majority of autopsy service directors who responded to the survey (70%). Any move to a competency-based model would require agreement among stakeholders on what constitutes competency in performing and reporting an autopsy. Agreement will require more standardization than currently exists regarding the responsibilities of an autopsy service director, the technical skills that constitute competency at performing an autopsy, a means of assessing these skills, and the responsibility and mechanism for reporting achievement of competency to the ABP and ACGME. The Autopsy Working Group recommends retaining 50 autopsies as the minimum number required for residency training until the stakeholders (see below) agree to standards of autopsy performance and reporting that will allow confidence that an assertion of competence

from one training program is equivalent to assertion of competence from another training program.

Future Developments

Any change as basic as altering the role of autopsy in pathology training will require discussion among stakeholders, including some or all of the following:

- Program directors
- Autopsy service directors
- Department chairs
- Private practice pathology groups
- Hospital administrators/Chief Quality Medical Officers
- Accreditation Council for Graduate Medical Education
- American Board of Pathology
- American Association of Neuropathologists
- American Society for Clinical Pathology
- College of American Pathologists
- National Association of Medical Examiners
- Society for Pediatric Pathology
- United States and Canadian Academy of Pathology
- American College of Medical Quality

As stated above, the Autopsy Working Group endorses the practice of autopsy as relevant to the practice of medicine and as an essential component of pathology training, now and in the future. Competent autopsy practice requires integration of medical knowledge with clinical history, scientific observation, and pathological test results more thoroughly than any other consultation in pathology. Autopsy has remained a bedrock for pathology training for this very reason—a thorough foundation in autopsy practice makes one a better pathologist in any aspect of anatomical pathology practice and informs clinical pathology practice too, for those pathologists with combined training in AP and CP.

Nevertheless, pathologists must reform autopsy to make it relevant to current practice. An autopsy report that took a month to complete may have been useful 50 years ago, but medicine is practiced at a much faster pace today, and pathologists must adjust to this demand by clinicians and patients alike. Reports that do not provide clinicopathological correlation are of little use to clinicians. Other users of autopsy data exist—quality assurance officers, public health agencies, family members of the decedent, insurance companies, and attorneys—and autopsy reports should address all these users, not primarily pathologists and clinicians.

Beyond this, pathology is positioning itself as the specialty best suited to manage vast data through informatics and computational algorithms. Autopsies generate a tremendous amount of data, but to be useful in the 21st century, these data must be reported electronically in a uniform format. Thus, it behooves pathologists to work together, and quickly, to agree to a standardized format for all autopsies so that all the autopsy data from the nation can be converted to a structured data format that can be mined as a uniquely powerful database for improving health care.

All things change. Even the autopsy is undergoing a transformation. Medical examiner and coroner offices in the United States are gaining access to computed tomography (CT) scanners for use in their autopsy work. Research in the use of CT imaging as an adjunct to autopsy pathology to determine the cause of death is still in its first decade, but it is already clear that autopsy and CT are complementary examination modalities. Computed tomography imaging is superior to autopsy pathology in demonstrating some diseases and injuries, while autopsy pathology is superior to CT imaging in showing other types of disease and injury.^{8,9} Together these approaches to examining a body provide the fullest account yet of the diseases and injuries that lead to death. These changes are coming to the hospital autopsy, too, as some of the offices acquiring CT scanners are joint forensic and hospital autopsy services. This model of postmortem examination represents a possible future in which pathologists and radiologists work more closely together as diagnostic specialists.

The autopsy still provides a wealth of information that can benefit medical practice and improve patient care. It is interesting that a nonpathology specialty recognizes this truth.¹⁰ Autopsy remains relevant to medical practice, and therefore, it remains relevant to pathology training. The saying “*Hic locus est ubi mors gaudet succurrere vitae.*” remains true.

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Supplemental Material

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A New Era in Pathology Consultation: The MyPathologist Electronic Consultation Tool

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Abstract

Pathologists and laboratory scientists provide valuable guidance on laboratory utilization, test ordering, interpretation, and quality control provided that clinical staff can easily access the laboratory team. To encourage consultation between clinicians with laboratory scientists and pathologists, we developed an easily accessible electronic tool termed “MyPathologist,” placed on the homepage of our electronic health record system. Over its 2-year pilot, utilization of this consultation tool climbed as we continued to publicize it and incorporated education into housestaff onboarding and electronic health record training. Physician satisfaction with the tool was high. Additionally, this became the primary source of consults to our residency call service. Evaluation of MyPathologist questions received during its pilot period showed that more than half the questions were of significant educational value to the residents, often focusing on results interpretation, appropriate test ordering, and quality control. MyPathologist is a novel electronic tool for pathology consultation within our electronic health record and also represents an avenue for educating residents, improving utilization of the laboratory, and improving patient care.

Keywords

consultation, clinical pathology, electronic medical record, communication, laboratory, residency training

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Introduction

Clinical medicine is increasingly complex, with the regular implementation of new laboratory tests, diagnostic algorithms, and consensus guidelines. It is difficult for practicing clinicians to stay abreast of the rapid advances in laboratory medicine, even in the area of their expertise. One survey of laboratory utilization patterns revealed that primary care physicians were uncertain of up to 23% of tests utilized, with test ordering uncertainty in 14.7% and test interpretation uncertainty in 8.3%.¹ The 2015 Institute of Medicine report, “Improving Diagnosis in Healthcare,” recognizes diagnosis as a team effort that requires pathologist input and interaction with clinical

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colleagues.^{2,3} Educating and providing consultation is a role that pathologists must embrace.³

Pathologists can offer guidance on the utilization of the laboratory, a function that is becoming critical in this era of cost control and health-care reform.^{4,5} A great opportunity exists for pathologists to advise clinical colleagues on appropriate test ordering, result interpretation, follow-up testing, and send-out tests. Increased consultation on correct ordering and interpretation of many laboratory tests can affect the speed, outcome, and cost of clinical management for many patients.

However, in this era of expanding, decentralized health systems and extensive use of the electronic health record (EHR), it is more difficult for physicians to access pathology and laboratory medicine staff for consultation and advice. A recent study noted that only 6% of primary care physicians consulted with laboratory professions in a given week.¹ The changing patterns of interphysician communication prompted by the EHR system, such as the electronic messaging system within the EHR, have also altered communication habits.

We have also noted shifting communication patterns in our clinical environment. Electronic communications have become the mainstay in our multihospital system, with many of our clinical colleagues practicing in ambulatory settings located at a distance from the hospital. Fewer of these physicians come to the pathology department to discuss laboratory findings, as the majority of inpatient care has shifted to hospital-based services and hospitalists; and thus, outpatient physicians may never be present in the hospital itself. The laboratory may be unknown territory for clinicians who may not understand which specific section of the laboratory a particular test is performed or may not know who to contact to obtain further information or interpretive assistance. Over time, we had noted the decreased frequency of traditional pager-based calls to our clinical pathologists and pathology residents. We postulated that in this era of electronic communication, we needed a new tool to enable clinicians in both the ambulatory and the inpatient settings to more readily query the pathology and laboratory medicine department.

To facilitate laboratory consultations, our goal was to build an easily accessible electronic communication function embedded in our EHR. We placed a laboratory icon on our EHR toolbar, linking it to several reference resources and an electronic consultation tool. This tool, named "MyPathologist," transmits electronic messages to a shared pathology inbox and triggers an immediate text page to the pathology resident on call. This article reviews the design of and our initial experience with this consultation tool.

Methods

IT Build

Working with hospital IT, we placed a laboratory consultation icon, called "MyPathologist," at the top of the main toolbar within our EHR. The MyPathologist icon remains accessible on the top toolbar throughout the EHR session for all

physicians in both inpatient and outpatient settings. This includes approximately 2000 hospital- and community-based physicians. This tool was launched in late spring of 2015.

Workflow

Departmental guidelines for use and response to MyPathologist consultations were discussed and developed in a series of faculty and resident meetings. During this pilot period, operating hours were defined as Monday through Friday from 8 AM to 5 PM. Questions received outside working hours were deferred to the next working day, while urgent questions could still be referred 24/7 directly to the appropriate laboratory or on call faculty member. Turnaround time was set at 2 hours for an initial reply to the physician. Clinicians were encouraged to submit questions covering the entire scope of the pathology department services, including clinical pathology laboratories (clinical chemistry, transfusion medicine/blood bank, microbiology, molecular pathology, hematopathology) and anatomic pathology.

Incoming messages generate an immediate text page to the clinical pathology resident on call. Consultative questions are reviewed and answered via the EHR inbox with guidance from the attending clinical faculty or anatomic pathologist. Messages are retained in the group inbox available to all residents and pathology faculty for review and discussion. A monthly departmental conference is used to review important MyPathologist questions. Questions and responses are also copied into a shared spreadsheet available to Pathology faculty and residents that allows for quick reference and also provided data for this article.

During the pilot phase, MyPathologist access was open to physicians, hospitalists, and medical interns, residents and fellows, with the inclusion of nurse practitioners and physicians' assistants planned after full implementation.

Publicity, Training, and Utilization

MyPathologist was initially publicized via instructional e-mails to all medical staff and housestaff as well as in-person presentations at multiple professional staff, medical group, and clinical division meetings during late 2015. Starting in 2017, it was included in housestaff orientation sessions and was formally added to the onboarding EMR training sessions for new physicians in late 2017.

In December 2017, a short survey was distributed to the professional staff via e-mail to gather data from users and nonusers to inform further revision of the tool.

Evaluation

All MyPathologist questions and answers during a pilot period from May 2015 to May 2017 were evaluated for educational value by 2 pathology residents (E.S. and T.T.) and an attending pathologist (K.K.) using a 3-point scale (routine, educational, or highly educational). MyPathologist questions were also

Table 1. Categorization of MyPathologist Questions.

Educational Value	Criteria
Routine	Involves operational response: location of result or information
Educational	Important question leading to useful clinical consultation and valuable educational experience for resident
Highly educational	Complicated clinical or laboratory question requiring significant chart review, literature review, or problem solving. High clinical and educational value
Question type	Examples
Test result interpretation	What is the meaning of these test results?
Test ordering question	How can I order this test? Should I order this test? What test should I use?
Test result request	Where are my test results?
Quality control request	Are these results are correct? Inconsistent with expectations
Specimen collection question	How do I collect specimens for this test? What instructions do I need to provide to the patient before collecting?

sorted by type into test result interpretation, test ordering question, result request, quality control review, specimen collection question, and miscellaneous (Table 1).

Frequency of physician use and time to response were also monitored.

Results

IT Build

The MyPathologist icon on the EHR home page is shown (Figure 1A). This icon is linked to a drop-down menu (shown) that contains key pathology resources for physicians, including our laboratory’s searchable test catalog, access to Department resources, links to Laboratory Tests Online, UpToDate, interpretative guidelines for test results, and at the top, a link to the MyPathologist consultation tool (Figure 1B). This tab links to a prepopulated electronic message window with the option of sending a general message or one linked to a particular patient. When sent or “accepted,” the in-basket message triggers a text page to the on-call clinical pathology resident indicating that an incoming query has been received in the MyPathologist inbox.

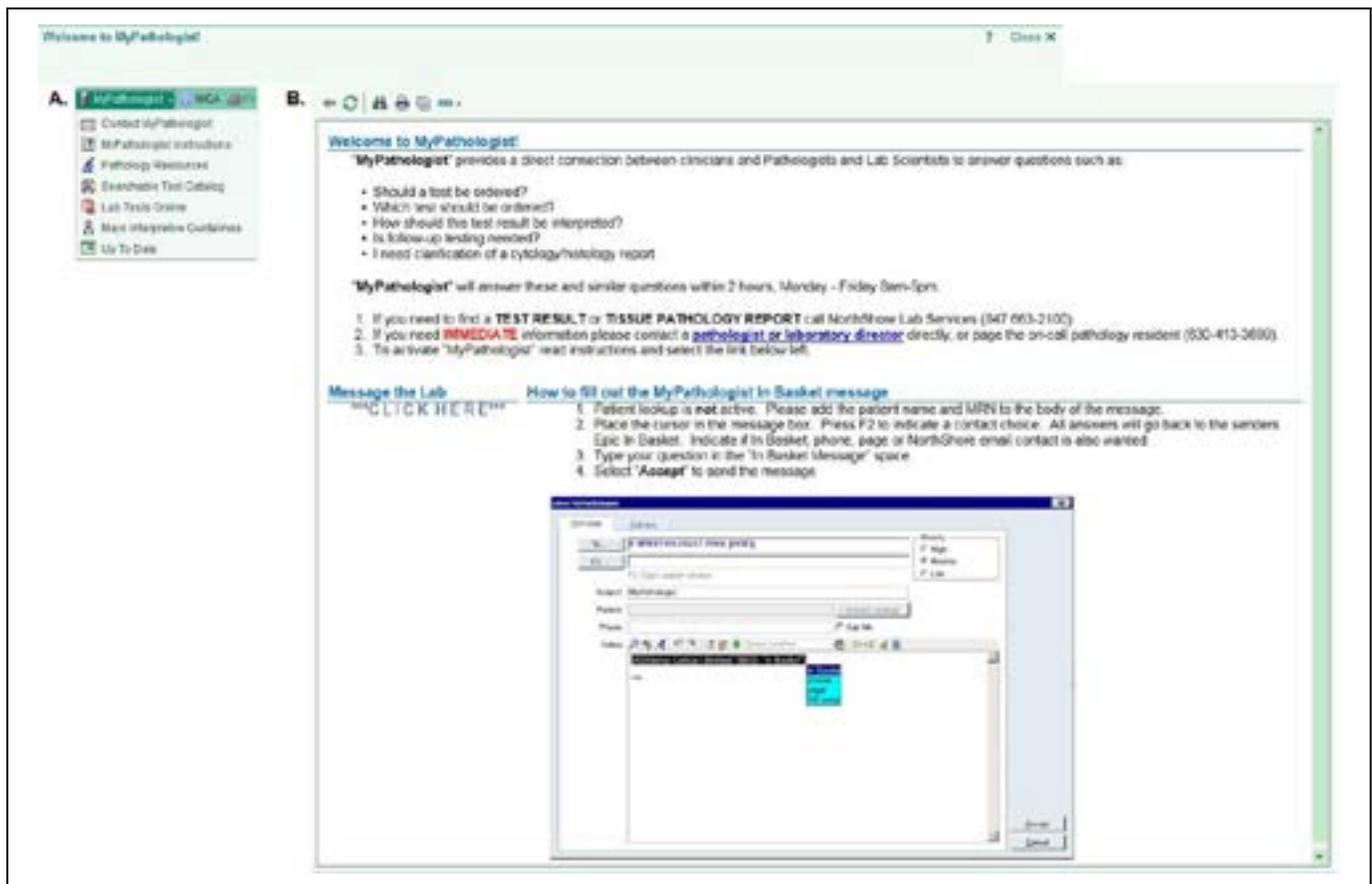


Figure 1. Screenshot images of the MyPathologist tool within our EMR. A, the MyPathologist icon in the EMR toolbar, along with the dropdown menu of additional tools and resources. B, The instructional display that appears when “contact MyPathologist” is selected, which includes the link to the electronic communication tool.

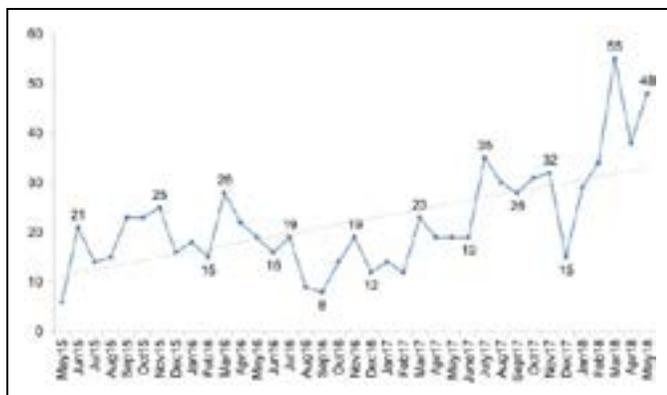


Figure 2. Frequency of consultations addressed via the MyPathologist tool. Notable increases occurred following presentation of the tool at housestaff orientation in 2017, and in early 2018 following inclusion of the tool in new physician training, and distribution of an e-mail to professional staff to remind them of the tool and request feedback.

Frequency of Use

As shown in Figure 2, utilization of the MyPathologist tool increased gradually over time since its launch in May 2015. During the 2-year pilot period, an average of 18 queries per month was handled by residents fielding consultations via MyPathologist. Notable increases in the frequency of questions were observed following the addition of training to housestaff orientation in June 2017 and also after an e-mail distribution to the professional staff in December 2017 (which contained the link to the survey).

Although response to the clinician survey was low, the results indicated that 40% of respondents who had not used the tool reported that they were not familiar with it. The uniqueness of this tool to our health-care system, and the need for additional publicity and training were underscored by these data, and the fact that usage increased following the distribution of the survey, which did promote the tool.

Surveyed users did report satisfaction with the ease of use within our EHR and with the speed and quality of responses and reported using it mostly for appropriate test selection and interpretive issues. Additional survey data will be collected.

Evaluation

A total of 433 MyPathologist questions were evaluated during the pilot period from May 2015 to May 2017. The clinical chemistry laboratory received the most questions followed closely by microbiology, surgical pathology, hematology, molecular, and blood bank (Figure 3A). The most commonly asked question types were quality control questions/requests followed by test ordering, test interpretation, test result requests, miscellaneous communications, and specimen collection questions (Figure 3B). Less than half of all questions were routine, with the remainder considered educational or highly educational (Figure 3C). Miscellaneous questions were mostly

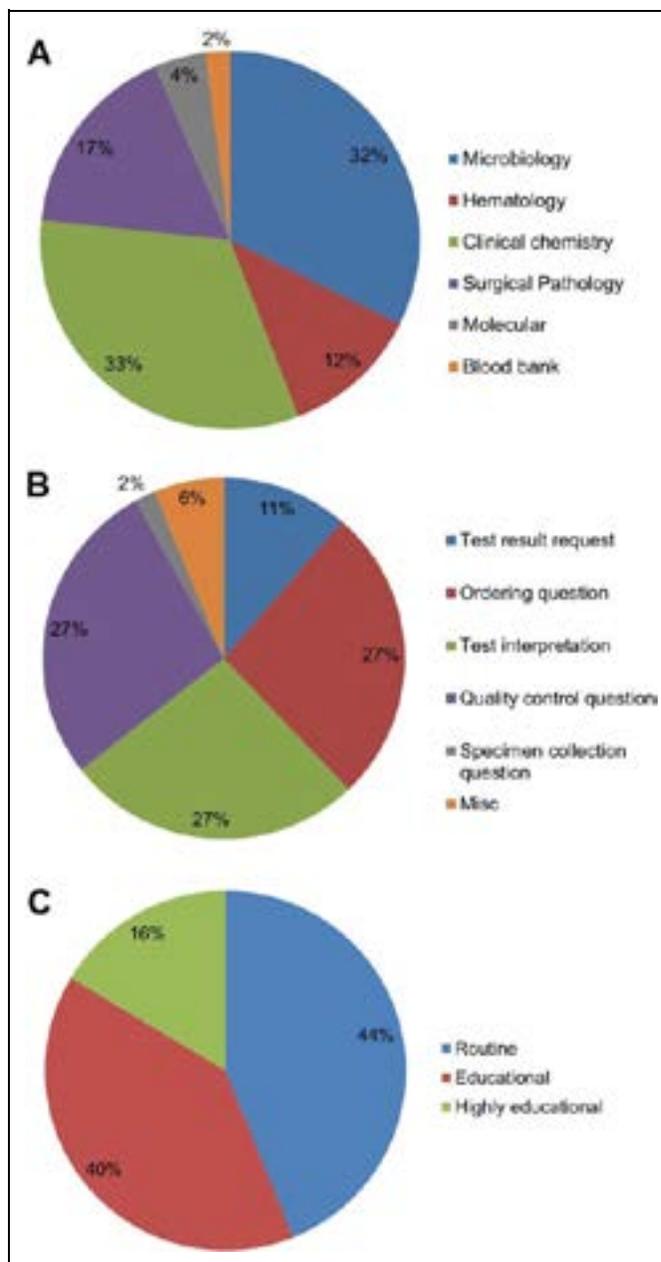


Figure 3. Types of consultative questions received via the MyPathologist tool, categorized by laboratory specialty (A), type of question (B), and assessed educational value (C).

physician orders and communication to the laboratory. A sample of questions received in the MyPathologist consultation service is listed in Table 2.

Questions stratified by educational value, laboratory, and question type are presented in Figures 4 and 5. Approximately 72% of clinical chemistry, 56% of microbiology, 47% of hematology, and 68% of molecular questions were either of educational or of high educational value, with 28% of clinical chemistry questions receiving the designation of high educational value, as shown in Figure 4.

The majority of questions with educational to high educational value were test interpretation or ordering questions

Table 2. Example MyPathologist Questions.

Laboratory Service	Educational Value*	Question Type	Question Text
Surgical pathology	Routine	Test result request	Could I get an update regarding status of path report? If it is not ready, when should we expect something back?
Clinical chemistry	Routine	Ordering question	Good morning. [patient] is interested in a venous blood pH for his self-assessment of risk and physiology. Is this a test we can do? If so, how do I order it as I can't find it on the EHR.
Microbiology	Educational	Quality control (results review)	Can you review the sputum gram stain on [patient]. The patient has pneumonia, with questionable improvement in levofloxacin Thanks ORIGINAL SPUTUM GRAM STAIN SCREEN <25 Squamous epithelial cells per 10× field 2+ WBCs (PMNs) 4+ Mixed respiratory flora
Hematology	Educational	Test interpretation	What the significance is of giant platelets on an otherwise normal CBC as noted in this patient?
Molecular	Educational	Ordering question	I am seeing a 6-week-old boy whose father carries a diagnosis of Familial Adenomatous Polyposis with a known genetic mutation: "5'UTRdel" in the APC gene. I wanted to test him for the same mutation to see if he has inherited the condition and was wondering how to order this test?
Surgical pathology	Educational	Test result request/ test interpretation	Is there a path or cytology available on the EGD or colonoscopy from on [patient identifier]? The clinician's notes imply that CMV was present on path. Would like to review.
Clinical chemistry	Highly educational	Test interpretation	This patient's celiac IgA test is abnormal but transglutaminase α is normal. What do we do with these conflicting results? Is further workup necessary?
Molecular	Highly educational	Ordering question	[patient identifiers] I wanted to order the genetic panel to screen for hereditary pancreatitis. How would I order this?
Clinical chemistry	Highly educational	Quality control	Ms. [patient identifier 1] had a comprehensive chemistry panel done on [date] and her glucose was 36. [Patient identifier 2] had a comprehensive chemistry panel done on [date]—his blood sugar was 42. We have had other patients with dramatically low glucose levels—Is something wrong with your glucose testing?
Microbiology	Highly educational	Ordering question	I have a question for Microbiology/and or Infectious Disease. One of my patients recently traveled to Jamaica and is concerned about Zika virus and wanting to try and conceive with wife now. After reading recommendations from the CDC, I indicated that there is no role for Zika testing (he is asymptomatic) and that if infected, it could be present in semen for several months, and they should wait 6-8 months before trying to conceive. He e-mailed me again today and said he spoke to someone in the "state" and they indicated that he should get IgM test through [laboratory name]. I wanted to confirm with you what I have already told him, which I have just reviewed again. If he has no symptoms, then there is no role for blood testing, and they should wait at least 6 months before having nonprotected intercourse.

Abbreviation: CBC, complete blood count; EGD, esophageal/gastric/duodenoscopy; EHR, electronic health record; IgA, immunoglobulin A; IgG, immunoglobulin G; PMN, polymorphonuclear leukocytes; WBC, white cell count.

*Educational value evaluated based on both questions and answer.

(Figure 5). In particular, most molecular questions were ordering questions, where test utilization and interpretation is a key issue. Specimen collection questions also tended to have educational to highly educational value; however, the total number was relatively small. Test result requests, as expected, were mostly routine.

A significant proportion of quality control questions were slide review requests of Gram stains and peripheral blood smears, representing the majority of questions in microbiology

(44%) and hematology (43%), respectively. These were often initiated because clinicians sought understanding of results that may not have been entirely consistent with expectations. Although the proportion of quality control questions with educational to highly educational value was less than that of ordering or interpretation questions, 46% of quality control questions proved to be of educational to highly educational value. Some questions in this category also required thorough investigation into laboratory management topics.

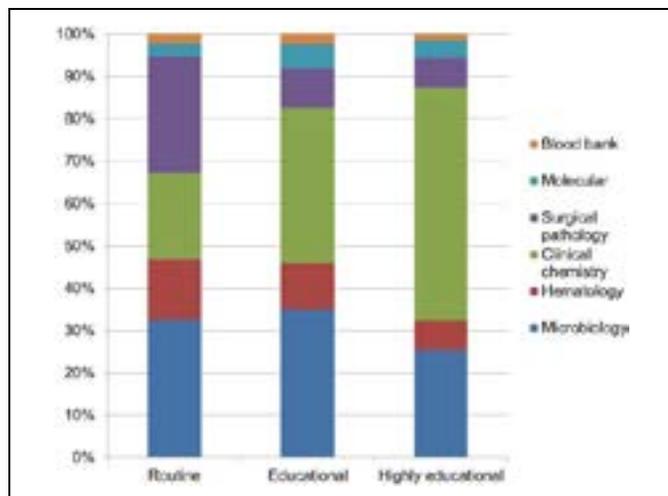


Figure 4. Relationship of the educational value of questions from the various laboratories.

The majority (71%) of surgical pathology questions were classified as routine, consisting of simple requests for results. The majority of more challenging surgical pathology questions went directly to attending anatomic pathologists, leaving routine queries of “low” educational value to be directed to MyPathologist. Of note, surgical pathology results are readily available in our EHR. Additional user training and redirection of these results requests are planned to facilitate efficient access to results and reports.

Discussion

The implementation of MyPathologist has provided a valuable consultation tool for clinicians in our institution. This tool is utilized by physicians and housestaff across our inpatient and ambulatory operation, with plans to eventually expand to physician assistants and nursing staff. The gradually increasing utilization of this tool reflects the slowly growing familiarity within our health-care system. Although this tool was initially introduced via e-mail announcements to the professional staff and a series of live presentations (including our housestaff orientation), we have found that a surprising number of physicians remain unaware of MyPathologist. We have recently had the tool implemented into EMR training during physician onboarding and are renewing our promotional announcements.

The MyPathologist electronic consultation tool is intended as an additional method to consult with the laboratory, complementing phone calls, and our traditional on-call system. Although we did not quantify traditional calls to laboratory directors and the residents during this period, there was no perception of a decrease. We believe that the easily accessible MyPathologist tool served to increase communications with the laboratory.

In addition, MyPathologist proved to be useful tool for pathology resident training. The majority of questions with high educational value were test interpretation or ordering questions suggesting that in these areas where pathologist

input is a valuable knowledge source for clinicians. These questions also provide an opportunity for clinician guidance regarding appropriate test utilization and cost considerations. Even routine questions have significant value in teaching pathology trainees to rise to the role of consultant and collaborator with clinicians. Clinical pathology consultation requires the exercise of good communication skills, critical thinking, and problem-solving. The MyPathologist call system simulates a clinical laboratory director’s role and helps fulfill ACGME pathology milestones.^{6,7} Since clinical pathology call responsibilities are proportionally handled by more senior residents (PGY3 and 4), this also became an important part of graduated responsibility within our program. Additionally, the use of a common file and a regular conference also helps in documenting and teaching real-life, problem-solving skills to all residents.^{8,9}

A number of challenges and opportunities remain for our implementation of an EHR-based clinical pathology consultation system. Blood bank questions were comparatively low, since clinicians tend to consult directly with our transfusion medicine attendings. This contrasts with a prior study of clinical pathology resident on traditional pager-based call demonstrated that approximately 30% to 50% of calls at their institution were related to the blood bank.^{6,10,11} This may reflect institutional cultural differences in the expectations of clinical physicians; in larger academic centers, there is an expectation of resident response to emergent calls such as are common in transfusion medicine, whereas in private hospitals and hybrid settings such as our institution, clinicians may be accustomed to direct communication with laboratory directors and anatomic pathologists. Additionally at our institution, senior clinical attendings, particularly specialists, have often continued established patterns of communication directly with laboratory directors.

Emphasizing the role and convenience of MyPathologist may help to increase usage. Additionally, modifying EHR training during orientation of new physicians, nurses, and physician assistants to include examples and references to MyPathologist may also promote use. In the 3 months prior to submission of this article, usage of this service approximately doubled compared to the pilot time period analyzed, suggesting that our ongoing efforts to promote MyPathologist continue to be effective.

If the MyPathologist system is expanded to include additional hours, weekends, or additional practitioners, resident and pathologist workload is expected to increase. In such a case, appropriate steps must be taken to ensure that resident education and general service duties are not compromised. Currently, the system serves as an educational adjunct, complementary but not conflicting with routine duties.

In conclusion, MyPathologist is a novel electronic tool for clinical pathology consultation and represents an avenue for educating residents for their future as clinical consultants. In the long term, it is hoped that this system will improve utilization of the laboratory, with resulting improvements in health-care cost and patient care.

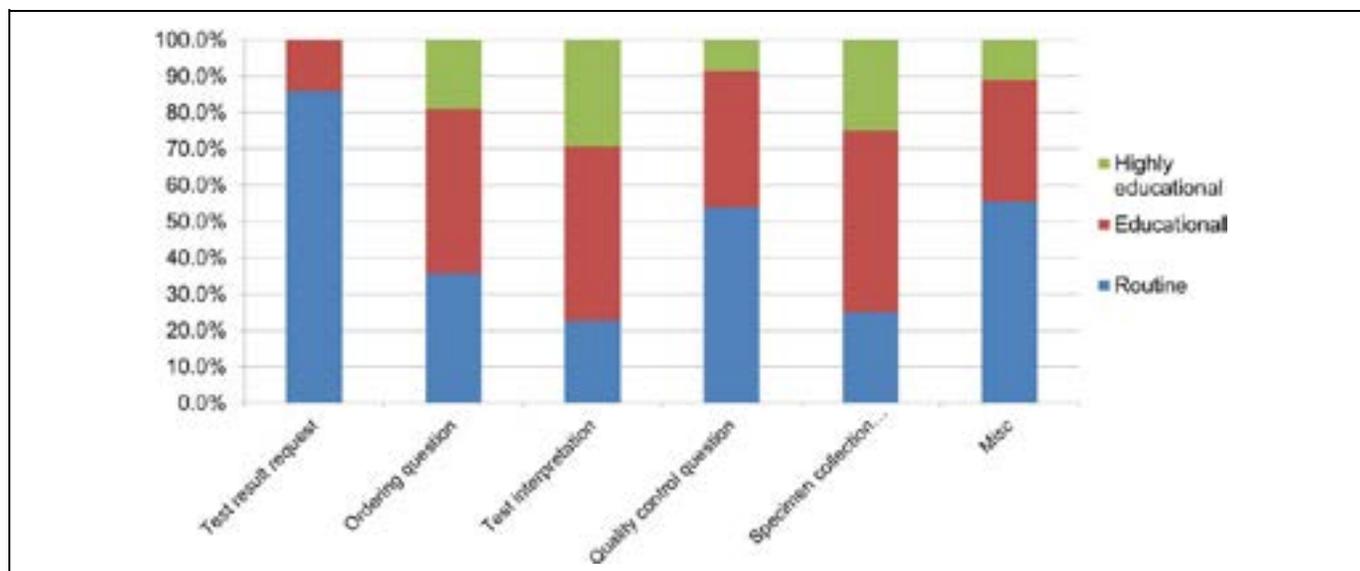


Figure 5. Relationship of the educational value of questions and the type of consultative question received.

Authors' Note

T.T. and E.S. contributed equally to this work.

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Declaration of Conflicting Interests

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Activation and Utilization of an Electronic Health Record Patient Portal at an Academic Medical Center—Impact of Patient Demographics and Geographic Location

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Abstract

The advent of the online electronic health record patient portal has provided an efficient and practical means for patients to become more involved in their health care. In this report, we analyze how demographic variables such as age, gender, race, and geographic location affect patient portal activation and usage at the University of Iowa Hospitals and Clinics, the sole academic medical center in the state of Iowa, a predominantly rural state. Our primary end points were activation of the patient portal (MyChart, Epic, Inc) and access of outpatient laboratory and radiology results, among the most commonly accessed and popular features of the patient portal. We thus analyzed data from 536 378 patients to determine rates of patient portal activation and data from 219 671 patient encounters to determine the frequency at which patients access their online diagnostic test results. Higher rates of patient portal activation and usage were associated with female gender, Caucasians/non-underrepresented minorities, geographic location in closer proximity to the medical center (Iowa City and neighboring cities/suburbs), and nonelderly adults. For underrepresented minority and rural patients, opportunities for improvement exist for both activation and more robust use of online patient portal accounts. Overall, these data highlight existing disparities with online patient portal usage and provide a base on which further studies and interventions can help to improve utilization of these systems.

Keywords

health information technology, electronic health records, patient portals, personal health information, computers/utilization

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Introduction

Electronic health records (EHRs) are common in industrialized countries and provide a way to store patient health information in a secure, efficient, and easily accessible manner.^{1,2} Online EHR portals (hereafter referred to as “patient portals”) are a tool for increasing patient engagement and high-value care.³ In the United States, EHR and patient portal use has become more prevalent in recent years in part due to the enactment of the HITECH (Health Information Technology for Economic and Clinical Health) Act, a program that seeks to improve the quality of health care in the United States by encouraging patient

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engagement in their health care through the concept of meaningful use.⁴⁻⁷ Financial incentives and penalties introduced by this program have led to EHR implementation in over 86% of US physician practices.⁶⁻⁹

Previous studies have shown that patients have a positive perception of participating in care via patient portals.^{10,11} Use of patient portals has been associated with improved care, decreased cost, and better patient–physician communication.¹²⁻¹⁷ Accessing of pathology results and radiology reports, in addition to other activities such as e-mail messaging or medication refills, are among the most popular features used within patient portals.^{18,19} Literature has also revealed that patient portal usage patterns differ depending on patient demographics. Patients who actively use patient portals tend to be Caucasian, younger, female, English speaking, and have fewer medical problems than nonusers.¹⁹⁻²³ Underreported in the literature are findings describing patient portal usage patterns by race and patient geographic location (eg, rural vs urban; in a previous study, we examined broad trends in release and patient access of diagnostic test results).²² That study showed that outpatient test results were reviewed in the patient portal at much higher rates than inpatient or emergency department test results but did not examine race and patient geographic location as variables.

In this study, we analyzed patient portal activation and usage at the University of Iowa Hospitals and Clinics (UIHC). University of Iowa Hospitals and Clinics is the only academic medical center in the state of Iowa, a predominantly rural state. In addition to patient portal account activation, we focused on online access of outpatient laboratory and radiology results, a popular patient portal feature available to all UIHC patients.

Materials and Methods

Setting

University of Iowa Hospitals and Clinics is a 761-bed tertiary/quaternary care medical center that includes outpatient services, pediatric and adult inpatient units, multiple intensive care units, and an emergency department with level I trauma capability. University of Iowa Hospitals and Clinics draws in significant referrals, both in state and out of state (predominantly neighboring states such as Illinois), and is located in a predominantly rural state with few urban areas. University of Iowa Hospitals and Clinics implemented the Epic EHR in 2009 and adopted the associated patient portal (MyChart) in 2010.^{22,24} To set up a MyChart account, patients are typically provided with paperwork (often as part of after visit summary documents) with an activation code at clinical encounters that they can then use to activate their portal account. Since June 2016, patients can additionally request an activation code online to sign up for MyChart. Parents can activate and manage the MyChart accounts of their children 11 years and younger with full functionality. Parents have restricted proxy access (eg, limited functionality such as immunization records) of childrens' portal accounts from ages 12 to 17 and lose proxy

access completely when children reach the age of 18. There are policies allowing for proxy access for caretakers and legal guardians of adult dependent patients. Once the MyChart account is active, patients can schedule appointments, fill out medical history surveys, view test results, renew prescriptions, access visit summaries, and communicate with the health-care team.

Patients

The present study had institutional review board approval as a retrospective study with waiver of informed consent (protocol #201710835). A total of 536 378 patients who had medical care at UIHC facilities (outpatient clinics, emergency department, inpatient units) were included in the analysis of overall MyChart activation rates. Patient data were organized based on age, gender, race, distance from UIHC, and city size (metropolitan, micropolitan, or rural). Distance from UIHC and city size utilized the zip code of the patient's primary address within the EHR. Metropolitan areas were defined as counties associated with cities that have a population of >50 000. The metropolitan areas in Iowa include Iowa City, Des Moines, Cedar Rapids, Waterloo, Sioux City, and their surrounding counties. Micropolitan areas are defined as cities with populations of 10 000 to 50 000; there are 17 micropolitan areas in the state of Iowa—Boone, Burlington, Carroll, Clinton, Fairfield, Fort Dodge, Fort Madison-Keokuk, Marshalltown, Mason City, Muscatine, Newton, Oskaloosa, Ottumwa, Pella, Spencer, Spirit Lake, and Storm Lake. Rural areas are defined as having less than 10 000 people in the town and surrounding area. Geographically, most of the state of Iowa falls into this rural category.²⁵ The results from the geographic data analysis are presented in aggregate by type of area (metropolitan, micropolitan, and rural) and distance from UIHC main campus (<10 miles, 10-50 miles, 51-100 miles, >100 miles).

Patient encounters were also organized based on self-indicated patient race as recorded in the EHR. This was divided into 8 categories—white, African American, Hispanic/Latino, Asian, Native Hawaiian/Pacific Islander, American Indian/Alaska native, Multiracial, and unknown. Most patients in the retrospective cohort described below that had outpatient diagnostic tests performed indicated white (n = 77 789) as their race, followed by African American (n = 3803) and Asian (n = 2814).

There were 91 207 unique patients and 219 671 total outpatient diagnostic test encounters included in the analysis of result viewing rates. Outpatient diagnostic test results were chosen, since access of those results was a popular feature for UIHC MyChart. In contrast, in a previous study, we found that patient access of inpatient and emergency department results is generally very low (<10%) across age and gender breakdowns, making it difficult to compare across patient subgroups.²² The analysis on outpatient diagnostic tests only looked at diagnostic testing that originated from UIHC clinics in the Iowa City and surrounding region (Coralville, North Liberty, Riverside, Muscatine). Inpatient and emergency department results were not included in the analysis for the present study.

The MyChart system at UIHC allows patient access to pathology results and radiology reports.²² Authorized health-care providers who have ordered these tests have the option to manually release the results to MyChart, at which time the results cross immediately to the patient portal. Manual release is typically done by the ordering provider when reviewing laboratory results in the Epic InBasket by clicking a button labeled “Reviewed/Release to MyChart.” This workflow is common for outpatient providers. For results not manually released by the provider, diagnostic test results autorelease according to a specific schedule. Most chemistry and hematology tests will autorelease at 03:00 AM on a business day following a full business day delay (eg, assuming no intervening holidays, a result finalized on Monday will autorelease on Wednesday or a result finalized on Friday will autorelease on Tuesday). Anatomic pathology and radiologic imaging reports autorelease following a delay of 4 full business days (meaning that autorelease occurs in approximately a week with intervening weekend days). Autorelease of microbiology results is either 1 or 4 business day delay, with sexually transmitted disease (eg, chlamydia and gonorrhea polymerase chain reaction [PCR]) testing typically being 4 business day delay. Human immunodeficiency virus screening and confirmatory results do not release to the patient portal.

Measures

This study involved 2 primary measures. The first primary outcome involved analyzing overall patient portal activation rates at UIHC. Patients considered “active” with respect to patient portals were those that registered their account online with their provided activation code. We did not distinguish between patient and proxy activation or access. Activation rates were then studied based on the previously described demographic variables.

The second category studied involved analysis of viewing patterns of outpatient diagnostic test results within MyChart. We included a selected group of pathology and radiology tests from the following 5 categories: Chemistry, Hematology, Imaging, Microbiology, and Anatomic Pathology. A breakdown of the specific tests are as follows: Chemistry (arterial blood gas, basic metabolic panel, hemoglobin A_{1c}, lactic acid, lipid panel, thyroid-stimulating hormone, and 25-hydroxy vitamin D), Hematology (complete blood count, partial thromboplastin time, prothrombin time/international normalized ratio), Imaging (chest X-ray, computed tomography [CT] scan of brain, CT scan of chest), Microbiology (*Chlamydia trachomatis* PCR, *Neisseria gonorrhoeae* PCR, urine culture), and Anatomic Pathology (gynecologic and nongynecologic cytology, dermatopathology, surgical pathology). Diagnostic test results were studied based on the same demographic variables as the activation rates.

Data Source

Epic Reporting Workbench (RWB) was used to retrieve patient demographics, MyChart status, pathology results, and

radiology reports covering dates from October 1, 2016, to October 1, 2017, using methods previously described.^{22,26,27} For the diagnostic test results, RWB captured whether patient had an active MyChart account and whether he/she (or a proxy) accessed outpatient diagnostic results. The RWB report included age, gender, MyChart status, zip code, patient location at order (inpatient, outpatient, or emergency department), and diagnostic test order. Zip codes were used to determine county of residency, state, city size, and distance from UIHC. Patients with an invalid or absent zip code (n = 199, 0.04% of total cohort) were not included in data analysis for geographic location.

Statistical Analysis

Analyses were performed using SPSS (PASW Statistics 18, Chicago, Illinois). To compare across groups, we used analysis of variance (for continuous variables) and χ^2 tests (for categorical variables).

Results

Patient Portal Activation Rates: Influence of Age, Gender, Race, and Geographic Location

Overall, female patients were found to have a higher rate of patient portal account activation than their male counterparts (Figure 1A). Activation rate across all female patients was 39.9%, while males had an overall activation rate of 31.9%. When broken down by age, females had higher activation rates across nearly all age groups. The largest difference was in the 31- to 40-year-old age-group—females at 43.2% and males at 29.6% activation. Males and females were nearly equal in activation rates for children (less than 18 years) and for patients 71 years or older. The highest overall rates of activation (greater than 60%) were in children 11 years and younger, an age range where patient portal access would be solely by proxy access by parents or guardians.

Patient portal activation rates also varied considerably among different racial groups (Figure 1B). Asian patients had the highest account activation rates at 59.1%. African American patients had the lowest rate of portal activation at only 22%. White patients, which make up the majority of the patient population in Iowa, had an intermediate activation rate of 37.2%. Multiracial patients had slightly higher activation rates than white patients.

Geographic location of patient’s home address also had a significant impact on patient portal activation rates (Figure 2). Users living within 10 miles of UIHC had the highest activation rates overall at 51.4%, 15.1% higher than the overall patient portal activation rate of 36.3% (Figure 2A). Activation rates steadily declined the further patients live from UIHC. Patients living in metropolitan areas (40.5% activation) had higher activation rates than patients living in micropolitan and rural areas (Figure 2B). Patients living in micropolitan areas had very similar activation rates to those living in rural areas (29.6% and 30.9%, respectively). Low activation rates were seen throughout the western and southernmost parts of Iowa. These regions of the state are notably devoid of any metropolitan areas.

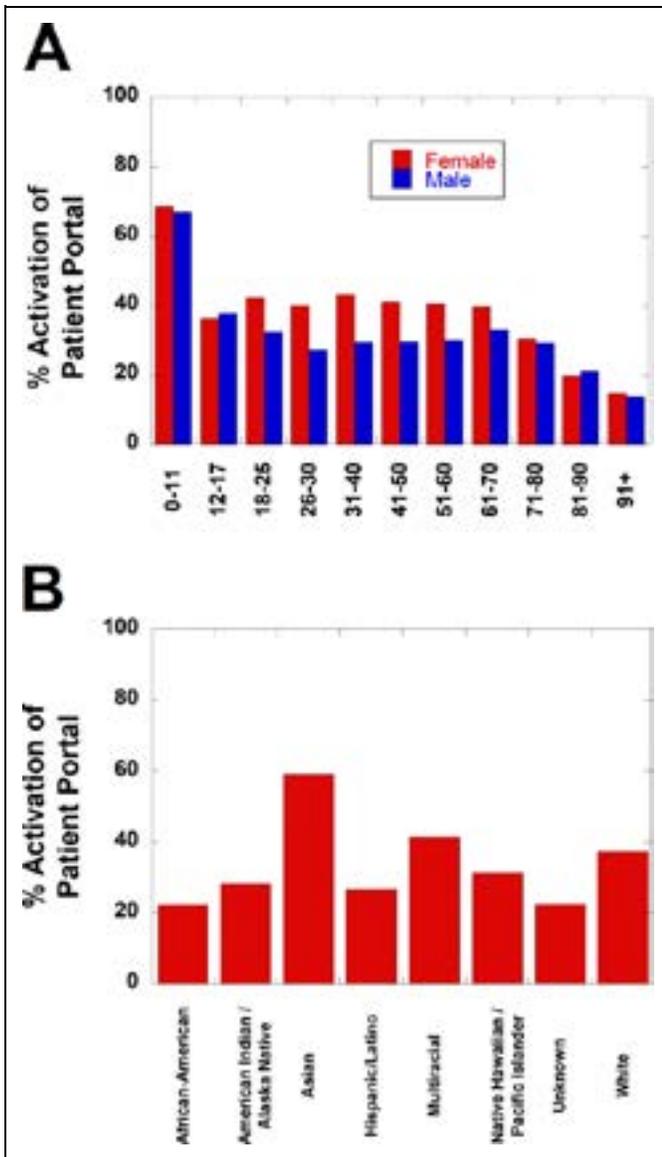


Figure 1. Patient portal activation rates by UIHC patients. A, Activation rates sorted by gender and subdivided into age distributions. Activation rates in patients 11 years and younger were significantly greater than other ages, while activation rates in patients 81 years and older were significantly lower than other ages ($P < .001$ for both groups, χ^2 without Yates' correction). Females showed significantly greater activation rates in all age distributions shown except 0 to 17 years and 81 years and older ($P < .001$). B, Activation rates sorted by self-declared patient race. Compared to the white population (the largest component of UIHC patients), African American, American Indian/Alaska Native, and Hispanic/Latino patients had significantly lower activation rates, while Asian patients had significantly higher rates ($P < .001$, χ^2 without Yates' correction). UIHC indicates University of Iowa Hospitals and Clinics.

Utilization of the Patient Portal: Patient Access of Outpatient Diagnostic Test Results

Accessing of outpatient diagnostic test results requires both an active patient portal account and then the patient or proxy accessing the results once available in the patient portal.

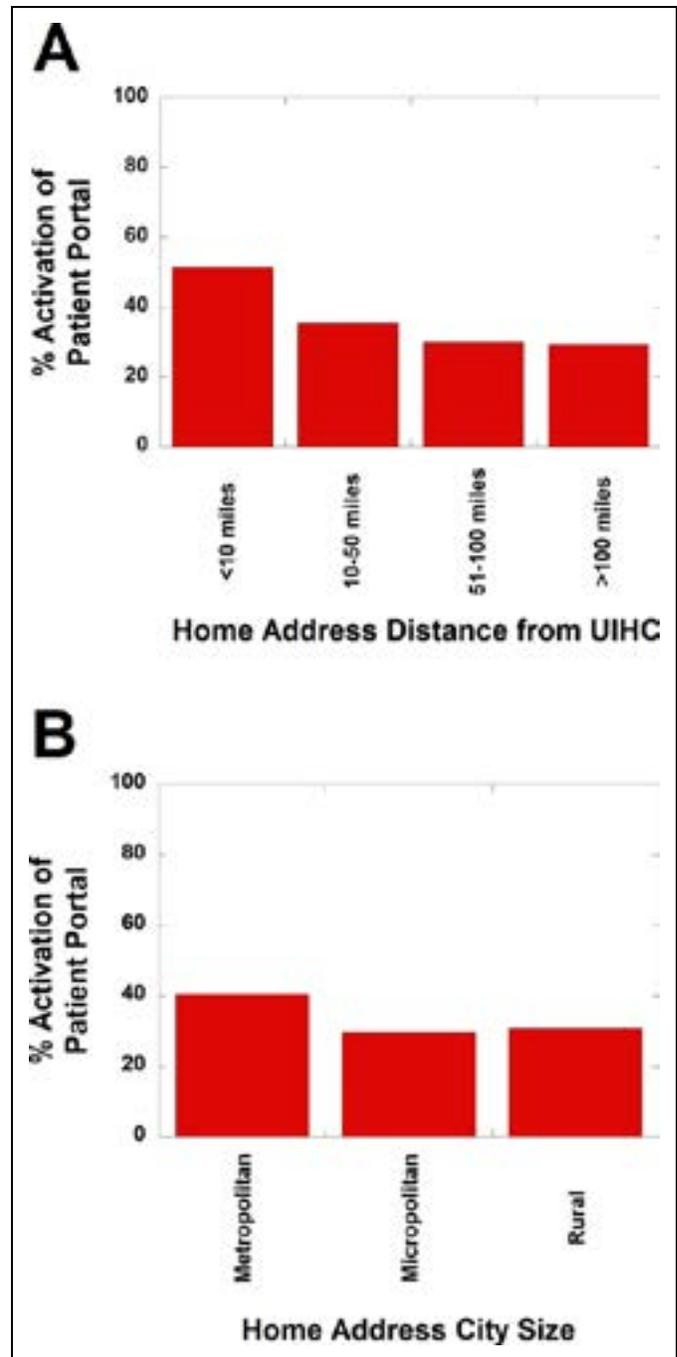


Figure 2. Patient portal activation rates by UIHC patients sorted by home address geographic location. A, Activation rates sorted by distance of patient's home address from UIHC. Patients within 10 miles of UIHC have significantly higher activation rates than those farther away ($P < .001$, χ^2 without Yates' correction). B, Activation rates sorted by whether patient's home address in metropolitan, micropolitan, or rural location. Patients in metropolitan regions have significantly higher activation rates than those in micropolitan or rural locations ($P < .001$, χ^2 without Yates' correction). UIHC indicates University of Iowa Hospitals and Clinics.

Overall, 39.5% of all outpatient diagnostic test results were viewed in the patient portal, and 44.4% of outpatients viewed at least 1 diagnostic test result. Figure 3A shows viewing of

outpatient test results (divided into Anatomic Pathology, Chemistry, Hematology, Microbiology, and Radiologic imaging), showing both view rates among only those with active patient portal accounts (red bars; excluding those with inactive patient portal accounts) and overall view rates that also include results associated with patients with inactive patient portal accounts (blue bars). Outpatients with an active patient portal account viewed 69.3% of their test results overall regardless of demographics. The most commonly viewed test category among outpatients was Microbiology at 71.1%. Chemistry, Pathology, and Imaging tests were all viewed in the 60% to 70% range. The least viewed test category is Hematology, at 58.3%.

Although females overall viewed outpatient diagnostic test results at rates higher than males, the difference between the 2 genders was less pronounced when looking at only those patients with active portal accounts (Figure 3B; contrast with activation data in Figure 1A). The most common test category viewed by females was Microbiology (71.8%), followed closely by Chemistry (71.4%). Microbiology was also the most commonly viewed category among males (68.2%), followed by Chemistry and Radiology, both at 61.1%. The largest difference among viewing patterns was among the Chemistry and Hematology categories; females viewed these labs 10% more frequently than males in both. The smallest gap was in the Microbiology category; females viewed microbiology results at only 3.6% more than their male counterparts.

Among those with active patient portal accounts, adults 26 to 40 years old showed the highest view rates of viewing outpatient diagnostic test results (Figure 3C). Above age 40, viewing patterns stay consistent until age 70, at which point they gradually start to taper downward. Young children (ages 0-11) had viewing rates comparable to the adult age groups. The one age category that was far less likely to view their test results is the 12- to 17-year-old age-group, with less than 40% of results viewed even among those with active patient portal accounts.

In regard to race, differences in outpatient test result viewing among those with active patient portal accounts (Figure 4A, red bars; patients with inactive portal accounts excluded) were less pronounced than the differences discussed earlier in patient portal activation rates (Figure 1B). In all categories, view rates exceeded 50% provided the patient had an active portal account. Asian outpatients were the most likely to view their test results at 76.2%; African Americans were the least likely at 53.8%. Figure 4A (blue bars) shows outpatient test view rates that includes both active and inactive patient portal users. The inclusion of inactive patient portal users drops overall view rates for African American and Hispanic patients to less than 30% and widens the differences between the races. Only the Asian population at UIHC (a group with the highest rate of active patient portal accounts; Figure 1B) exceeds 50% in overall viewing of outpatient test results even when inactive portal users are included.

Figure 4B shows outpatient test result view rates among those with active patient portal accounts subdivided by location of patient's home address. Although users in metropolitan areas had slightly higher view rates than those in micropolitan or

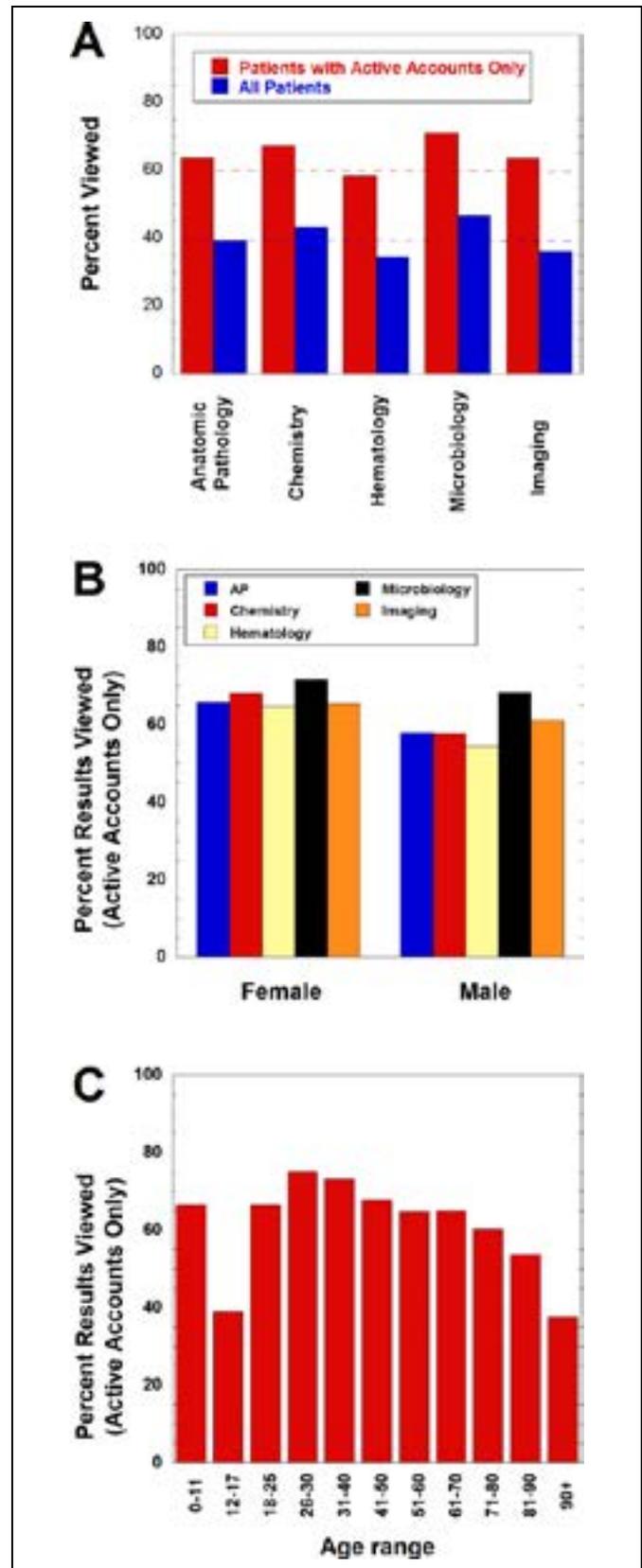


Figure 3. View rates of outpatient diagnostic tests sorted into Anatomic Pathology, Chemistry, Hematology, Microbiology, and Radiologic Imaging. A, Overall view rates of outpatient diagnostic tests

rural areas, this was less pronounced than the differences in patient portal activation rates discussed above (Figure 2C).

Figure 5 shows view rates of specific outpatient diagnostic tests among those with active patient portal accounts. Tests with higher view rates than the average for patient with active portal accounts include CT scans of the brain, thyroid-stimulating hormone with reflex to free thyroxine (T4), lipid panel, hemoglobin A1C, Pap test, chlamydia PCR, *N gonorrhoeae* PCR, and urine cultures. Interestingly, lactic acid and arterial blood gas analyses had very low view rates (<20%).

Discussion

Previous studies have demonstrated that patients who actively use patient portals are more likely to be Caucasian, younger, female, English speaking, and have fewer medical problems than nonusers.¹⁹⁻²³ Our findings also show that females were more likely than males to activate their patient portals across all but 2 age categories, with the largest differences existing between adults ages 18 to 70. Only among the 12- to 17-year-old and 71+ year groups did males have nearly equal or even slightly higher portal activation rates than females. Females were also more likely than males to view their outpatient diagnostic test results, although the percentage gaps were smaller overall with respect to diagnostic test viewing when looking at those with active patient portal accounts. One possible explanation for the higher activation rates among males in the 12- to 17- and 81- to 90-year-old age groups would be that these accounts may be activated by proxy users (ie, parents for children or caretakers of adult dependents) or with the assistance of partners, other relatives, or others. The literature on patient portal activation rates via proxy users and caretakers is limited, but one study has shown that low-income and elderly patients are more likely to access their online health portals if they have in-person assistance,²⁸ and that patients who have better health literacy and higher self-reported ability to use the Internet are also more likely to use their online portals.^{29,30} The finding that females tend to participate in care via an online health portal more than males is consistent with some previously described literature,^{19,23} but other studies found no significant difference in portal use based on gender.^{30,31}

Figure 3. (Continued). showing view rates among only those with an active patient portal account (red bars; patients with inactive portal accounts excluded) and total including those without an active account (blue bars). The upper dashed line shows the overall average view rates of all tests for those with an active account. The lower dashed line shows the overall average view rate (including those with inactive portal accounts). B, View rates of outpatient diagnostic tests subdivided by gender and showing view rates among only those with an active patient portal account (patients with inactive portal accounts excluded). C, View rates of outpatient diagnostic tests among only those with an active patient portal account subdivided by age distribution (patients with inactive portal accounts excluded). Patients aged 12 to 17 years and 81 years and older had significantly lower view rates than other ages ($P < .001$).

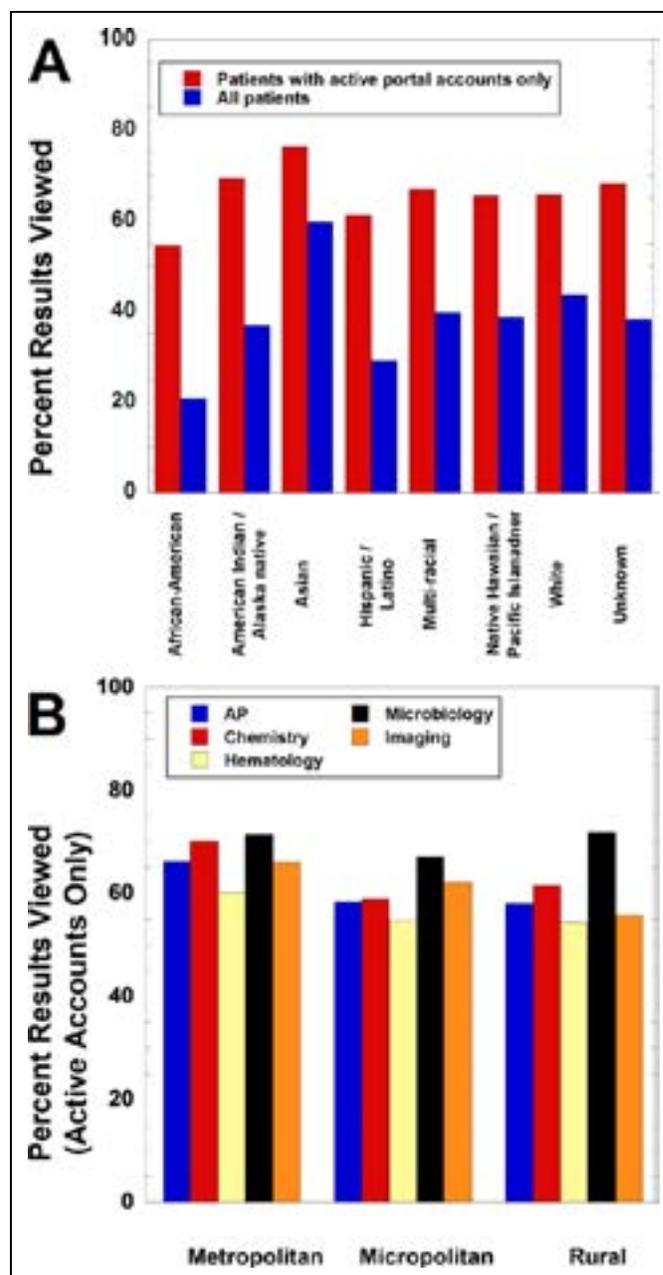


Figure 4. View rates of outpatient diagnostic tests sorted into race and geographic location of home address. A, View rates of outpatient diagnostic tests subdivided by self-declared patient race and showing view rates among those with an active patient portal account (red bars; patients with inactive portal accounts excluded) and total including those without an active account (blue bars). In both groups, compared to the white population (the largest component of UIHC patients), African American, American Indian/Alaska Native, and Hispanic/Latino patients had significantly lower view rates, while Asian patients had significantly higher rates ($P < .001$, χ^2 without Yates' correction). B, View rates of outpatient diagnostic tests subdivided by whether patient's home address in metropolitan, micropolitan, or rural location and showing view rates among only those with an active patient portal account (patients with inactive portal accounts excluded). UIHC indicates University of Iowa Hospitals and Clinics.

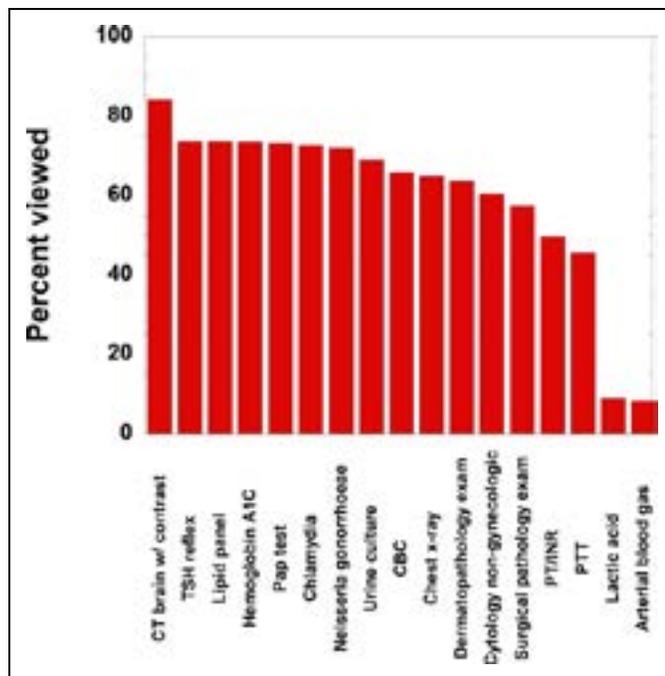


Figure 5. View rates of selected outpatient diagnostic tests. The tests on the left side of the plot are those that are higher than the overall average view rate. The right side of the plot has some tests with lower than average view rates.

Our data show that patients 71 years and older are less likely to utilize their patient health portals, which is also consistent with previously described literature.^{20,32} Portal activation and diagnostic test viewing rates remain relatively stable from 18 to 70 years old. Above 70 years old, there is decline in activation rates. This suggests that some older adults may encounter difficulties in activating their accounts, but once active, they tend to use them. One plausible explanation for this may be that online health portals select for older individuals who are more technologically literate, and therefore, those who are able to activate their accounts are also able to use them. It is also possible that the elderly population with active patient portal accounts are more likely to have help from a spouse, child, or some other caretaker. The existing literature contains sparse data on the extent to which relatives or other people help elderly patients with patient portal use. This is not something that our own institution has collected survey data on, although it is a future goal to probe these questions. The data in the present study do not contain information on the educational status of patients.

Trends among children and teenagers in our data set are somewhat variable. Children 11 years and older have the highest portal activation of all categories (much higher than adults) and also outpatient diagnostic test viewing rates comparable to adult age groups. Older children 12 to 17 years old have activation rates similar to the adult population, but their viewing of outpatient diagnostic test results is much lower. A probable explanation for some teenage patients is that parents may be activating these accounts through proxy access when the

children were younger. Either way, teenagers are less likely than other age categories to utilize their active health portal accounts. It is unknown whether this is due to lack of health literacy, lack of interest, or both. It has been shown that many adolescents have problems with overall literacy—statistics from the *The Nation's Report Card* show that only 36% of US fourth grade students and 34% of eight grade students read at or above a “proficient” level, but studies have not been conducted that measure adolescent health-care literacy specifically.³³

Our study reinforces others studies that show patient portal activation and utilization are lowest among underrepresented minorities.³⁴⁻³⁶ In a previous study, we showed that patient portal access of diagnostic test data were much higher in outpatient versus inpatient or emergency department encounters.²² However, the present data show that subgroups are utilizing the functionality of accessing the patient portal for outpatient diagnostic tests results at lower rates, driven in large part by lower patient portal account activation rates. Interestingly, once patient portal accounts are activated, utilization of the portal in accessing outpatient tests results was much less divergent between races. This suggests that once minority patients with low activation rates (African American, Hispanic/Latino) activate their accounts, they are using the account functions with rates closer to that of the high-activation groups (Asian, Caucasian). Therefore, there may be some barrier to activation among minority groups that is preventing these groups from activating their accounts, but once active, they are engaged in using the patient portal. Previous studies have shown that patients with English-language barriers, patients with low incomes, and patients with lower education levels are less likely to utilize health-care portals,³⁴⁻³⁶ which could in part account for the low usage among these groups. It has even been reported that African Americans and Hispanics are less likely to be offered access to patient health portals compared to patients of other racial demographics.³⁷ Other potential barriers to activation could be a lack of provided information, lack of health literacy, difference in socioeconomic status, and/or poor access to broadband Internet. However, although usage rates are higher among minorities once they activate their accounts, a gap still does exist among diagnostic test result viewing percentages based on patient race. So, it is a possibility that minority patients also encounter barriers to using their activated accounts for a more complex function such as accessing diagnostic test results.

Patients who live in metropolitan areas and patients who live in closer proximity to UIHC were more likely to both activate and use their patient portal accounts. Higher health portal account use seems to be related to distance within a 50-mile radius around the hospital. Patients living further than 50 miles from UIHC seem to have universally lower use rates, regardless of how far beyond the 50 miles they live. One possible explanation for this trend is that patients living within 50 miles of the hospital may be more likely to be regular patients at UIHC, and patients may be more motivated to use the health portal at their regular hospital. Additional factors may be

differences in socioeconomic and educational status. Patients living further than 50 miles from UIHC may be more likely to be those who are attending appointments for one-time referrals and may therefore be less motivated to participate in the UIHC patient portal. Lack of reliable access to broadband Internet may also be a factor in rural areas.^{30,38,39} Research on the relationship between geographic location and patient portal use is limited and requires further investigation.

In a previous study, we showed that patient access of inpatient diagnostic test results via the patient portal was much lower than outpatient test results.²² One possible explanation for this finding is that inpatients may be less likely to have a regular primary care provider than their outpatient counterparts, and it has been previously described that patients without regular primary care are less likely to engage in an online health portal.³⁵ Other explanations may be that inpatients may be less likely to receive routine medical care from UIHC and might have primary physicians who are outside the UIHC system—these patients may be engaging in non-UIHC patient portals. It is also possible that they are not engaging in an outside portal at all, but do not utilize the UIHC portal because their inpatient hospitalization at UIHC is a limited occurrence and setting up a patient portal would not provide much benefit to them once they leave. There are many possible explanations to this, but the question requires further study. The data in this study can guide marketing and other efforts to enhance activation and utilization of the patient portal across demographic groups, as is ongoing at our institution.

Conclusions

Overall activation rates within the UIHC patient portal were highest among women, patients of Asian, multiracial, and white ethnicity, young to middle-aged adults, patients who live in close proximity to Johnson county (where UIHC is located), and patients who live in other more populated areas in Iowa. Some of the groups with the lowest activation rates include African American patients, Hispanic/Latino patients, and teenagers. Our data suggest that activation of the patient portal account is a significant barrier in differences between subgroups of patients. Once patients have active accounts, they are more likely to use their patient portal, at least as it pertains to outpatient diagnostic test results. More research should be done to determine how to minimize these discrepancies in patient portal usage and increase access to underserved populations.

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Benchmarking Subspecialty Practice in Academic Anatomic Pathology: The 2017 Association of Pathology Chairs Survey

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Abstract

Assessment of physician workloads has become increasingly important in modern academic physician practice, where it is commonly used to allocate resources among departments, to determine staffing, and to set the compensation of individual physicians. The physician work relative value unit system is a frequently used metric in this regard. However, the application of this system to the practice of pathology has proven problematic. One area of uncertainty is the validity of using work relative value unit norms that were derived from general surgical pathology practice to assess the various subspecialties within anatomic pathology. Here, we used data from the 2017 Association of Pathology Chairs practice survey to assess salary and work relative value unit data for single-subspecialty practitioners in US academic pathology departments in the prior year (2016). Five subspecialties were evaluated: dermatopathology, gastrointestinal pathology, hematopathology/hematology, renal pathology, and neuropathology. Data for general surgical pathologists and cytopathologists were included for comparison. For this analysis, survey data were available for 168 practitioners in 43 US academic departments of pathology. Salary ranges varied little among subspecialties, with the exception of dermatopathology, where salaries were higher. In contrast, work relative value unit productivity varied widely among different subspecialties, with median values differing as much as 4- to 7-fold between subspecialties. These results suggest that the use of a single overall work relative value unit standard is not appropriate for specialty- or subspecialty-based anatomic pathology practice, and that either the benchmark norms should be tailored to individual practice patterns, or an alternative system of workload measurement should be developed.

Keywords

anatomic pathology, benchmarking, clinical effort, salary, subspecialty practice, work relative value units

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Introduction

Assessment of physician workloads has become increasingly important, as many physicians move to salaried, hospital-based, or group-based practices and as bundled payments by third-party payers make it difficult to attribute specific dollar reimbursement amounts to individual practitioners. The physician work relative value unit (wRVU) system was introduced in 1988¹ as a system for quantifying the professional effort required for diverse physician activities both within and across specialties. Time, technical skill and effort, mental effort and

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judgment, and any attendant stresses are among the factors ostensibly used in ascribing wRVUs to a given physician activity. The original study by Hsaio and coworkers¹ was based on surveys of physicians in only 4 specialties that, notably, did not include pathology. This system has since been applied across virtually all clinical specialties, including pathology, to determine workload—and reimbursement—by third-party payers as well as by individual hospitals, university-based practice plans, and private groups.

The application of this system to the practice of pathology has proven problematic. In particular, there is as yet no recognized system for assigning wRVUs to many areas of pathology practice, such as autopsy pathology, forensic practice, or almost all of laboratory medicine. For the specialties of general surgical pathology and cytopathology, wRVUs are commonly used to measure workload and productivity, although reported benchmark numbers vary widely based on the methodologies used to define and calculate these benchmarks.² A question that remains is the applicability of surgical pathology wRVU norms, which are derived from general surgical pathology practice, to practitioners of individual subspecialties. To our knowledge, there has not previously been a systematic study of wRVU measures as they apply to specific subspecialty practices within anatomic pathology.

Methods

The Association of Pathology Chairs Practice Survey

The Association of Pathology Chairs (APC) practice survey design has been described in detail by Ducatman and Parslow.² The present report is based exclusively on the APC's 2017 annual survey, which gathered data from the preceding year (ie, 2016). The survey was conducted by the APC's Practice and Management Committee, and all member departments of the APC were invited to participate. The APC represents pathology departments in 170 US medical teaching institutions, including virtually all 88 US academic medical centers who are members of the Association of Academic Health Centers.³ Ducatman and Parslow² previously reported a detailed analysis of data from the 2015 APC survey, providing normative information on clinical effort (both Part A and Part B), educational effort, research effort, median total salary, annual days on clinical service, and wRVUs for surgical pathologists practicing (1) general surgical pathology, (2) one or more subspecialties, or (3) a hybrid of general surgical pathology plus some subspecialty practice, using data from 2014. However, assessment of those data for specific subspecialty practices was limited by low numbers of practitioners within each subspecialty in the 2015 survey database.

Definitions of Survey Salary Terms

The survey asked respondents for the following 3 data points (in addition to other data points) for individual pathologists: (1) base salary for individual (last full year available) not

including fringes, (2) incentive salary for individual (last full year available) not including fringes, and (iii) fringe rate as a decimal. These terms were not further defined in the survey.

For the 2017 survey, conducted from January to April 2017, respondents were asked to preferentially provide data on single subspecialty practitioners for 2016, with the aim of obtaining a robust representation of such practitioners that would allow further subspecialty analysis. Chairs or administrators at participating APC institutions were asked to provide specific data on individual faculty pathologists practicing at their own institution during the most recently completed fiscal year. Because all data were completely anonymized and deidentified as to program and individual prior to submission to the APC, this study was exempt from institutional review board review. The present study used data from the 2017 survey only, which was merged into a single Excel[®] spreadsheet.

Compensation Analyses

We included data from all responding institutions to develop mean, median, and quartile data for pathologists' total annual compensation (base + incentive), stratified by doctoral-level degree, by academic rank, and by geographic region. Geographic regions were used as defined by the APC.⁴ We also assessed fringe benefit rates and incentive salary as a percentage of total salary. We further analyzed salary data by years-in-rank for assistant professors.

Subspecialty Analyses

Reporting departments were asked to specify the scope of each individual's practice, choosing from a list of specialties and subspecialties. Our present analysis focused on those anatomic pathology categories for which data were reported on 10 or more practitioners, except that all autopsy and forensic pathologists were excluded. The subspecialties analyzed were dermatopathology, gastrointestinal (GI) pathology, hemato-pathology/hematology, renal pathology, and neuropathology. Data for practitioners of general surgical pathology and of cytopathology were included for comparison. Mean, median, and quartile data for total compensation and for wRVUs were assessed. Departments were also asked to specify the proportion of each individual's professional effort that was devoted to such practice (ie, the clinical full-time equivalent, cFTE).

Work Relative Value Unit Analyses

Except where otherwise noted, all analyses presented here focused on absolute (raw) wRVU production as reported for each pathologist in a given practice category. Two alternative formats were prepared for purposes of comparison. The first alternative format likewise depicts raw wRVU data but only for the subset of practitioners within each category who had a reported cFTE of 0.67 or greater; this is intended to approximate the method used by the Medical Group Management Association (MGMA) to report physician wRVU data. The

Table 1. Total Compensation Data (US\$) by Degree and Academic Rank.*

	Instructor	Assistant Professor	Associate Professor	Associate Professor and Chief	Professor	Professor and Chief	Professor and Chair
Pathologists—PhD							
Count	0	24	24	0	51	2	0
25th	-	123 750	127 000	-	165 125	-	-
Median	-	131 307	140 598	-	187 900	-	-
75th	-	154 494	173 734	-	215 274	-	-
Mean	-	134 982	147 444	-	190 115	286 277	-
Pathologists—DO							
Count	0	9	0	0	0	0	0
25th	-	185 428	-	-	-	-	-
Median	-	215 791	-	-	-	-	-
75th	-	261 267	-	-	-	-	-
Mean	-	228 584	-	-	-	-	-
Pathologists—MD							
Count	3	203	174	7	169	17	5
25th	-	188 270	215 190	270 659	249 161	324 926	394 615
Median	75 000	203 974	246 630	290 000	289 836	343 233	454 980
75th	-	232 998	278 756	296 682	329 861	395 383	496 516
Mean	96 121	210 156	248 173	301 259	291 121	360 545	453 194
Pathologists—MD, PhD							
Count	0	57	50	0	51	8	6
25th	-	186 712	213 412	-	246 204	317 133	405 857
Median	-	198 401	243 388	-	277 636	337 116	425 214
75th	-	213 055	259 810	-	332 662	397 237	512 500
Mean	-	202 312	237 447	-	282 668	354 692	458 488

*Tabulated data indicate the median, mean, and 25th- and 75th-quartile annual salaries (in US\$) for pathology faculty. Salary was defined to include base plus incentive pay, excluding benefits.

second alternative format includes data only for those practitioners with a reported cFTE of 0.60 or greater (or, in the case of hematopathologists, 0.5 FTE or greater) but normalized each practitioner's actual wRVU production to that individual's reported cFTE; the resulting wRVU/cFTE ratio is intended to approximate the method used by Vizient (and previously by the Faculty Practice Solutions Center, FPSC) to report physician wRVU productivity. See Ducatman and Parslow² for a discussion of the implications of these alternative benchmarking methodologies.

Statistical Analysis

Statistical tests for significance were performed in JMP version 13.0 (Cary, North Carolina) by one of the authors (B.S.D.). Since the data are nonparametric, particularly when using MGMA and Vizient methodologies, the Wilcoxon Kruskal-Wallis test was applied for most analyses reported here.

Study Population

Anonymized survey data from 2016 were available for a total of 918 faculty members from 43 US departments of pathology. We first analyzed individual pathologists' total compensation (defined as base pay plus any incentives but excluding fringe benefits) as a function of academic rank, professional degree, and geographic region, determining the mean, median, first

quartile, and third quartile of compensation for each group. Analyses of the distributions of fringe benefits and incentive salary (each as a percent of total salary) were performed for 836 faculty members for whom these data were available, and the results were then further substratified by geographic region.

For analyses of wRVU data, we focused on the subset of 168 faculty members who were identified by their departments as exclusively practicing general surgical pathology (n = 54), cytopathology (n = 15), or 1 of 5 subspecialties for which requisite data on at least 10 practitioners had been reported. The latter subspecialties were hematopathology (n = 39), renal pathology (n = 19), neuropathology (n = 15), dermatopathology (n = 14), and GI pathology (n = 12). Practitioners of 2 anatomic pathology subspecialties for which wRVU data are not available (autopsy and forensic pathology) were not included in our analysis.

Results

Median Salary Compensation Data for All US Pathology Faculty

Salary data for US academic pathologists, stratified by degree, by academic rank, and by senior administrative titles (Chief or Chair), are presented in Table 1. For PhD faculty, median salaries range from US\$131 000 for assistant professors to US\$188 000 for full professors. The respective figures for those

Table 2. Total Compensation Data (US\$) by Region—Pathologists MD, DO, and MD/PhD.*

	Instructor	Assistant Professor <2 years	All Assistant Professor	Associate Professor	Professor	Professor and Chief	Professor and Chair
Midwest							
Count	0	7	63	42	34	4	3
25th	-	177 500	188 404	217 210	243 277	-	-
Median	-	180 000	192 474	252 478	319 249	395 469	423 427
75th	-	197 098	239 246	279 961	365 550	-	-
Mean	-	183 045	213 881	251 748	297 140	386 768	424 341
Northeast							
Count	0	10	61	62	47	4	2
25th	-	194 988	191 380	226 703	260 681	-	-
Median	-	198 705	203 511	252 493	294 128	321 777	-
75th	-	220 006	213 660	287 149	328 713	-	-
Mean	-	211 874	206 021	258 029	301 575	298 517	371 809
Southeast							
Count	3	14	99	97	118	14	5
25th	-	203 232	187 272	207 518	238 274	305 097	-
Median	-	212 904	204 000	236 440	266 400	332 512	541 000
75th	-	227 894	234 600	258 182	312 079	346 433	-
Mean	91 667	219 057	207 635	233 928	271 254	335 780	552 403
West							
Count	0	3	16	23	22	4	2
25th	-	-	204 850	227 926	199 127	-	-
Median	-	209 000	227 500	292 423	239 038	236 000	-
75th	-	-	249 213	346 500	317 024	-	-
Mean	-	225 623	229 835	298 935	286 572	230 436	227 416

*Tabulated data indicate the median, mean, and 25th- and 75th-quartile annual salaries (in US\$) for MD, DO, and MD/PhD pathology faculty. Salary was defined to include base plus incentive pay, excluding benefits.

with medical degrees (MD, DO, or MD/PhD) range from US\$198 000 for MD/PhD assistant professors to US\$290 000 for MD professors. Interestingly, median salaries for MD/PhD faculty are consistently lower than those for MD-only faculty, although the absolute differences are small and not statistically significant (Wilcoxon Kruskal-Wallis). For all subsequent analyses, data for faculty with different medical degrees (MD, DO, or MD/PhD) were pooled to maximize the numbers of individuals in each subcategory. When total annual compensation was further substratified according to years-in-rank for either MD (including MD/PhD) or PhD faculty, the lines of regression were essentially flat for all ranks, suggesting that rank remains the primary determinant of salary, whereas time-in-rank has a comparatively minor and statistically insignificant effect at least when compared across departments nationally.

Median Salary Compensation Data for Geographic Regions

Analyses of total compensation data by geographic region are presented in Tables 2 and 3. Some variation is apparent: For example, median salaries are lowest in the Midwest and highest in the West for faculty at the rank of assistant professor, whereas the opposite relationship prevails for those at the level of professor (Table 2). For PhD faculty (Table 3), by contrast, median salaries are highest in the Northeast for

assistant professors and highest in the Midwest for professors. However, none of these differences reached statistical significance.

Distributions of Fringe Rates and Incentive Salary

Reported fringe rates showed dramatic variation across our data set, ranging from 0% to 59% across the 836 practitioners for whom data were obtained. This distribution is shown graphically in Figure 1. Approximately two-thirds of practitioners had fringe rates between 15% and 30% (Figure 2). Incentive salary, as a percentage of total compensation, varied from 0% to 54%. Interestingly, a significant number of practitioners (ranging from fewer than 10% in the Northeast to approximately 50% in the West) received no incentive compensation at all in 2016, as reported by their departments, although it is not clear what proportion of this group might have been eligible for incentive pay but did not receive it (see Figure 2). In contrast to fringe rate data, there is no identifiable subrange that accounts for a majority of individuals, although incentive compensation rates above 20% are only seen for a small minority of practitioners. Surprisingly, there were marked statistically significant differences in the ratio of incentive pay to total compensation across regions ($P < .0001$), with the Southeast having the highest median fraction of incentive compared to total pay (9.35%), followed by the Northeast (5.32%), with the West and Midwest tied (4.76%).

Table 3. Total Annual Salary by Region—Pathologists PhD.*

	Assistant Professor	Associate Professor	Professor	Professor and Chief
Midwest				
Count	6	7	6	0
25th	110 590	156 143	268 911	-
Median	120 893	204 566	310 893	-
75th	129 042	221 655	344 336	-
Mean	114 089	197 441	312 888	-
Northeast				
Count	7	2	5	0
25th	167 772	-	180 536	-
Median	196 761	-	191 791	-
75th	198 000	-	204 000	-
Mean	179 258	233 460	192 520	-
Southeast				
Count	11	17	34	2
25th	127 498	132 798	164 086	-
Median	136 116	140 598	187 469	-
75th	165 040	165 239	211 354	-
Mean	141 777	150 027	187 577	286 277
West				
Count	0	0	1	0
25th	-	-	-	-
Median	-	-	-	-
75th	-	-	-	-
Mean	-	-	216 900	-

*Tabulated data indicate the median, mean, and 25th- and 75th-quartile annual salaries (in US\$) for PhD pathology faculty. Salary was defined to include base plus incentive pay, excluding benefits.

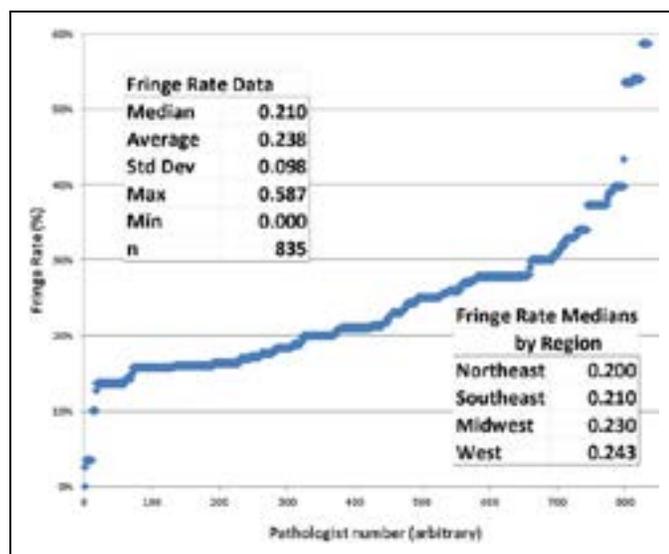


Figure 1. Distribution of salary fringe rates, as a percentage of total compensation, across the entire data set of 836 pathology practitioners.

Salary and Work Relative Value Unit Data for Single-Subspecialty Practitioners

A major focus of the 2017 APC Practice and Management survey was on the collection of salary and wRVU data for

single subspecialty practitioners. These data are presented in Tables 4 and 5. Sufficient data (ie, for 10 or more practitioners) were available for analysis of 2 anatomic pathology specialties (general surgical pathology and cytopathology) and for 5 subspecialties (dermatopathology, GI pathology, hemato-pathology, renal pathology, and neuropathology). Except for dermatopathology (median total salary US\$347 309), the salaries for these groups do not vary widely, with median salaries ranging from about US\$230 000 to US\$270 000 (see Table 4). Pairwise comparisons among these groups failed to reach statistical significance, even when stratified by rank, except that salaries of dermatopathologists were significantly higher than those of practitioners in any of the other individual categories ($P < .014$), both overall and when stratified by academic rank.

In contrast to salary, wRVU productivity varied widely among different anatomic pathology specialties and subspecialties (Table 5). Differences were highly statistically significant and were apparent regardless of the type of analysis applied: (1) raw actual wRVU data per practitioner; (2) raw actual wRVU data per practitioner only for practitioners with at least 0.67 cFTE (MGMA method), or (3) wRVUs normalized for cFTE, and only for practitioners with >0.60 cFTE (Vizient method). As has been observed previously,² values derived using methods (1) and (2) were generally concordant, whereas method (3) yielded substantially higher values in all subcategories, largely as a result of normalizing raw wRVU production to reported cFTE. Regardless of the method used, dermatopathologists consistently showed the highest wRVU numbers, with annual medians of 8023 actual wRVUs, 8119 actual wRVUs for cFTE ≥ 0.67 (MGMA method), and 10 053 normalized wRVUs for cFTE >0.60 (Vizient method). Neuropathologists, by contrast, consistently showed the lowest wRVU numbers, with annual median productivity of 1361 for actual wRVUs, 1153 by MGMA methodology, and 1593 wRVUs by the Vizient method. For general surgical pathologists, the corresponding medians are 5790 actual and 6073 or 8343 wRVUs by the MGMA or Vizient methods, respectively.

We compared the results of the present survey, which were based on data from 2016, to those in our earlier report² that utilized data from 2014, in search of historical trends. In accord with MGMA-type methodology, the earlier paper had focused primarily on “full-time” practitioners, defined as those with cFTE of 0.67 or greater, so the present comparison was restricted to that subgroup as well. Both reports presented relevant data from sufficient numbers of (ie, 10 or more) practitioners of surgical pathology, cytopathology, dermatopathology, neuropathology, and renal pathology to allow direct comparisons within those categories.

In comparing the present data with the previous survey (analyzed in 2015 based on 2014 data, and herein referred to as 2015 survey to keep the reference dates similar), we found that median salary data for all MD/DO faculty showed small increases from 2015 to 2017 (assistant professor US\$202 710 in 2017, $n = 265$ vs US\$200 391 in 2015; $n = 252$), associate professor (US\$245 689 in 2017; $n = 223$ vs US\$243 176 in 2015; $n = 166$), and full professor (US\$294 890 in 2017;

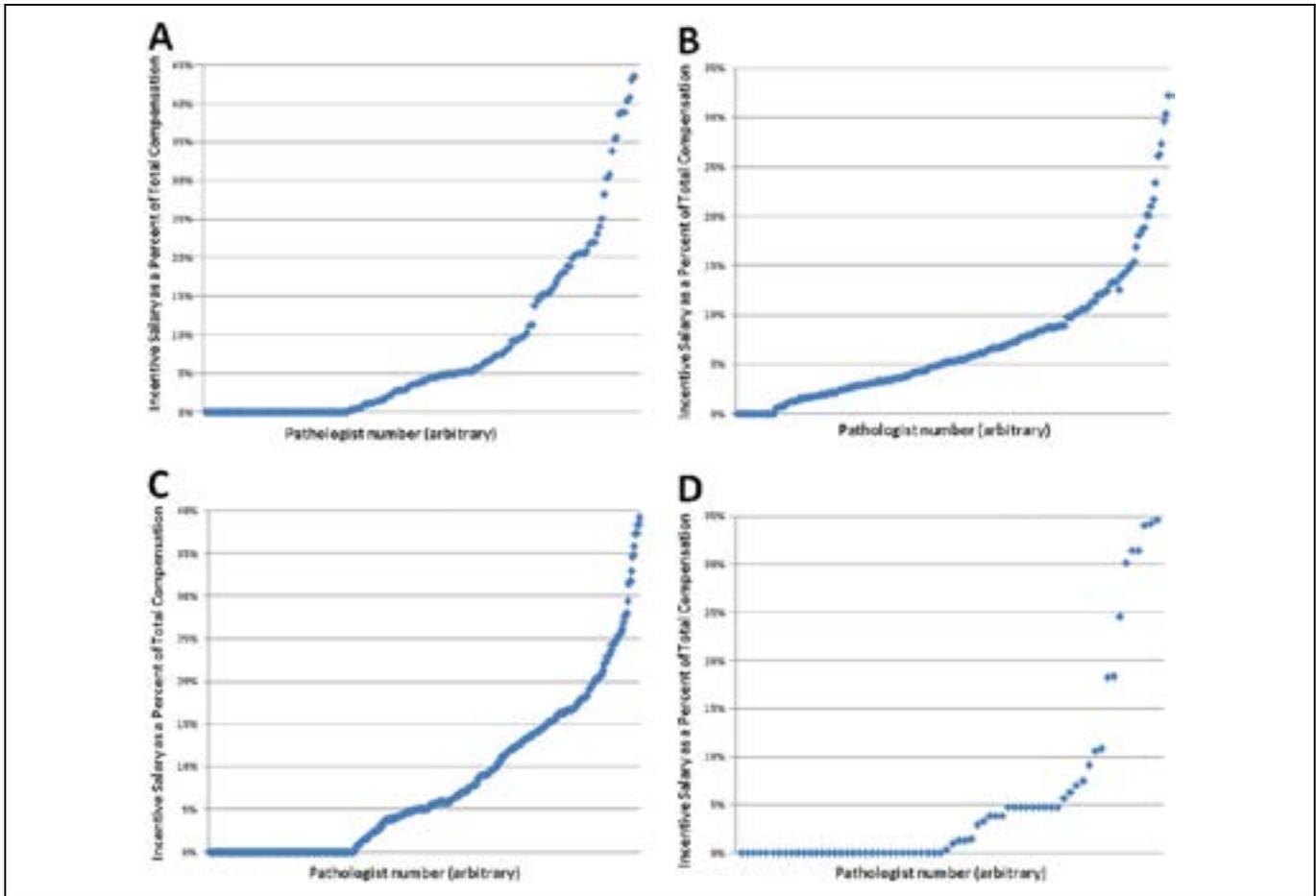


Figure 2. Incentive salary as a percentage of total compensation, by geographic region, across the entire data set of 836 practitioners. Panels A to D present data for the Midwest, Northeast, Southeast, and West regions, respectively.

Table 4. Total Annual Salary by Subspecialty (in US\$).*

	Derm	GI	SP	Cytopath	Heme	Renal	Neuro
Count	15	13	54	15	39	19	15
25th	239 121	206 022	203 478	227 172	221 177	218 910	184 365
Median	347 309	271 179	245 655	239 878	239 857	270 000	220 139
75th	395 901	356 494	269 282	280 488	290 000	304 860	264 419
Mean	313 502	285 096	247 969	266 156	264 197	279 900	237 275

Abbreviations: Cytopath, cytopathology; Derm, dermatopathology; GI, gastrointestinal pathology; Heme, hematopathology/hematology; Neuro, neuropathology; Renal, renal pathology; SP, general surgical pathology.

*Tabulated data indicate the median, mean, and 25th- and 75th-quartile annual salaries (in US\$) for each specialty (SP and Cytopath) or subspecialty (Derm, GI, Heme, Renal, or Neuro) for which requisite data were reported on at least 10 (count) academic pathologists whose practice was limited to that specialty or subspecialty. Salary was defined to include base plus incentive pay, excluding benefits.

$n = 258$ vs US\$289 405; $n = 189$). Whether these small differences are meaningful cannot be determined. As for workload, we compared data from the 2 surveys for general surgical pathologists, and found that the median wRVU workload (MGMA-type analysis) was quite comparable between the 2 surveys (5371 wRVUs in 2017 vs 5,786 wRVUs in 2015). We did find differences in median workload for subspecialists between the 2 surveys, but given the small number of

individuals in both surveys in this pool, we believe the numbers are too small for meaningful comparison.

Discussion

The 2017 APC survey gathered comprehensive nationwide data on the compensation and wRVU productivity for academic anatomic pathologists in individual anatomic pathology

Table 5. Total Annual wRVU Productivity by Subspecialty.*

Raw (uncorrected) wRVUs, including all practitioners [†]							
	Derm	GI	SP	Cytopath	Heme	Renal	Neuro
Count	14	12	54	15	39	19	15
25th	5727	5293	2896	3068	3154	1410	825
Median	8023	5790	4936	4770	4607	3322	1361
75th	9832	6570	6568	5919	6965	5147	2363
Mean	7937	5851	4945	4765	4909	4038	1641
Raw (uncorrected) wRVUs, including only practitioners with cFTE 0.67 or greater [‡]							
wRVUs	Derm	GI	SP	Cytopath	Heme	Renal	Neuro
Count	10	7	29	10	15	8	4
25th	6803	5500	3227	4767	4153	1125	900
Median	8119	6075	6073	5495	5650	3516	1153
75th	10416	6697	7123	6763	6993	5811	4120
Mean	8550	6137	5611	5801	5499	3484	2058
wRVUs/cFTE, including only practitioners with cFTE 0.60 or greater [§]							
RVUs	Derm	GI	SP	Cytopath	Heme	Renal	Neuro
Count	12	9	38	13	17	13	8
25th	8619	7843	4507	4704	6186	3804	1561
Median	9439	8320	7311	5817	8133	5147	2177
75th	11599	8437	8807	6668	10870	6714	3551
Mean	9872	8112	6996	5686	8749	4795	2549

Abbreviations: cFTE, clinical full-time equivalent; Cytopath, cytopathology; Derm, dermatopathology; GI, gastrointestinal pathology; Heme, hematopathology/hematology; Neuro, neuropathology; Renal, renal pathology; SP, general surgical pathology; wRVU, work relative value unit.

*Tabulated data indicate the median, mean, and 25th- and 75th-quartile annual wRVU production in 2016 by academic pathologists whose practices were limited to the indicated specialty (SP and Cytopath) or subspecialty (Derm, GI, Heme, Renal, or Neuro) that year.

[†]Raw (uncorrected) wRVU production in each specialty or subspecialty for which requisite data were reported for at least 10 (count) academic pathologists.

[‡]Raw (uncorrected) wRVU production only for the subset of pathologists within each group from panel A whose reported cFTE (defined as the proportion of full-time effort devoted to Part B service that year) was 0.67 or greater. This was intended to approximate the productivity benchmarking metric reported by the Medical Group Management Association (MGMA).

[§]Raw wRVU production normalized to reported cFTE only by the subset of pathologists within each group from panel A whose reported cFTE (defined as the proportion of full-time effort devoted to Part B service that year) was 0.60 or greater (1 or 0.5 or greater for hematopathologists). This analysis was intended to approximate the productivity benchmarking metric reported by Vizient-AAMC Faculty Practice Solutions Center (FPSC).

subspecialties. Anonymized data were gathered on more than 160 faculty subspecialists from 43 academic pathology departments; these had been submitted by departmental leaders with a nuanced understanding of pathology practice patterns and terminology, which is likely to have maximized the validity of the data obtained. Based on data from this survey, the present study has yielded detailed information on salaries and wRVU outputs of single-subspecialty practitioners in 5 major fields of anatomic pathology and allowed comparison of those data with the corresponding values for cytopathologists and general surgical pathologists from the same survey database. These benchmarks were further substratified by academic rank, years at rank, academic degree, senior administrative title, and geographical region as summarized in the tables contained in this report.

A key finding of this study is that average annual wRVU productivity varies widely across different subspecialties. Median raw annual wRVU outputs of academic dermatopathologists and GI pathologists, for example, were found to exceed

those of neuropathologists by 5.8- and 4.2-fold, respectively, and were 17% to 74% higher than the corresponding values for generalist surgical pathologists, cytopathologists, or hematopathologists (Table 4). We do not believe that academic department chairs will be surprised by those disparities, nor find them a valid reflection of either clinical workload or relative value across these vital, demanding clinical disciplines.

Our findings suggest that wRVUs have limited validity as a measure of pathologist workloads or productivity for individual practitioners. This is particularly true for academic pathology departments, where a variety of practice models and wide disparities in effort allocations exist among institutions, especially when comparing across subspecialties. Accordingly, caution must be exercised when applying wRVUs to define individual productivity benchmarks or to set targets for incentive-based compensation models. Concerns arise when wRVU output is normalized to cFTE, since the allocation model used to assign cFTE values to individual practitioners varies widely among departments and institutions.² Normalizing wRVUs by

dividing by clinical effort allocation can significantly overstate actual wRVU production, yielding artificial “benchmark” values for median wRVU output that are achieved by only a small fraction of practitioners (Table 5). These findings argue that the use of wRVUs as a productivity metric in anatomic pathologists should be narrowly tailored to local practice environments or that alternative systems of workload measurement should be considered.

Indeed, it is both notable and reassuring that, aside from the higher salaries presently commanded by dermatopathologists, median compensation varies relatively little, either between the other 4 subspecialties we examined or in comparison to general surgical pathologists and cytopathologists nationally (Table 4). We view this as evidence that pathology departments set compensation in a relatively egalitarian manner that presumably reflects market forces and is not closely linked to individuals’ wRVU productivity. Thus, although wRVUs are a poor marker for productivity, academic departments have found a way to balance workloads and compensation across subspecialties. In addition, most academic pathology departments take into account not only clinical productivity but also administrative, educational, and research metrics; thus finding ways to reward pathology faculty across all the academic missions. Finally, the trend toward ever-higher clinical productivity bears close watching, as this may impact our other academic missions, especially if unaccompanied by commensurate salary increases.

As for alternative systems of measuring workload and productivity in pathology, Cloetingh et al⁵ compared 3 methods for measuring workload in surgical pathology and cytopathology: (1) the wRVU system, (2) a point system developed by the Royal College of Pathologists (RCP),⁶ and (3) a slide-count system developed by the authors at the University of Washington in Seattle (UW).⁵ They found that the wRVU system favors specialties with higher volumes of small specimens (eg, dermatopathology), whereas the RCP system provides more weight for higher complexity specimens, and the UW system favors specialties with extensively sampled large specimens. Horne et al,⁷ however, specifically applied the RCP system to dermatopathology workload in a time-motion study, and concluded that this system underestimated workloads achieved by experienced dermatopathologists, and thus was not ideally applicable to that subspecialty.

Meijer et al⁸ measured the actual time that pathologists spent in various steps of specimen preparation and diagnosis (eg, gross examination, microscopical examination, dictation, etc). These authors found that such time measurements correlate well with numbers of tissue blocks and/or slides per specimen, thus suggesting that counts of tissue blocks or slides might be a useful system for measuring pathologist workload in a variety of practice settings.

Yet another system for measuring workload in surgical pathology was developed by Cheung et al⁹ at the University of Toronto and is known as the Automatable Activity-Based Approach to Complexity Unit Scoring (AABACUS). This system uses clinical laboratories’ information systems to calculate

“complexity factors” for different activities and, based on these, generates “complexity units” (CUs) for each of activity performed. The system has the advantage that it can be automated (as the name suggests), thus requiring little additional work after initial implementation. A major finding in this latter study is that the resulting CU counts are generally comparable for different anatomic pathology subspecialists, ranging from dermatopathology to neuropathology, which may suggest that AABACUS is a better index of actual work performed than are other extant systems.

As mentioned above, workload assessment for autopsy or forensic pathologists is particularly problematic, as their work products have no assigned wRVU value and do not involve billing to third-party payers. The Autopsy Committee of the College of American Pathologists developed a recommendation,¹⁰ based on a survey of autopsy pathologists, that one full adult autopsy be valued at 5.5 times a CPT code 88309-26, with an additional value of 1.5 times 88309-26 attributed for full-brain examination. They also recommended a value of 4 times 88309-26 be attributed for a fetal or neonatal autopsy.

Our study is survey based and, as such, we cannot independently verify the data submitted nor establish that the results are representative of all academic departments. However, the substantial number of departments participating in the survey (43 academic departments of pathology) represents nearly half of the 88 US academic medical centers who are members of the Association of Academic Health Centers.³ Responding departments were not required to submit data for every faculty practitioner but instead were given the option of providing data only for a minimum of 10 representative practitioners. This was to encourage survey participation by larger departments, which might otherwise find the survey overly burdensome, but it may have introduced selection bias. For the 2017 survey, departments were asked to focus on single subspecialty practitioners where possible, thus enriching the survey population in this regard. This approach was different from that of previous APC surveys, which did not request such selective inclusion,² and it is this enrichment that allowed us to perform, for the first time, meaningful analysis of subspecialty practice in US academic pathology departments.

Summary and Conclusions

The use of wRVUs as a measure of workload and productivity by pathologists is inherently flawed. Although wRVUs might be of some use in comparing pathologists who have identical practice patterns (eg, general surgical pathologists, cytopathologists, or practitioners of a single given subspecialty), this measurement system fails dramatically when used to compare different anatomic pathology subspecialties, even when restricted to nonautopsy and nonforensic practices. Of course, the lack of a valid, standardized, and widely accepted workload measurement system for clinical pathology practice is well recognized.

Unfortunately, insofar as the wRVU system has been adopted as the metric for payment by the government and most insurers, it inextricably forms the basis for reimbursement and,

consequently, for compensation. If, as is widely assumed, future reimbursement shifts increasingly from a fee-for-service model centered on wRVUs to value-based payments, it is possible that wRVUs will lose their importance other than as a benchmark for departmental staffing. Until that time, we recommend that pathology departments try to use wRVU production as a department-wide rather than an individual benchmark, although it is still highly problematic as the former. Additionally, we recommend that pathology chairs understand both the effort allocation and the subspecialty issues associated with wRVU benchmarks in order to more effectively advocate for their faculty and to design equitable compensation policies. Fortunately, this seems currently to be case for most departments who participated in the 2017 APC survey.

Declaration of Conflicting Interests

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A Professionalism and Mentoring Curriculum for Pathology Residents in Training

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Abstract

Professionalism is a core Accreditation Council for Graduate Medical Education competency. The Mentoring and Professionalism in Training Program was developed to promote humanism in health-care professionals in our health system. A modified version was implemented in the pathology residency program for professionalism competency. Twenty-one trainees were divided into 3 groups, with a facilitator who was a graduate of the system Mentoring and Professionalism in Training Program. Five sessions included topics on appreciative inquiry, active role modeling, conflict resolution, team building, feedback, mindfulness, and physician well-being. Participants completed pre- and postsurveys. Qualitative responses were very positive, for example, one participant felt the sessions helped “understand intricacies of workplace relationships and ways of effective, respectful, communication.” The Mentoring and Professionalism in Training is a curriculum that teaches team building, conflict resolution, and feedback along with strategies to balance well-being with professional commitments and growth. It is an effective educational tool that can satisfy the Accreditation Council for Graduate Medical Education professionalism curriculum.

Keywords

professionalism, mentoring, structured curriculum, Accreditation Council for Graduate Medical Education core competency, pathology residency training

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Introduction

According to the Accreditation Council for Graduate Medical Education (ACGME) guidelines, professionalism and “interpersonal communication skills that result in effective information exchange” are core competencies of residency training.¹ Knowledge and skills along with the appropriate attitude are all equally essential in the development of an ideal health-care professional. It is often assumed that professionalism will be innately instilled; however, no formal established curriculum on professionalism exists in pathology residency training.^{2,3}

Mentoring is a crucial part of modern day training in medicine. Proper guidance and strong professional bonds with peers, faculty, and chairs are imperative in carving out a

meaningful career path resulting in higher levels of job satisfaction and performance. Mentoring, however, is usually performed in an informal manner, and residency training would benefit from a more formal training in mentorship.⁴⁻⁸

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Table 1. Original MAP-IT Curriculum.

Session 1	Appreciative inquiry and active role modeling	Appreciative inquiry is used as strategy to successfully navigate issues encountered in mentoring. Active role modeling: Through role-playing, participants practice skills inherently involved in coaching.
Session 2*	Objective structured teaching encounter	Mock encounter session with a standardized learner seeking mentorship stimulating a real-life situation.
Session 3	Team building	Working on highly functional teams—Learn origins of team conflict and employing useful tools to decrease or resolve conflict.
Session 4	Team building (Conflict resolution)	Working on high performance teams.
Session 5	Feedback	Role-play and small group discussions aimed at understanding: Differences between feedback, formative, and summative evaluation barriers to effective feedback/evaluation. The importance of goal setting, learning climate, and observation. Fostering self-assessment and self-correction to assure high-quality feedback. Providing feedback to resistant learners.
Session 6*	After the error	How to obtain a meaningful learning experience from a professional error.
Session 7	Enhancing well-being, self-care, resilience	Professional burnout is dysfunctional and leads to behaviors not exemplifying humanistic behaviors. It is important to be able to recognize burnout. Resilience is an important link to well-being through self-care. Using reflection, groups will focus on aspects of professional identity that supports resilience. Involves learning to demonstrate skills of mindfulness beginning with the skills of noticing. Participants will apply skills of mindfulness to professionalism challenges and discuss how clinicians can maintain the sense of well-being which allows one to reach out to others.
Session 8*	Cynical humor in the clinical setting	Reflection on the use of humor in the clinical setting.
Session 9	Mindfulness and self-care	Discussing skills of noticing and reaching out to professional colleagues.
Session 10*	Focused program reflection	Obtain feedback on the MAP-IT series and complete postassessment tools.

Abbreviation: MAP-IT, Mentoring and Professionalism in Training.

*These sessions were omitted in the resident-modified MAP-IT due to time constraints and because the other sessions were thought to be most beneficial to resident training in professionalism. Sessions 7 and 9 were combined into one session. None of the content from the retained sessions was modified from the original system curriculum.

Despite curricular reforms, an alarming number of medical students and postgraduate trainees report increasing cynicism, depressive symptoms, and burnout. Lack of well-being can challenge the altruistic and humanistic focus ultimately affecting professional growth and development.^{9,10} This is an area that is often not actively addressed during training and has been often documented to affect essential core competencies.^{11,12}

To address these issues, the Mentoring and Professionalism in Training (MAP-IT) Program was developed as a unique project to implement an interprofessional curriculum incorporating humanism as a core value in the professional development of health-care professionals throughout the Northwell Health System. The system MAP-IT curriculum was adapted by one of the authors (A.F.) from the original curriculum created by Dr William Branch.¹³ This adaptation was structured as a 10-month program sponsored by the Arnold P. Gold Foundation and directed at medical faculty and nurses¹⁴ (Table 1). “Appreciative Inquiry” was introduced as a foundational principle of the course. Appreciative inquiry is looking for what works well in making any organization run effectively and doing more of it. This is more motivating and effective than looking for what does not work and doing less of it, as it serves as a positive reinforcement. Skill building specific to humanistic mentoring for each session focused on the following topics: active role modeling, team building, giving feedback, cynical

humor, clinical errors, enhancing wellness and resilience, and mindfulness were incorporated in this course to provide a comprehensive overview. Three faculty members from the pathology department took part in the system-wide training program. Graduates of the system program were charged with bringing back the curriculum to their departments and utilizing it in some manner to enhance mentoring and professionalism. The pathology residency program was looking to initiate a curriculum in professionalism and mentoring to satisfy the ACGME professionalism milestones and enhance the well-being of their residents. It was decided to use a modified version of the system-wide MAP-IT program to achieve this end. To the best of our knowledge, this is the first attempt to introduce a structured formal professionalism and mentoring curriculum in pathology residency training.

Materials and Methods

Study Sampling

The study participants consisted of 21 residents and fellows of the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell Health pathology residency training program, Lake Success, New York. The participants were equally divided into 3 groups of 7. Each group included a range of first- through

fourth-year residents along with fellows to achieve a good balance in professional experience. Each group was moderated by a faculty facilitator (MD) who was a graduate of the system MAP-IT program. This differed from the system MAP-IT, which included nurse facilitators and participants. Paired facilitators were not considered necessary as there were no allied health professionals in our groups. The local institutional review board approved an exemption for this study.

Study Design

Each session included critical reflection using appreciative inquiry, skill building, and application of content to the clinical work environment postsessions. These sessions were incorporated as part of the daily morning didactic sessions for residents. A total of 5 sessions of 90-minute duration each were held over a period of 6 months (Table 2). Each individual session incorporated one of the following topics: appreciative inquiry and active role modeling, team building, conflict resolution, giving effective feedback, and mindfulness and physician well-being. Pre-session source reading material was assigned for each session and completed by all participants (course material available to program directors upon request, see Authors' Note). The sessions were based on an active learning model with emphasis on participation and sharing of experiences by all the members. Role-playing to build the intended skills of mentoring and narrative writing to support critical reflection among peers and enhance connection to the selected topics were also utilized.

The original system-wide MAP-IT had 10 sessions as outlined in Table 1. The pathology residency program MAP-IT utilized 6 of the 10 sessions (2 of the original sessions were combined into 1 session) which were believed to be of most benefit to residents in keeping with the ACGME guidelines and to fit into the schedule of the residents' didactic session (Table 2).

Data Analysis

All participants completed a pre-MAP-IT quantitative online survey (Survey Monkey, Palo Alto, California) comprised of 12 questions on fundamental humanistic qualities based on the previously validated 10-item Humanistic Teaching Practices Effectiveness (HTPE) questionnaire^{14,15} (Table 3). At the end of 6 months, all participants completed a post-MAP-IT semi-quantitative survey consisting of the same 12 questions, as well as an additional qualitative survey questions asking how MAP-IT had enhanced their mentoring and professionalism skills. Means, standard deviations, medians, minima, and maxima were calculated for each question in the pre- and postsurveys. The Wilcoxon signed rank test was used to test for differences in responses between pre- and postsurveys. A result was considered significant if $P < .05$. All analyses were conducted using SAS version 9.4 (SAS Institute Inc, Cary, North Carolina). The survey was designed to be anonymous so as to improve honesty and accuracy of feedback.

Table 2. MAP-IT Program Curriculum.

Session	Topic	Summary
1	Appreciative inquiry and active role modeling	Appreciative inquiry is used as strategy to successfully navigating issues encountered in mentoring. Active role modeling: Through role-playing, participants practice skills inherently involved in coaching.
2	Team building	Discuss high functioning team formation. Skills are practiced through interactive group exercises, self-reflection, and storytelling.
3	Conflict resolution	Learn origins of team conflict and employing useful tools to decrease or resolve conflict.
4	Feedback	Role-play and small group discussions aimed at understanding: Differences between feedback, formative, and summative evaluation. Barriers to effective feedback/evaluation. The importance of goal setting, learning climate, and observation. Fostering self-assessment and self-correction to assure high-quality feedback. Providing feedback to resistant learners.
5	Enhancing well-being, resilience, self-care, and mindfulness	Professional burnout is dysfunctional and leads to behaviors not exemplifying humanistic behaviors. It is important to be able to recognize burnout. Resilience is an important link to well-being through self-care. Using reflection, groups will focus on aspects of professional identity that support resilience. Involves learning to demonstrate skills of mindfulness beginning with the skills of noticing. Participants will apply skills of mindfulness to professionalism challenges and discuss how clinicians can maintain the sense of well-being which allows one to reach out to others

Results

There were 21 participants, 9.5% were male and 90.5% were female. Sixty-seven percent were in the age-group of 25 to 34 years and 33% were in the age-group of 35 to 44 years. There were 15 pathology residents, 3 oral pathology residents, and 1 fellow each in surgical pathology, hemato-pathology, and cytopathology, respectively (Table 4). All the participants had informal experience in supervising junior residents, medical students, undergraduates, and volunteers who regularly rotate through the Department of Pathology. This included assistance in grossing, previewing surgical pathology cases and autopsy, but no formal mentoring in professionalism.

For each of the 12-survey questions, 19 of the 21 participants (18 for question 10) completed both the pre- and post-survey as 2 participants had graduated from the health system at the time of the postsurvey. No significant difference was observed between pre- and postsurvey responses for any of the

Table 3. Analysis of the HTPE Self-Assessment Pre- and Postsurvey.

Question	Pre (n = 21)			Post (n = 19)			*Diff = Post-Pre (n = 19)		P Value
	Mean	Standard Deviation	Median	Mean	Standard Deviation	Median	Mean	Standard Deviation	
1. Listen carefully to connect with others (eg, colleagues)	4.38	0.67	4	4.32	0.67	4	-0.11	0.74	.77
2. Inspire mentees to grow personally	4.00	1.05	4	4.05	0.91	4	0.05	1.08	.75
3. Skillfully recognize and support emotions of patients, team members, mentees, and of myself in difficult situations	4.19	0.93	4	4.16	0.76	4	-0.05	0.91	.97
4. Actively use teaching opportunities to illustrate humanistic care	3.57	1.25	4	3.68	0.95	4	0.16	1.30	.74
5. Stimulate reflection by the team on their approach to the care of the patient (clinical decisions, management, and treatment plans)	3.67	1.06	4	3.74	0.99	4	0.11	0.99	.82
6. Help others to use social history to inform the care of the patient clinical decision-making	3.43	1.12	3	3.63	1.01	3	0.26	0.56	.13
7. Serve as an outstanding role model for how to build strong relationships with learners and colleagues	3.62	0.92	4	3.74	0.99	4	0.16	0.83	.59
8. Serve as an outstanding role model for how to build strong relationships with patients	3.29	1.15	3	3.42	1.07	4	0.21	0.79	.40
9. Explicitly teach communication and relationship—building skills	3.24	1.00	3	3.47	1.26	4	0.32	0.89	.19
10. Inspire others to adopt caring attitudes toward patients to provide quality care	3.86	0.85	4	3.68	0.95	3	-0.16	0.90	.63
11. Learners and colleagues come to know me as both a good clinician and a caring person	3.90	1.04	4	3.89	0.94	4	0.00	0.82	1.00
12. Patients come to know me as both a good clinician and a caring person	3.76	1.18	4	3.89	0.99	4	0.16	0.83	.59

Abbreviations: HTPE, Humanistic Teaching Practices Effectiveness; MAP-IT, Mentoring and Professionalism in Training.

*Means from the pre-MAP-IT responses were calculated for 21 individuals and the means for the post-MAP-IT responses were calculated for the 19 individuals who completed the survey after the intervention. As a result, the mean of the differences and the difference of the means were not the same.

Table 4. Characteristics of the Participants.

Characteristics	No of participants		
Age	25-34 years	14	
	35-44 years	7	
Sex	Women	19	
	Men	2	
Residents	Pathology	15	
	Anatomic/Clinical (AP/CP)		
	Oral pathology	3	
Fellows	Surgical pathology	1	
	Hematopathology	1	
	Cytopathology	1	
Post graduate year (PGY) distribution	Resident PGY level	Pathology	Oral pathology
		AP/CP	
	PGY1	4	1
	PGY2	4	1
	PGY3	4	1
PGY4	3	0	
Medical degree	MD	14	
	DO	3	
	MD, PhD	1	
	DDS	3	

12 questions (Table 3). Difference in responses whether the resident was a graduate from an allopathic versus osteopathic school was not evaluated in this study.

Discussion

Professionalism as defined by Stern involves a set of 4 main principles: excellence, humanism, accountability, and altruism.¹⁶ Appreciative inquiry, team building, conflict resolution, and giving and receiving feedback are essential skills that enhance the development of professionalism. Literature review on professionalism training in residency shows that while there are many articles emphasizing the importance of teaching professionalism, no definite guidelines or structured curriculum to help guide such training has been published.^{2,3} The MAP-IT is a pioneer effort to establish a curriculum for professionalism training in residency programs.

The first session was on appreciative inquiry and active role modeling. People are most productive when their work is personally meaningful, and they feel that they are making a difference.¹⁷ Often there are certain events in the life of a physician which act as turning points in their professional development and are based

on active modeling by their teachers and/or mentors.^{18,19} Each group member recollected a scenario involving appreciative inquiry and active role modeling. One participant felt the session on appreciative inquiry helped them realize the value of their work on a daily basis, which they found very gratifying.

The second session was on team building. Team building helps a work group evolve into a cohesive unit with greater productivity and is an essential element of professionalism.²⁰ Each participant narrated an experience where they were part of a team focusing on interactions and relationships and why the team succeeded. This was followed by an exercise where the group recreated a situation where they would be required to work as a team. The session ended with a discussion of the attributes of good team cohesiveness, communication, role clarity, and common goals.

The third session was on conflict resolution. Interpersonal conflict will arise when working as a team.²⁰ A conceptual tool called the cone in a box model was discussed to show that 2 people might have different perspectives about the same situation depending on the angle at which they are looking at it. The group learned about asking “curious questions,” which is an essential tool for exploratory dialogue. Curious questions are questions that come from a place of genuinely not knowing, where the person you are asking is absolutely the unique and final authority on their answer and where there is no theory or interpretation hidden in the question. It assists in deepening the understanding of oneself and each other and makes the implicit explicit without leaving any room for assumptions. Examples of curious questions include: “What is hard for you in this? What is your greatest fear?” These 2 tools were utilized by each group member to reflect on and discuss a previously experienced conflict situation that they had been in. This was followed by a debriefing on 2 skills to address conflict: ARTS of communication (Ask, Respond with empathy, Tell your perspective, Seek together for solutions) and PEARLS skills (Partnership, Empathy, Acknowledgement, Respect, Legitimation, Support). The most important teaching point was to listen to the other person’s point of view before drawing any conclusions. The session helped another participant “think of the other person’s perspective when dealing with conflict.”

The fourth session was on feedback. “Formative evaluation” is an essential learning tool that improves performance. However, giving and receiving feedback in a constructive, nonjudgmental manner can be challenging.²¹⁻²⁴ It should be performance-specific, objective, nonjudgmental, timely, and in an appropriate location and time. The ‘S’-FED Model (Self-Assessment, Feedback, Encouragement, Direction) of giving feedback was discussed followed by role-play based on the key elements of the model. Allowing the learner time for reflection, discussing specific suggestions for improvement, and creating an interactive partnership are the essence of successful feedback. This session was the most effective as 8 participants felt that they were now more confident in giving “effective,” constructive” feedback without “being judgmental.” A participant pointed out that the ‘S’-FED model requires one to be aware of his/her strengths and weaknesses, which leads to “self-correction.”

Another resident thought the ‘S’-FED model would be particularly effective in providing “feedback” for those learners who have difficulty with constructive criticism.

The last session was focused on how to maintain a sense of well-being, which allows one to reach out to others, including learners, colleagues, and patients. Physician burnout is defined as a psychological syndrome in which one loses enthusiasm for work (emotional exhaustion), treats people as if they were objects (de-personalization), and results in a sense that work is no longer meaningful (low personal accomplishment).^{25,26} Mindfulness is “the awareness that arises as we pay attention, on purpose, in the present moment, nonjudgmentally.” Several studies have shown the benefits of practicing mindfulness training in successfully dealing with physician burnout.²⁷ In order to emphasize the importance of meaning in one’s life, each participant including the mentor brought an object (trigger), which symbolized a meaningful aspect of their professional roles.²⁸ This exercise helped discover something new about one another as well as encourage reflection of one’s own well-being. This was followed by a 15-minute meditation session. This session was also very well received. A participant remarked that “sharing of stories was very powerful in establishing a connection within their group” and another resident commented that “it took them on a beautiful journey of rediscovering themselves and each other.” To another participant, the session on physician burnout served as an eye opener as it “highlighted lack of self-care” and made them realize the importance of “including time for themselves and to make time for their favorite hobby.”

Several limitations of this study should be considered. Interestingly, despite strong positive qualitative feedback after the sessions, the differences between the pre- and post-MAP-IT quantitative survey were not statistically significant. This may be due to the fact that there was not enough time to practice the skill sets after completion of the sessions. Since the cohort was predominantly female, gender bias may have been a limiting factor. In addition, there was a lack of long-term follow-up to assess the possible benefits of this curriculum.

The sample size of the participants was small and limited to trainees of the pathology department of one institution, and our findings may not apply to residents in other programs. A self-assessment measuring tool in the form of an online quantitative survey was used. Another limitation was the pre- and postsurvey questions were taken from the original system-wide MAP-IT program which targeted physicians and nurses of all specialties. The questions were based on the original HTPE questionnaire modeled on an internal residency program.^{14,15} In pathology training, however, we have very limited patient access and some of the questions were not directly relevant in the context of pathology training and should be omitted. This could also explain the marginal difference between the pre- and post-MAP-IT quantitative surveys as participants felt some of the questions didn’t directly apply to their immediate work environment. We conclude that the questions in the surveys should be structured keeping in mind the target participants and their immediate work environment. Another future opportunity to better understand the impact of the program would be

to analyze written reflections from the sessions. After the success of the first MAP-IT initiative in our program, the 5-session series has been officially incorporated as part of our formal didactic series to be repeated on a 2-year cycle. Additionally, 3 more senior attending pathologists participated in the system-wide program to enable more facilitators within the department.

In conclusion, the residents welcomed the MAP-IT program with enthusiasm and it had a positive impact on their training. The sessions helped residents understand the intricacies of workplace relationships and highlighted methods of effective, respectful, and productive communication and professionalism in the work environment. In the words of a participant, MAP-IT “makes us pause a moment and reflect that there is a lot more to career development than just knowledge-based learning.”

We believe that the modified MAP-IT workshop series is a reproducible, essential, and compact educational tool that every residency program should consider making a part of their curriculum to help achieve the ACGME core competency goals.

Authors' Note

Course materials can be made available to residency program directors via electronic files upon request. These include session instructions for facilitators, PowerPoint presentations, and reading materials. Please e-mail requests to Michael Esposito, MD, at mesposit@northwell.edu. Dr Jane Cerise, Biostatistics Unit, Feinstein Institute for Medical Research, Northwell Health, for assistance in statistical analysis.

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What Advice Current Pathology Chairs Seek From Former Chairs

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Abstract

The 2018 Association of Pathology Chairs annual meeting included a panel discussion of Association of Pathology Chairs senior fellows (former chairs of academic departments of pathology who have remained active in Association of Pathology Chairs) about the type of advice that current (sitting) pathology chairs ask them. To inform the panel discussion, information was obtained from the senior fellows by e-mail and subsequent conference call. Of the 33 respondents, 24 (73%) had provided consultation advice (9, <5; 11, 5-10; 2, 10-20; and 2, >20). Most (>75%) of the consultations were provided face-to-face and outside the framework of Association of Pathology Chairs, with 70% of those seeking advice being well known by the consultant(s). Of the senior fellows providing advice, 71% had themselves sought consultation from former pathology chairs and 75% from nonpathology chairs. Modest correlation was found between the number of consultations senior fellows sought when they were chairs and the number of consultations they subsequently provided. The most frequent topics of consultation were strategic planning, balancing the missions, setting department priorities, recruitment of faculty and staff, conflict management, issues specific to new chairs, and resource (money/space) issues. Those who had provided such advice the longest and to the most people indicated that there was no significant change in the type of questions asked over time. Former department chairs can be a valuable source of counseling for current chairs, and organizations of department chairs should consider formalizing the use of these individuals as consultants to sitting chairs.

Keywords

consultation, advice, pathology chairs, senior fellows, former chairs

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Introduction

There is a very limited literature on how former department chairs can be a useful source of advice for current chairs in the discipline. Moreover, these reports are often institutional or professional organization documents that only reference this fact in passing.¹⁻⁴ Other reports provide useful information that department chairs should know, based upon personal experience.^{5,6} The Association of Pathology Chairs (APC) senior fellows (former department chairs who remain active in APC) have been previously described⁷ and have contributed to the literature on lessons to be learned by department chairs.⁷⁻⁹

Because the APC senior fellows comprise a formal membership group of the APC, this provided a unique opportunity to

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Table 1. Frequency of Consultations Provided.

Senior Fellows (33)	Number of Consultations
9	0
9	1-5
11	5-10
2	10-20
2	>20

investigate in some detail the frequency and the types of advice asked of them by current (sitting) pathology chairs. The 2018 APC annual meeting included a panel discussion that focused on this topic. This is a report of the findings gathered for and presented by the panel as well as pertinent observations made during the audience discussion.

Methodology

The APC senior fellows were asked to provide input based upon questions provided to them by e-mail. The fellows were then divided into 3 work groups, each of which discussed the findings in more detail and generated further input. A panel discussion was subsequently held at the 2018 APC annual meeting to comprehensively assess and evaluate these findings. A summary of these discussions has been incorporated into this report. Because the findings in this article were the output of an informed panel discussion, the University of California, San Diego Human Research Protections Program does not require institutional review board review.

Demographic Information

Thirty-three senior fellows (92% participation) engaged in this project. These fellows had provided an average of 15.4 years of service (standard deviation [SD]: 8.8), and an average of 10.0 years (SD: 7.7) had elapsed since they had stepped down as chair.

Results

Of the 33 participants in this project, 24 (73%) reported that they had performed consultations. As shown in Table 1, of those who provided consultations, 9 senior fellows gave fewer than 5 consultations each; 11 provided between 5 and 10; 2 provided between 10 and 20; and 2 provided more than 20. Interestingly, there was no significant correlation between the number of consultations provided by senior fellows and their respective years of service as chair ($r = 0.10$) or the number of years that had elapsed since they had stepped down as chair ($r = 0.14$). This may be due, at least in part, to the fact that many individuals had stepped down as chair long before the APC Senior Fellow Group was founded.

In assessing how the consultations were arranged, it was found that more than 75% of consultations were made independently of the APC. More than 75% were performed face-to-face, with some also using telephone and electronic media.

Table 2. Most Frequent (>50%) Areas of Consultation.

Strategic planning, balancing the missions, and setting department priorities
Faculty and staff recruitment
Conflict management, including dealing with difficult people at all levels
Issues specific to new chairs (eg, where to get leadership training, "traps" to avoid)
Resource issues (eg, money, space)

Table 3. Additional Topics Specifically Mentioned.

Medicare part A negotiations
Merger of departments
Transitioning to higher administrative positions
Service as an interim chair
Dealing with the health system chief executive officer and/or dean
For the successor chair: sharing the historical perspective about current department issues

Most (70%) of the individuals seeking advice were well known to the consultant, and, in fact, this familiarity was a main driver of which senior fellows were consulted. (No senior fellow consultations were assigned.) When the senior fellows were sitting chairs themselves, 71% of them had sought consultation from former pathology chairs and 75% had sought consultation from other (nonpathology) chairs. There was modest correlation between the number of consultations provided by senior fellows and the number they had sought from pathology chairs ($r = 0.48$) and from nonpathology chairs ($r = 0.47$) when they were sitting chairs.

When asked specifically, no senior fellows indicated that they had felt uncomfortable providing consultation, and of those 13 who had provided such service for more than 5 years and to more than 5 people, 11 said that there was no substantial change in the type of questions asked over the years. One individual did indicate that there were more questions about transitioning to dean and also about transitioning back to faculty. Another indicated that the questions being asked now reflect more recognition of resource responsibilities being tied to performance and outcome measures.

The most frequent areas of consultation (occurring more than half the time) are shown in Table 2. Additional topics mentioned are shown in Table 3.

During the discussion of these results at the APC annual meeting, it was emphasized that it is not a sign of weakness to ask for advice. After all, it is the person seeking the advice who must make the final decision. The importance of knowing the background and expertise of the individual being consulted and of seeking consultation from more than one person was stressed as well. Individuals seeking consultation should not ask for it "on the fly," so to speak, but should schedule the consultation in order to allow sufficient time for a complete discussion.

It was noted that some chairs may feel awkward about asking a predecessor chair for advice since it might suggest that

they are not ready to assume the chair. Quite to the contrary, prior chairs (if still available in the department) usually constitute a rich source of history about why circumstances are the way they are and can often provide invaluable advice about the department's strengths and its vulnerabilities that may not be obvious to a new chair. In fact, the loyalty of prior chairs to the department frequently motivates their desire to see the new chair succeed. Such advice can be especially useful for chairs who were recruited from outside the institution. Accordingly, in their final year(s) of service as chair, individuals should be thinking about the type of advice and the materials they wish to impart to their successor chair.

Discussion

There is only a limited literature on the subject of using former academic department chairs as consultants to current (sitting) chairs. Although it is a small population size, the APC senior fellow group provided a homogenous and useful group of individuals available to study consultation activity since the group as a whole and its individual members have identified availability to provide advice to sitting chairs as their primary mission.

This study has several limitations. In addition to the small population size (33 respondents), the number of consultations was probably underestimated in some cases because they occurred before the advent of the senior fellow group and were forgotten or not viewed as consultations. Alternatively, the selection bias in studying consultations provided by APC senior fellows, who have chosen to remain active in helping sitting chairs, likely results in overestimation of the frequency of consultations provided by former chairs overall.

Another limitation of this study is that the types of consultations were not differentiated. From the preliminary work group discussion sessions, the types of consultation were found to have ranged from informal "hallway" conversations to objective written documents. They also included "consultations" that more technically could be considered advising, mentoring, and coaching. Nonetheless, this study does document that, at least for a defined group of former pathology chairs, consultation to current chairs occurs and is probably correlated with the number of consultations they sought when they themselves were sitting chairs. Perhaps not surprisingly, most topics could be subsumed under the categories of strategic planning, resource management, and conflict resolution.

Most consultations were outside the framework of APC, again perhaps due to the senior fellow group having been created only relatively recently and long after some chairs had stepped down. Indeed, the discussions indicated that some consultations occurred at meetings of other professional pathology organizations. The fact that most consultants knew their advisees well is probably not surprising since people tend to discuss sensitive issues with those they know best.

As noted in Table 2, conflict management, including dealing with difficult people at all levels, was a common area of consultation. Not surprisingly, it was noted during the discussion that conflict is a common cause of chair "burnout."

The advantages of using former academic department chairs as consultants are several. Usually former chairs are seasoned administrators who have been "around the block." If former chairs are used as a group by a professional organization of department chairs, their services can be "marketed" by the organization, and consulting teams can be formed, representing multiple points of view and expertise in different areas. Despite the potential value of advice from predecessor chairs, current chairs may be reluctant to ask such individuals since they want to be viewed as independent. Thus, having a group of former chairs from other institutions provides a rich base of consultants who can be objective and have perspectives different than those of the immediate former chair or other leaders at that institution.

Although the focus of the discussion was on use of former chairs as consultants, it was noted that "inter-chair" consults can also be helpful since they may provide a different perspective on common issues. In fact, to use the *cliché*, "misery loves company"!

It was also noted that senior fellow consultations need not be limited to advising sitting chairs. In fact, senior fellows can be a rich source of information for individuals aspiring to be chairs. After all, by definition, most senior fellows were once in that position themselves.

Many senior fellows who consulted most extensively often tended to do so for their successor chairs, and they did not report a significant change in types of questions asked. However, the work group discussions indicated that the advice and the answers to the questions have been changing due to the rapid and substantially changing health-care environments, especially in the delivery of education and clinical services, as well as in the financing of pathology activities. It would be of interest to conduct further studies to evaluate over time the changes that have occurred in advice provided by former chairs as well as the effectiveness of the consultations that have been provided.

In summary, professional organizations of academic department chairs should consider utilization of former chairs as consultants, either on an ad hoc basis or, as was done by APC, by creating a formal section of former chairs who, in addition to consultation, could support the other missions of the organization including education and fundraising. By virtue of their experience, collectively they are able to address essentially all of the issues listed in Tables 2 and 3, again indicating the importance of choosing the individual providing consultation based upon the stated background and expertise of the consultant. Indeed, the APC provides such a listing for each senior fellow.

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The Legal Aspects of Diversity in Academic Pathology

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Abstract

Diversity and inclusion in academic pathology center on building a diverse, inclusive pathology faculty. Understanding the basics of federal law, and the US Supreme Court cases that interpret those laws, allows one to consider good practices in diversity hire recruitment and retention that protects the pathology chair, the pathology department, and the institution. Consideration of inclusion and unconscious bias are helpful in building and sustaining robust, valuable academic pathology faculty diversity.

Keywords

diversity, inclusion, African American, mentoring, unconscious bias

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It remains an enduring challenge to our nation's education system to reconcile the pursuit of diversity with the constitutional promise of equal treatment and dignity.¹

Diversity Law

Diversity is a compelling governmental interest,² but it is discriminatory to use gender or race as the sole criteria in faculty hiring.³ A homogeneous faculty does not provide the diversity of views and experiences fundamental for a broad education, rendering an institution vulnerable to damaging discrimination lawsuits³; however, institutions risk “reverse discrimination” claims if they fail to establish and follow good practices regarding diversifying their faculty.⁴ For any faculty diversity issue, it is imperative that there be a good understanding of the law surrounding the recruitment, hiring, and retention of faculty.

The legality of considering gender and race in faculty employment decisions generally depends on whether an institution is acting on its employment decision in a remedial context or is acting in an attempt to enhance its overall faculty diversity in order to best realize its broad educational mission.⁵ While the remedial rationale has been strongly established in Supreme Court precedent, the rationale of enhancing overall faculty diversity has gone unexamined by the Supreme Court.

As such, the diversity rationale applied today in the setting of student admissions, derived from Supreme Court precedent grounded in First Amendment-protected academic freedom interests, are assumed to logically extend to faculty hiring and relating faculty employment issues.⁵ It is that reasonable assumption that currently informs institutional and good practices in academic faculty recruitment, hiring, and retention. That the Supreme Court has not to date addressed faculty hiring diversity strongly supports the reasonableness of extending its rationale in student admissions to faculty employment.

Federal Law

Institutional efforts to diversity faculty are governed by federal constitutional and statutory provisions, the case law interpreting them, and corresponding legal principles regarding the consideration of gender and race in educational programs.⁵ The

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principal legal standards informing employment discrimination law are those established under the Equal Protection Clause of the 14th Amendment to the Constitution, Titles VI and VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, and their related case law.⁴

Equal Protection Clause (US Constitution, 14th Amendment)

The Equal Protection Clause is part of the 14th Amendment to the United States Constitution, which reads, “No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.”⁶

Title VI (42 USC § 2000d)

Title VI of the Civil Rights Act of 1964 states that no one in the United States can be excluded from participation in, denied the benefits of, or be subjected to discrimination under any program receiving federal financial assistance, due to race, color, or national origin.⁷ Courts and agencies interpret Title VI as prohibiting both disparate treatment discrimination—intentional discrimination—and disparate impact discrimination—the use of facially neutral procedures or practices that have the effect of subjecting a person to discrimination based on that person’s race, color, or national origin.⁵

Title VII (42 USC § 2000e)

Title VII prohibits employment discrimination—regarding hiring, firing, wages, promotion, fringe benefits, job assignments, and other employment conditions—on the basis of race, color, sex, religion, or national origin; it applies to public employers, and to private employers with 15 or more employees.^{5,8} All educational institutions are subject to Title VII; however, Title VII applies only to employment, whereas Titles VI and IX apply to all aspects of an institution’s operations.⁵

Title IX (20 USC §§ 1681-1688)

Title IX prohibits sex/gender discrimination by education programs receiving federal financial assistance.^{5,9} “Title IX applies to all aspects of ‘education programs or activities’ that are operated by recipients of federal financial assistance, including admissions, treatment of and programs for participants, and employment.”⁵ As does Title VI, Title IX recognizes 3 general types of discrimination—disparate treatment, disparate impact, and retaliation.⁵

Private Institutions Receiving Federal Funds = Public Institutions

All public institutions are bound by constitutional restrictions; that is not the case for private institutions. Courts, though, have

held Title VI to be coextensive with the Equal Protection Clause as it relates to race discrimination. Also, Title IX generally follows the 14th Amendment’s equal protection principles regarding sex discrimination. As such, private institutions receiving federal funds are subject in effective to the same restrictions as those arising under the Equal Protection Clause, under Title VI with regard to race, and under Title IX with regard to gender.⁵

Executive Orders 11246 and 11375

In 1965, Executive Order 11246 stipulated that federal contracts of a certain dollar amount must contain provisions that prohibit discrimination based on race, color, religion, or national origin. Two years later, in 1967, Executive Order 11375 added sex discrimination provisions to the provisions required under Executive Order 11246. Further, it requires not only equal employment opportunity but also affirmative action. Under Executive Order 11246, federal contractors must develop and annually update an Affirmative Action Plan that includes goals and timetables for the increased women and minority utilization.⁵ Affirmative Action concerns actions appropriate to overcome the effects of past or present practices or policies and may be court-ordered after a finding of discrimination, negotiated as a remedy in consent decrees and settlement agreements, or conducted pursuant to government regulation.⁵ Employers may also effect voluntary affirmative action plans to eliminate a perceived manifest imbalance in a traditionally segregated job category.⁵ Importantly, quotas and preferential hiring and promotions are specifically prohibited in an Affirmative Action Plan.⁵

Supreme Court History Regarding Diversity

In 1954, the Supreme Court of the United States held, in *Brown v Board of Education*, that segregation by race in public schools was unconstitutional. Over the next 15 years, the Supreme Court issued several other landmark rulings involving race and civil liberties; however, it permitted lower courts to supervise southern school desegregation.¹⁰

“The first case taken by the Supreme Court on the subject of the constitutionality of affirmative action in higher education was *DeFunis v Odegaard* (1974)”; however, “the Supreme Court dismissed the case, 5-4, holding that as DeFunis had almost completed his studies, there was no longer a case or controversy to decide. Justice William Brennan . . . accused the court of ‘sidestepping’ the issues, which ‘must inevitably return to the federal courts and ultimately again to this court’.”¹⁰ Indeed, 4 years later, the Supreme Court took on the challenge of affirmative action constitutionality.

Regents of the University of California v Bakke, 438 US 265 (1978) “was a landmark decision by the Supreme Court of the United States. It upheld affirmative action, allowing race to be one of several factors in college admission policy. However, the court ruled that specific racial quotas . . . were impermissible.”¹⁰

The Supreme Court's decision in *Grutter v Bollinger*, 539 US 306 (2003) "largely upheld the position asserted . . . in *Regents of the University of California v Bakke*, which allowed race to be a consideration in admissions policy, but held that quotas were illegal."¹¹ As the Court's decision in *Grutter* made clear, "[p]ublic universities and other public institutions of higher education [were] allowed to use race as a plus factor in determining whether a student should be admitted. While race may not be the only factor, the decision allows admissions bodies to take race into consideration along with other individualized factors in reviewing a student's application. [Justice] O'Connor's opinion answers the question for the time being as to whether 'diversity' in higher education is a compelling governmental interest. As long as the program is 'narrowly tailored' to achieve that end, it seems likely that the Court will find it constitutional."¹¹

While it did not specifically address faculty diversity, the language in *Grutter* supports diversity in faculty hiring. ". . . *Grutter* upheld the use of race as a factor in the admissions program of the University of Michigan Law School. [And although] *Grutter* did not address whether this rationale extends to faculty diversity [, s]cholars, lawyers[,] and commentators have widely discussed the issue . . . The same First Amendment right of academic freedom that the Court emphasized in *Bakke* arises in the context of faculty hiring. Indeed, the *Bakke* Court identified the 'four essential freedoms' that constitute 'academic freedom': the freedom of an institution to determine for itself, on academic grounds, who may teach, what may be taught, how it shall be taught, and who may be admitted to study."⁴ The *Grutter* court clarified 3 things that touch on faculty diversity; first, is affirmed diversity as a compelling state interest. It found that "[t]he need for faculty diversity is another component of overall diversity on campus, and would this be supported by the courts finding educational diversity to be a compelling interest under federal law."⁴ Second, "[t]he Court . . . endorsed the concept of giving deference to educators to make educational decisions. When the makeup of the faculty is tied to the educational mission and pedagogical decisions of the university and its faculty, faculty hiring should also be entitled to such deference."⁴ Third, "[t]he Court stressed the importance of context in analyzing racial classifications, and that strict scrutiny was a framework for considering the importance and sincerity of the reasons for the use of race in that particular context. Given the Court's acceptance of the educational value of diversity, and deference to academic decisionmakers, this focus on context may apply beyond the student admissions scenario [into the faculty hiring scenario]."⁴

The Supreme Court in *Fisher v University of Texas*, 579 US (2016) (*Fisher II*) summarized . . . 3 controlling principles: strict scrutiny of affirmative action admissions processes, judicial deference to reasoned explanations of the decision to pursue student body diversity, and no judicial deference for the determination of whether the use of race in admissions processes is narrowly tailored."¹²

Twenty-Five Years Later

"The [2003 *Grutter* opinion, authored by Justice O'Connor] read, 'race-conscious admissions policies must be limited in time.' "The Court takes the [school] at its word that it would like nothing better than to find a race-neutral admissions formula and will terminate its use of racial preferences as soon as practicable. The Court expects that 25 years from now, the use of racial preferences will no longer be necessary to further the interest approved today.' The phrase '25 years from now' was echoed by Justice Thomas in his dissent. Justice Thomas, writing that the system was 'illegal now', concurred with the majority only on the point that he agreed the system would still be illegal 25 years hence."² On July 3, 2018, the executive office reversed former President Obama's policy on affirmative action in schools, abandoning Obama administration policies that called on universities to consider race as a factor in diversifying their campuses, signaling that the administration will champion race-blind admissions standards."¹³ "The Trump administration's decision . . . strongly encourages the use of race-neutral methods for assigning students to elementary and secondary schools."¹³ This is occurring at a time when "[a] highly anticipated case is pitting Harvard against Asian-American students who say one of the nation's most prestigious institutions has systematically excluded some Asian-American applicants to maintain slots for students of other races. That case is clearly aimed at the Supreme Court."¹³ It is through this prism of turbulence and uncertainty that decisions regarding faculty diversity must be considered and made.

Successful Planning Is Necessary

Given the dynamic legal environment surrounding academic diversity, successful planning for faculty recruitment, hiring, and retention is critical. *Fisher II* remains the Supreme Court's current "final word" on diversity in academia; and it is to it *Fisher II* one can turn for some valuable cues. *Fisher II* suggests faculty diversity goals and policies be worded as precisely as possible, without resorting to numbers only. Further, the necessity for diversity action should be based on evidence-centered academic judgments.¹⁴ The goals and policies should be as limited as possible; indeed, the entirety of the institution's policies, and resultant practices, should "inform an institution's conclusion that other 'workable' race-neutral efforts alone will not achieve its goals."¹⁴ And these policies should have "evidence of meaningful, if limited, positive impact on the achievement of the institution's goals."¹⁴ Finally, the institution should "engage in constant deliberation and continued reflection" to ensure that policies are appropriately focused and limited; indeed, "[t]he broader social context counsels that institutions should use *Fisher II* as an impetus for recommitting to their institutional goals."¹⁴

Good Practices

Process and context are paramount for successful recruitment and retention of a diverse faculty. Isolated or individual

departmental programs and practices that are designed and meant to increase diversity do not help establish effective institutional practice or support in the community. These inconsistent, isolated, and scattered initiatives may be well meaning; however, they generally fail to support an institution's need to show compelling need and narrowly tailored action, as required by the Supreme Court.⁴

The institution must lead the way, with institution-wide policies, procedures, and programs, appropriately funded and appropriately accountable, and there must be expressed commitment from leadership—president and dean down to the department chairs—leading their teams toward a clearly expressed institutional diversity initiative. An institution's diversity policy should express the institution's strong commitment to using "legal means to achieve diversity," commitment to the importance of an expanding applicant pool (both of faculty and of students), and commitment to equal opportunity. These strong statements in support of institutional diversity are protective to the institution, as they provide evidence of an institution's strong, well-reasoned, and routinely reviewed commitment to diversity. Without institutional leadership, individual, sporadic efforts may appear noncompelling, and as such risk the allegation of reverse discrimination.⁴

Diversity officers or coordinators, and affirmative action offices, can assist in building and effecting institutional practices aimed at growing diversity; however, that assistance should be part of the overall institutional strategy, and not isolated, independent, or overly deferred to. While enlisting the assistance of the diversity officer can be extremely helpful and protective, diversity officer overinvolvement with specific faculty recruitment or retention situations may appear as undue influence or overinfluence and could arguably be evidence of reverse discrimination.⁴ It is important to make clear to faculty that "[t]he intent of Affirmative Action is the hiring of competent people."¹⁵

Consider perceptions throughout the diversity hire recruitment process; it is critical to avoid any perception that any diversity hiring choice is not merit-based. If that perception develops, then diversity hires risk appearing to have been imposed upon the department, rather than chosen by the department for their merit. The diversity hire then risks being isolated, unsupported by the department, and without proper mentoring. This situation is unfair to both the diversity hire and to the department.⁴

Recruitment

Some well-established tools used in building academic faculty diversity—expanding networks to bring in more potential applicants, well-crafted position descriptions, and wide advertising of positions—are not as relevant to pathologists as they are to others in academia. The pathology community is relatively small, position descriptions are often very standard, and positions are generally advertised in a relatively small number of well-known pathology journals and web sites.⁴ One good opportunity for ensuring robust pathology diversity hire

recruitment is via the search committee. It is important to choose a search committee that is itself diverse and to educate the committee to understand and avoid stereotypical assumptions. Search committees can also benefit from a better understanding of what should and should not be said or asked in an interview and an understanding of how to conduct a search within legal boundaries. During the interview period, it is critical to demonstrate the true collegiality of the department to minimize the threat of isolation upon hiring. And it is important that the employment offer provides a competitive salary to counter any appearance of "low balling" the applicant. These methods are ultimately protective of the department and institution, diminishing the perception that the diversity hire is not merit-based.^{3,4,16}

Beyond recruitment efforts, some institutional hiring programs that were specifically targeted to increase diversity have been attempted, sometimes successfully; however, care must be taken in their use. These programs are at tension legally with the laws and regulations regarding nondiscrimination, and the more clearly specific they are, the greater the risk such programs will be legally challenged as reverse discrimination. Although considering race or gender as one factor is currently legal under the holdings of the US Supreme Court, consideration of race or gender as a sole factor would violate the Constitution and Title VII.⁴

Retention

The pathology chair leads the department and has the best opportunity to set a positive tone for diverse hire faculty retention and in fact to assist the institution in setting that tone. Critical for the success for all new faculty is strong mentoring on teaching, research, and the process of promotion and tenure. Promotion and tenure standards should be clearly communicated in writing, and the tenure process should be open and supportive, rather than adversarial. There should be formal mechanisms for assisting faculty as they progress toward tenure. It is very helpful if the department has the critical mass to provide a new diversity hire a like mentor. A lack of critical mass of other diverse faculty for new faculty support increases the likelihood that a new diversity hire will feel isolated; as such, new diversity hires can best be served by becoming integrated not only in the departmental but in the institutional, academic community. It is also important to ensure the new diversity hire has an appropriate and equitable service load.^{3,4,16}

There are great risks of not acting. Hostile climate claims may arise from a faculty member's feeling of being unwelcome or unable to succeed, or from feeling that one is being overwhelming if one speaks up, while irrelevant if one does not speak up—a catch 22 problem. Further, institutional bias claims may arise from the feeling of bias, which may begin at the time of recruitment, with a continuing sense of "otherness," perhaps arising from other faculty's unconscious bias. It is also critical to understand that diversity hires may face greater pressures with work-life balance than other

Table 1. Summary of Key Points.

Diversity	<ul style="list-style-type: none"> ➤ Compelling governmental interest² ➤ Discriminatory to use gender or race as the sole criteria in faculty hiring³
The legal standards informing federal diversity law	<ul style="list-style-type: none"> ➤ The Equal Protection Clause of the 14th Amendment to the Constitution⁶ ➤ Title VI of the Civil Rights Act of 1964⁷ ➤ Title VII of the Civil Rights Act of 1964⁸ ➤ Title IX of the Education Amendments of 1972⁵ ➤ Executive Orders 11246 and 11375⁵ ➤ Related case law
US Supreme Court holdings	<ul style="list-style-type: none"> ➤ <i>Regents of the University of California v Bakke</i>, 438 US 265 (1978)—Upheld affirmative action; race is one factor to be considered in college admission policy¹⁰ ➤ <i>Grutter v Bollinger</i> 539 US 306 (2003)—Upheld <i>Bakke</i>, reaffirming race is an allowable consideration for college admissions; held quotas are not permitted¹¹ ➤ <i>Fisher v University of Texas</i>, 579 US (2016) (<i>Fisher II</i>)—reaffirmed the key principles of strict scrutiny of affirmative action admission processes, judicial deference to well-reasoned explanations for pursuing student body diversity, and the lack of judicial deference in determining if the use of race in admissions processes has been as narrowly tailored as possible¹² ➤ It is reasonable to assume that the Supreme Court holdings regarding diversity in student admissions extends to faculty hiring⁴
Executive position	<ul style="list-style-type: none"> ➤ During President Obama’s administration, affirmative action was supported¹³ ➤ President Trump has recently indicated the administration in the future will support race-blind student admission standards¹³
Good practices	<ul style="list-style-type: none"> ➤ Inconsistent, isolated, or scattered initiatives for diversity hiring generally fail to support an institution’s need to show compelling need and narrowly tailored action and put the institution at risk for allegations of reverse discrimination⁴ ➤ Institutional diversity officers may be extremely helpful; however, their overinvolvement may appear as undue influence or overinfluence, putting the institution at risk for allegations of reverse discrimination⁴ ➤ It is important to avoid any perception that diversity hiring choices are not merit-based¹⁵ ➤ In the recruitment of diversity hires, it is important to choose a search committee that is itself diverse and to educate the committee to understand and avoid stereotypical assumptions¹⁶ ➤ In the retention of diversity hires, it is important that promotion and tenure standards are clearly communicated in writing, that the tenure process is supportive, and that the diversity hire be offered a like mentor if possible¹⁶
Unconscious bias	<ul style="list-style-type: none"> ➤ Unconscious bias toward women in medicine can affect decisions regarding their hiring, promotion, and professional development²² ➤ Women and minority faculty are especially vulnerable to unconscious bias due to long-standing stereotypes questioning their scientific and intellectual abilities²⁴ ➤ Pathologists can work to overcome unconscious bias and then help others learn about it²⁵

faculty.¹⁷ Departmental and institutional diversity itself brings unique benefits to new diversity hires, including opportunities for focused mentorship and particular networking opportunities.¹⁷

Pathologists must continue to strive to recruit and retain diversity faculty hires and can do more. For example, the Women in Science & Engineering Leadership Institute’s menu of recruiting resources, a valuable tool for women pursuing science careers, contains no pathology resources.¹⁸

Unconscious Bias

“Stereotypes about many groups fall along two dimensions, one relating to agency/competence and the other morality/warmth.”¹⁹ Educating a department’s faculty about unconscious (implicit) bias is paramount. “Unconscious bias includes opinions and attitudes that we are not consciously aware of having. Unconscious bias can be difficult to grasp because it contradicts what we intuitively believe about human behavior:

we tend to think that most of our behavior and our thoughts are intentional and chosen.”²⁰ Unconscious bias can arise from natural mental shortcuts. “. . . unconscious bias results from the way in which our brains process and store information . . . all of use mental shortcuts in order to quickly process new information about the world.”²⁰ Mental shortcuts are normal, and “. . . ‘not necessarily a bad thing. Without them we would be paralyzed by the amount of information that we receive from the outside world . . . [h]owever, mental shortcuts become a problem when they lead to stereotyping—when we make assumptions about an individual based on what we think members of that person’s social group are like.”²⁰ “. . . we learn [unconscious biases], starting at an early age, from our family, friends, teachers, and the media. There is evidence that young children often hold the same bias that adults do.”²¹ “. . . our unconscious biases tend to be stable over time. They are so ingrained in us that at the fundamental level they are probably exceedingly difficult to change. However, by becoming more aware of them, we may be able to self-correct for their

influence on our behavior.”²¹ “Although most people express a conscious desire to be fair and objective, unconscious bias influences the way [we] perceive other people.”²¹

“[Unconscious] bias against women in medicine is prevalent, affecting their hiring, promotions, development, and well-being.”²² “In the context of academic medicine, women and minority faculty may be especially vulnerable to the effects of unconscious bias . . . [they] are at special risk because of longstanding stereotypes that question their scientific and intellectual abilities.”²³

Pathologists “. . . can take steps to consciously self-correct for them, thereby limiting their influence on our thoughts and behavior; . . . the first step [is to become] more aware of what unconscious bias is and how it affects people’s behaviors. [Then, it] is also important to educate others about unconscious bias.”²⁴ It is important for a chair to help the department faculty, perhaps especially new diversity hires, to develop a growth mindset rather than maintaining a fixed mindset. “People with a fixed mindset tend to view human abilities, such as intelligence, as stable and difficult to change. In contrast, people with a growth mindset view human abilities as malleable and changeable through sustained effort.”²⁵ “These differences in mindset have particular relevance to people who belong to stereotyped groups. Because people with fixed mindsets view human traits as inherent and stable, they are more prone towards stereotyping others. They are also less likely to cope well in environments where stereotypes are pervasive.”²⁵

“Adopting a growth mindset is helpful for many people, but it might be especially important for individuals who belong to negatively stereotyped groups.”²⁵ New diversity hires should pay close attention to what they are telling themselves—is success or failure indicative of your inherent ability? They should also recognize that they have a choice—failure can be interpreted in different ways, including as a challenge. New diversity hires who have a fixed mindset need to learn to talk back to the fixed mindset “voice”—instead of failure being proof that one should not pursue an academic career, remind oneself it is an opportunity to improve and grow. And as they learn to accept challenges and interpret the results within a growth mindset, they will learn that if it is ok to fail, then new challenges do not bring as much anxiety and fear.²⁵

Conclusion

Table 1 summarizes the key points. Faculty diversity law is essentially federal law, arising from the United States Constitution, Congressional law, and Executive orders, and their interpretation by the United States Supreme Court. The use of good practices can assist a department in legally meeting its faculty diversity needs. Successful diversity faculty recruitment and retention requires chair oversight, formal processes, and close attention to unconscious bias.

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Due Process in Medical Education: Legal Considerations

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Abstract

Throughout the medical education continuum, some students encounter difficulty in meeting academic or professional standards that leads to remediation or dismissal. Termination of a student without due process may lead to litigation by deprivation of a student's property or liberty interest. This article outlines the concept of procedural and substantive due process as applied to litigated student dismissal cases in undergraduate and graduate medical education. Determination of the amount of due process owed is based on whether the dismissal is academic or nonacademic. The decision to dismiss a student where the entire student record has been reviewed, due process provided, and the institution complied with its own policies is usually upheld by the courts in litigation.

Keywords

due process, student remediation, student dismissal, case law, professionalism

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“University faculties must have the widest range of discretion in making judgments as to the academic performance of students and their entitlement to promotion or graduation.” This excerpt from the US Supreme Court's decisions in *Board of Curators, Univ. of Missouri v Horowitz* and *Regents of the University of Michigan v Ewing* serves as a guiding principle in how due process of the law is meted out in both remediation and termination processes in undergraduate medical education (UME, medical school) and graduate medical education (GME, internship/residency).^{1,2} Where academic decisions appear arbitrary and capricious, the courts take a different approach even if the decision is purely academic. Ignoring due process during student termination has the potential to lead to litigation by deprivation of liberty or property interests. This article presents an overview of due process considerations through a series of litigated cases. Table 1 outlines due process issues raised in medical education and Table 2 outlines common scenarios encountered in student dismissal cases.

Due Process Defined

Section 1 of the 14th amendment to the US Constitution states in part: “No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.”³

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Table 1. Due Process Issues in Medical Student/Resident Dismissal Cases.

What is due process?
How does procedural due process differ from substantive due process?
Was the student dismissal for academic or nonacademic reasons?
How much due process is owed?
Does the amount of due process owed vary if it is an academic versus nonacademic reason?
Is a resident considered a student or an employee?

Table 2. Common Scenarios in Student Due Process Dismissal Cases.

Undergraduate medical education
Failure of courses/modules in the preclerkship curriculum
Failure of USMLE Step exams
Failure of clerkships
Lack of professionalism
Graduate medical education
Failure of in-service exams/USMLE Step 3
Lack of clinical skills and judgment
Lack of professionalism

Due process of law refers to safeguards and procedures that are in place to protect a person's rights from state government (14th amendment)³ or federal government (5th amendment)⁴ action.⁵ Due process has 2 components, procedural due process and substantive due process. Procedural due process implies that an individual being deprived of a liberty or property interest will receive notice and is presented with the opportunity to be heard. Substantive due process implies that the state's (institution's) decision is not arbitrary or capricious.

In the academic setting, students dismissed from their respective UME or GME programs have argued deprivation of liberty and property interests due to lack of due process. In *Horowitz*, discussed subsequently, the student alleged that dismissal from medical school "deprived her of 'liberty' by substantially impairing her opportunities to continue her medical education or to return to employment in a medically related field."¹ The US Supreme Court (Supreme Court) in *Horowitz*, held where the results are not published as to stigmatize an individual but are communicated directly to a student, there is no liberty interest deprivation.¹ Additionally, they held there is no fundamental right to education in the US Constitution.

Whereas property interests are a creation of state law, some jurisdictions hold that admission to medical school is a property interest requiring due process.^{1,2} This view is not universal.^{6, 7}

Accreditation Standard

Due process is a UME and GME accreditation standard (Table 3).^{8,9} Students dismissed from their respective programs for not meeting academic and professional requirements have raised accreditation standards in litigation.

Table 3. Liaison Committee on Medical Education (LCME)* and ACGME[†] Due Process Accreditation Standards.

LCME Standard 9.9 states:
9.9 Student Advancement and Appeal Process
 "A medical school ensures that the medical education program has a single set of core standards for the advancement and graduation of all medical students across all locations. A subset of medical students may have academic requirements in addition to the core standards if they are enrolled in a parallel curriculum. A medical school ensures that there is a fair and formal process for taking any action that may affect the status of a medical student, including timely notice of the impending action, disclosure of the evidence on which the action would be based, an opportunity for the medical student to respond, and an opportunity to appeal any adverse decision related to advancement, graduation, or dismissal."⁸

ACGME institutional requirements IV C states:
 "IV.C. Promotion, Appointment Renewal and Dismissal
 IV.C.1. The Sponsoring Institution must have a policy that requires each of its ACGME-accredited programs to determine the criteria for promotion and/or renewal of a resident's/fellow's appointment. (Core)
 IV.C.1.(a) The Sponsoring Institution must ensure that each of its programs provides a resident/fellow with a written notice of intent when that resident's/fellow's agreement will not be renewed, when that resident/fellow will not be promoted to the next level of training, or when that resident/fellow will be dismissed. (Core)
 IV.C.1.(b) The Sponsoring Institution must have a policy that provides residents/fellows with due process relating to the following actions regardless of when the action is taken during the appointment period: suspension, non-renewal, non-promotion; or dismissal. (Core)
 IV.D. Grievances: The Sponsoring Institution must have a policy that outlines the procedures for submitting and processing resident/fellow grievances at the program and institutional level and that minimizes conflicts of interest. (Core)"⁹

*The Liaison Committee on Medical Education (LCME) accredits US and Canadian allopathic medical schools.

[†]The Accreditation Council for Graduate Medical Education (ACGME) accredits US internships and residencies.

Legal Precedent Used by the Courts

Medical education is divided into UME and GME. Failure to provide due process is raised in many cases of medical student and resident dismissal. The critical question is how much due process is required. This question was addressed in the following 2 Supreme Court cases. The Court's findings are summarized in Table 4.

Case 1

Charlotte Horowitz was a medical student admitted to the University of Missouri with advanced standing in 1971. Her pre-clerkship grades and National Board of Medical Examiners (NBME) examination scores were passing. During her clerkship in pediatrics, the faculty expressed dissatisfaction with her clinical performance (including her personal hygiene, peer and patient relationships, and timeliness) concluding it was below the standards of her peers. As part of the institutional policy, student performance was reviewed by a committee composed

Table 4. Summary of US Supreme Court's Decisions in *Horowitz and Ewing*.^{1,2}

- There are strong policy considerations for allowing academic institutions wide latitude, especially in the field of medicine, in developing academic standards and insuring student compliance with the standards.
- Academic institutions are in the best position versus a judicial hearing to determine whether a student's performance meets the profession's requirements.
- Dismissal of a student for academic reasons requires expert evaluation of cumulative facts.
- Courts are particularly ill equipped to evaluate academic performance. Judicial review of purely academic decisions is not warranted. Courts lack the professional judgment on what characteristics are appropriate for the practice of medicine.
- Student dismissal based on academic and professional factors is subjective in nature.
- Courts should defer to the faculty's professional judgment in purely academic decisions.
- Courts should not overrule an institution's decision unless the institution's decision deviates from acceptable academic norms raising concerns that the institution did not exercise professional judgment.
- Due process is an extremely flexible concept when applied to educational decision-making.
- School decisions that are arbitrary and capricious or where the student was not notified are issues for a judicial venue.
- The amount of due process owed is based on whether a case is framed as academic vs nonacademic (disciplinary).
- For purely academic dismissals in the education arena, a formal hearing is not required where a student's liberty or property interest is at risk. For disciplinary (nonacademic) dismissals, that are objective and factual, a hearing is required.
- A school's decision to dismiss a student, where the entire student record has been reviewed, due process provided, and the institution complied with its own policies are usually upheld in litigation.

of faculty and students (Council of Evaluation) who made a recommendation on student disposition including probation and dismissal. Their findings were subsequently reviewed by a faculty committee and then by the Dean. The Council of Evaluation recommended probation for Horowitz. Further faculty dissatisfaction was encountered as the year progressed and the Council recommended absent "radical improvement" dismissal. On all occasions, Horowitz was notified of the committee's findings and dissatisfaction with her performance. As part of an appeal process, the school allowed her to be examined by 7 practicing physicians. Two of the 7 recommended she continue as a student. The other 5 recommended continuation on probation or dismissal. Subsequently, the student received poor evaluations in 2 more clinical rotations and the Council recommended dismissal. The Coordinating Committee and Dean upheld the recommendation. Upon appeal by Horowitz to the Provost, the Provost upheld the Dean's recommendation. Based on the school's action, Horowitz filed a lawsuit stating she had not received due process. The district court found due process was adequate.

On appeal, the Court of Appeals reversed the lower court's findings stating there was failure of procedural due process,

since Horowitz was not allowed a formal hearing before the Council of Evaluation. The Supreme Court reviewed the case and concluded there was adequate procedural and substantive due process and upheld the student's dismissal.¹

Case 2

Scott Ewing was a student enrolled in a 6-year program of study at the University of Michigan in 1975 where an undergraduate degree and MD degree were awarded upon successful completion of the program. In 1981, he completed the requirements of the first 4 years of the program. The program had a requirement that students pass Part 1 of the NBME exam (predecessor to United States Medical Licensing Examination (USMLE) Step 1). Ewing failed Part 1 with a score of 235 (345 was passing, 380 was required for state licensure, and the national mean was 500). The 235 score was the lowest score ever recorded in that program. The performance of several students was subsequently reviewed by a 9-member Promotions and Review Board. The Board reviewed Ewing's entire academic record that included marginally passing grades, a number of incompletes and makeup examinations while on a reduced course load, and recommended dismissal. Ewing subsequently appeared before the Board offering reasons for his substandard performance to include his mother's heart attack 18 months prior to the exam, breaking up with his girlfriend 6 months prior to the exam, and being distracted with an essay contest. The Board affirmed their original recommendation. Ewing subsequently appeared in front of the Executive Committee on several occasions who upheld the decision and denied readmission. In 1982, Ewing commenced litigation in District Court arguing that his "dismissal was arbitrary and capricious, violating his 'substantive due process rights' guaranteed by the 14th amendment." Testimony documented that Ewing had academic difficulties throughout his tenure even with a reduced course workload and had appeared on several occasions before the Board. Evidence was introduced that other students who had failed Part 1 were given subsequent opportunities to pass the exam. The school admitted that should a student fail either part of the NBME exam, an opportunity is given to the student to retake the exam.

The District Court found Ewing had a property right in his education, but there was no violation of his due process rights. The court stated the "decision to dismiss the student was reached in a fair and impartial manner, and only after careful and deliberate consideration." It was "not arbitrary or capricious." Upon appeal, the Court of Appeals reversed the decision stating the failure for Ewing not to be allowed to retake the NBME exam violated its practice of allowing students a second retake opportunity. Evidence indicated Ewing was the only student who initially failed between 1975 and 1982 who was not allowed to retake the exam. The Court directed the University to allow him to retake the exam and if he passed the exam to reinstate him. The University of Michigan appealed the decision to the Supreme Court.

The Supreme Court reversed the Court of Appeals' decision and agreed with the District Court. They commented that there was no established rule that students had a right to retake the

exam. It was just a customary practice. Evidence indicated other students with academic deficiencies were not allowed to take Part 1 at all. Their conclusion was that the Board's decision was "made conscientiously and with careful deliberation, based on an evaluation of the entirety of Ewing's academic career." The decision to dismiss him "rested on an academic judgment that is not beyond the pale of reasoned academic decision-making when viewed against the background of his entire career at the University of Michigan, including his singularly low score on the NBME Part 1 examination."²

The Supreme Court held the school's decision to dismiss Horowitz "rested on the academic judgment of school officials that she did not have the necessary clinical ability to perform adequately as a medical doctor and was making insufficient progress toward that goal. Such a judgment is by its nature more subjective and evaluative than the typical factual questions presented in the average disciplinary decision. Like the decision of an individual professor as to the proper grade for a student in his course, the determination whether to dismiss a student for academic reasons requires an expert evaluation of cumulative information and is not readily adapted to the procedural tools of judicial or administrative decision-making."¹ The Court majority held, for purely academic reasons, a hearing was not required with the dissenting opinion commenting that an informal hearing should be required. The decision stated a hearing is expected, however, in a disciplinary (nonacademic) scenario.

In *Ewing*, the court held the dismissal of Ewing "from the Inteflex program rested on an academic judgment that is not beyond the pale of reasoned academic decision-making when viewed against the background of his entire career at the University of Michigan, including his singularly low score on the NBME Part 1 examination."² Ewing's dismissal did not "substantially deviate from accepted academic norms when compared with its treatment of other students."² The Supreme Court further commented that the "Promotion and Review Board presumably considered not only the raw statistical data but also the nature and seriousness of the individual deficiencies and their concentration in particular disciplines—in Ewing's case, the hard sciences."² The Board did take into account the "numerous incompletes and makeup examinations Ewing required to secure even marginally passing grades, and it could view them in connection with his reduced course loads. Finally, [the Board] was uniquely positioned to observe Ewing's judgment, self-discipline, and ability to handle stress, and was thus especially well-situated to make the necessarily subjective judgment of Ewing's prospects for success in the medical profession."² The Court stated that even if the institution had looked at the dismissal from Ewing's perspective, it might have concluded, "that Ewing's sensitivity to difficulties in his personal life suggested an inability to handle the stress inherent in a career in medicine. The inordinate amount of time Ewing devoted to his extracurricular essay writing may reasonably reveal to the University a lack of judgment and an inability to set priorities." Therefore, rejection of Ewing's arguments was not irrational.²

In both *Horowitz* and *Ewing*, the Supreme Court concluded that adequate due process was provided. In deciding the cases, the Court assumed Horowitz and Ewing had a property interest but never decided that issue. Relying on *Horowitz*, the critical question is whether a dismissal is *academic or non-academic*.¹ Other questions do remain, however. Most important is how much due process is owed, is a formal hearing required, does a student have a right to an attorney or have the meeting transcribed, and what distinguishes an academic from nonacademic dismissal?

Due Process in Undergraduate Medical Education

Common issues in UME resulting in student dismissal are classified into failure of basic science course work, failure of USMLE Step examinations, failure of clerkships, and professionalism. Table 5 outlines several cases where the preceding issues and lack of due process arose in addition to other causes of action.^{1,2,5-7,10-30}

Failure of Courses/Modules in the Preclerkship Curriculum

Case 3

Jacqueline Leacock was a student at Temple University School of Medicine. During her first year of medical school, she received nonpassing grades in 7 courses obtaining 21 of 30 points in their grading scheme. Based on their written policy available to students, the student had not achieved the required 30 points to be promoted to the next academic year. The student was notified she would be dismissed by the Associate Dean for Curriculum consistent with the student handbook. The student appealed the decision to the Student Promotions Committee citing learning difficulties that became apparent during the first year. The record indicated she asked for a leave of absence and that she had never notified the school of the issue (learning difficulties) prior to her appeal letter. The Committee deferred on her request requiring more documentation on the learning deficit. The student was evaluated and found to have attention deficit disorder and mixed receptive expressive language disorder by an expert. Expert opinion from 2 other individuals in testing and education was not conclusive of the disorder. Based on the documentation received, the Promotions Committee upheld its decision for dismissal. Consistent with the student handbook, Leacock appealed the decision to the Dean. Stating no procedural irregularities, the Dean upheld the Promotions Committee's recommendation.¹⁰

The student filed legal action claiming her procedural due process rights were violated by the school for not notifying her that the Promotions Committee met to discuss her case and did not speak to her about the alleged disability. The Court held that the only procedural due process required was more of an "informal give-and-take" in purely academic decisions. In this

Table 5. Medical Student Dismissal Cases That Raised Lack of Due Process in Addition to Other Causes of Action.

Case and Year Decided	Type of Dismissal	Case Scenario	Outcome
Failure of courses/modules in preclerkship curriculum			
<i>Giles v Howard University</i> ⁵ (1977)	Academic	Student passed all first semester courses except biochemistry. School allowed him to continue and he passed all second semester courses but failed biochemistry retake, a curriculum requirement. Student was put on academic probation and required to repeat first-year courses including biochemistry. During his repeat first year, he passed biochemistry and failed anatomy and was dismissed. Student requested readmission. The school said they would consider the request provided he passed the NBME subject exams in anatomy, biochemistry, microbiology, and physiology. He failed all 4 exams and his request for readmission was denied. He filed a lawsuit raising due process issues. The court found under the school's promotion policy it had the right to dismiss failing students and it had provided the student an opportunity to remediate. See text Case 3.	Dismissal upheld
<i>Leacock v Temple University School of Medicine</i> ¹⁰ (1998)	Academic		Dismissal upheld
<i>Naglak v Berlin</i> ¹¹ (1989)	Academic	Student failed 2 second year courses, pathology and pharmacology at Penn State and was dismissed for academic reasons. She filed a lawsuit for due process violation. Penn State settled with her in which she agreed to withdraw from the school and not seek reenrollment. Penn State had agreed to accept her remedial courses in pathology and pharmacology from another school and state she had completed 2 years of medical school and was a student in good standing. The student subsequently applied to other schools but was informed she could not be considered a transfer student without passing the NBME Part 1 exam. Not having student status, she was ineligible for the NBME exam or admission as a transfer student. She filed a lawsuit alleging she was fraudulently induced to settle with Penn State and that Penn State's failure to provide her means to transfer to a different accredited medical school deprived her of her educational property rights without due process.	Dismissal upheld
<i>Nichols v McDonald</i> ¹³ (1990)	Academic	Student was admitted to the University of Iowa's College of Medicine Educational Opportunities Program designed to give disadvantaged students access to a medical education. In this program, basic sciences courses are taken during the first 3 semesters. Student had academic difficulties failing biochemistry during the first semester that he remediated, failing physiology during the spring semester that was remediated at a different school after having been put on probation. He was taken off probation and passed all second-year fall courses. During his fourth semester, he failed the school's Introduction to Clinical Medicine (ICM) course and was put on probation with the requirement to pass the course during the spring semester. Student appealed the decision requesting he take a make-up exam. The school's Promotions Committee denied the request. He took a leave of absence and failed the ICM course upon his return for the spring semester. The Promotions Committee reviewed his entire academic record and recommended dismissal. On appeal, the school's Executive Committee upheld the dismissal. The student filed a lawsuit claiming the Promotions Committee's decision deprived him of his procedural due process rights.	Dismissal upheld
<i>Watson v University of South Alabama College of Medicine</i> ¹⁴ (1979)	Academic	Student was admitted to University of South Alabama. During his first year, he was enrolled in 10 different courses. He received 4 failing grades, 1 below average but passing grade, 1 average grade, and 4 passing grades. The school's promotions committee reviewed the student's entire academic record and recommended dismissal. The student appeared in front of the committee stating financial difficulties and family problems interfered with his studies and requested that he be allowed to repeat the first year. The committee reaffirmed their dismissal decision which was upheld by the Dean on appeal. The student filed a lawsuit alleging racial discrimination, breach of contract for failing to comply with the student bulletin, and lack of due process.	Dismissal upheld

(continued)

Table 5. (continued)

Case and Year Decided	Type of Dismissal	Case Scenario	Outcome
<p>Failure of USMLE Step examinations</p> <p><i>Regents of the University of Michigan v Ewing</i>² (1985)</p> <p><i>University of Mississippi Medical Center v Hughes</i>¹⁵ (2000)</p>	<p>Academic</p> <p>Academic</p>	<p>See text Case 2.</p> <p>Student at time of enrollment in 1992, based on the school's academic guidelines, was required to maintain a grade point average (GPA) of 75. There was no requirement to pass the USMLE, although it was a state requirement for licensure. In 1993, the school's faculty recommended passage of the USMLE as a requirement to enter the junior year, a requirement set by most medical schools. Students were notified of the requirement in 1993. Student passed all his courses, but failed the USMLE twice in 1994. The school provided him the option to enroll in a self-study program with leave of absence until the 1995 exam. In 1995, the school required passing Step 1 and students failing the exam would be dismissed. In 1995, student failed the exam, his third attempt and was dismissed. Student appealed the dismissal but it was upheld. Student filed a lawsuit alleging breach of contract by the school for changing its graduation requirements and lack of due process. A lower court stated that the school's decision was arbitrary and for the school to allow the student to sit for the 1997 exam and readmit the student so he could sit for the exam. The school challenged this decision at an appellate court. The appellate court reversed the lower court's decision and stated due process had been provided and the school had the right to modify its education requirements given that passage of the USMLE was a state requirement for licensure.</p>	<p>Dismissal upheld</p> <p>Dismissal upheld</p>
<p><i>Ward v Rush-Presbyterian-St. Lukes Medical Center</i>¹⁶ (1986)</p>	Academic	<p>Rush Medical College adopted a rule requiring students pass the NBME Part 1 exam prior to starting their third year. Students failing the exam by November of their third year were put on probation with their entire academic record reviewed by the Promotions Committee. Students who failed it 3 times were subject to dismissal and removed from clinical duties to prepare for the exam. Several students filed a lawsuit alleging the school's NBME requirement was arbitrary and capricious and they were victims of racial discrimination. The court held the faculty's professional judgment on standards was not reviewable and there had been adequate due process and no evidence of discrimination.</p>	Dismissal upheld
<p>Failure of clerkships</p> <p><i>Bain v Howard</i>¹² (2013)</p>	Academic	<p>Student enrolled at Howard University. He passed his first-year courses. During his second year, he failed a neuroscience course which he successfully remediated. He subsequently failed USMLE Step 1 but passed it on his second attempt. During his third year, he failed the NBME subject exams in psychiatry and surgery. He failed retake exams which led him failing the clerkships. He also failed the subject exam in obstetrics but did not take a retake. Per Howard's policy, he could have been dismissed for failing 2 clerkships; however, Howard let him repeat the third year. During his second attempt at the third-year curriculum, he failed the NBME subject exams in pediatrics, psychiatry, and obstetrics leading to his dismissal per school policy. He subsequently filed a lawsuit alleging breach of contract and failure to comply with LCME standards. The court agreed there was a contractual obligation; however, stated that his repeated NBME subject exam failures, exams graded external to Howard, did not indicate arbitrariness on Howard's part and his dismissal was for academic reasons.</p>	Dismissal upheld
<p><i>Board of Curators of University of Missouri v Horowitz</i>¹ (1978)</p>	Academic	<p>See text Case 1.</p>	Dismissal upheld

(continued)

Table 5. (continued)

Case and Year Decided	Type of Dismissal	Case Scenario	Outcome
<i>Eiland v Wolf</i> ¹⁷ (1989)	Academic	Student had completed all the school's academic requirements except for a fourth-year elective course in community health that led to his dismissal. He filed a lawsuit alleging lack of due process and violation of his equal protection rights. A lower court agreed with the student and directed reinstatement and awarding of the MD degree. The school appealed the decision. The appellate court reviewed the student's entire academic record and commented that the student had failed 4 clinical rotations that included internal medicine, pediatrics, and dermatology that were remediated. The school's Promotions Committee that reviewed the entire student record prior to graduation recommended dismissal. The student had requested the committee to reverse their recommendation which was to no avail. The student then appealed to the Dean who reversed the committee's dismissal decision and put the student on probation. The student subsequently remediated the clerkships he failed, but failed the community health requirement, a graduation requirement. The Promotions Committee reviewed the student's entire record again and recommended dismissal, which was upheld by the Dean the second time leading to the student to seek legal redress.	Dismissal upheld
<i>Greenhill v Bailey</i> ¹⁸ (1974)	Academic	Student was accepted with advanced standing after his application for admission through the traditional process had been rejected twice. His undergraduate GPA was 2.54 where the mean of the accepted class was 3.4. Prior to his acceptance, he completed 2 years at the College of Osteopathic Medicine where his grades were at the bottom of the class. He failed the NBME Part I exam but passed it on retake. During his clerkships, he failed obstetrics and internal medicine and received the lowest passing grade in pediatrics. The Promotions Committee reviewed the student's entire academic record and recommended dismissal which was upheld by the school. The student filed a lawsuit alleging the school's decision was arbitrary and capricious based in part on subjective evaluation during clerkships and that there was lack of procedural due process due to the student not being allowed to be present at a Junior Class Promotion Committee meeting. See text Case 4.	Dismissal upheld
<i>Hill v University of Kentucky</i> ¹⁹ (1992) <i>Lunde v Iowa Board of Regents</i> ²⁰ (1992)	Academic Academic	Student entered medical school in 1985. During her preclerkship courses that she passed, she was noted to have issues relating to others, inappropriate behavior, falling asleep in class, and the inability to prioritize information, separating relevant from irrelevant data. During her clerkships, her behavior toward faculty, residents, and her peers was inappropriate and she was unable to synthesize relevant information leading to her failing several clerkships, neurology, urology, and obstetrics. She was placed on probation and allowed to retake the clerkships she failed. She failed them a second time and the school dismissed her. She filed a lawsuit alleging sexual discrimination, equal protection violation, and violation of free speech and due process concerns.	Dismissal upheld Dismissal upheld
<i>Moire v Temple University School of Medicine</i> ²¹ (1985)	Academic	Student was enrolled in Temple. During her third year, she failed her psychiatry clerkship. The Student Promotions Committee, after reviewing her entire record, recommended she repeat the entire third year on probation. The Committee's decision was upheld after appeal to the Dean. She subsequently graduated from Temple and obtained an internal medicine residency. She then filed a lawsuit alleging sexual harassment (Title IX) leading to her failure of psychiatry clerkship and lack of due process.	Claim dismissed. No due process violation. No sexual discrimination.
<i>Mustell v Rose</i> ²² (1968)	Academic	Student passed his preclerkship courses and failed medicine and surgery during his third-year clerkships. The school's policy was that a student could repeat a failure of one course but failure of 2 courses in the same academic year led to dismissal. The student Promotions Committee reviewed the entire student record and recommended dismissal. The student was notified by mail of the Committee's decision. The Dean approved the recommendation and notified student. The student filed a lawsuit alleging he did not have the opportunity to appear before the Promotions Committee and his failing grades were arbitrarily decided.	Dismissal upheld

(continued)

Table 5. (continued)

Case and Year Decided	Type of Dismissal	Case Scenario	Outcome
<i>Sofair v State University of New York</i> ²³ (1976)	Academic	Student had academic difficulty during his medical school curriculum. He failed pathology during his second year that was remediated. He failed medicine and surgery during his third year that were successfully remediated. He failed nephrology during his fourth year. At the time his peers graduated, he still lacked 2 courses required for graduation. The school's Promotions Committee, based on review of his academic record including grades and narratives, recommended he repeat the entire fourth year following a structured program designed by the Promotions Committee. During his repeat fourth year he took 4 courses, passing 3 and failing a 6 week surgery internship. He had secured an internship in medicine. The Fourth Year Medical Grades Committee notified student in writing they were recommending dismissal because he failed to demonstrate adequate clinical aptitude. He was notified that he had the right to appeal. The school's Committee on Academic Promotions had reserved time for him later that day, the day he was notified. He received a second letter from the Committee that day stating they were following the Grade Committee's recommendation. Student filed a lawsuit alleging the school's decision was arbitrary and capricious. Student stated that there was lack of procedural due process given that he received notice of dismissal without notifying him of the factual basis for the deficiencies noted in his clinical aptitude and not providing him time to appear in front of the Academic Promotions Committee to present his side of the case. The court reversed the student's dismissal and notified the school to provide the student a detailed written statement regarding findings used to conclude student lacked clinical aptitude and provide student the opportunity to be heard after he had time to review the written statement. After the hearing, the school could make a more informed decision regarding dismissal the court stated.	Dismissal reversed pending adequate notice to student and hearing
<i>Stoller v College of Medicine</i> ²⁴ (1983)	Academic	Student entered school in 1976. During the fall term, he failed microbiology and was placed on probation. In the winter term, he failed biochemistry. His record was reviewed and he was informed he would be subject to dismissal without improvement. He was allowed to enter the second year on probation. During his second year, he passed behavioral science but the course director commented his responses to questions reflected poorly on his discretion and judgment. His record was reviewed and based on comments from the behavioral science course was considered for dismissal. He was directed to discontinue research and focus on academics. Subsequently, he was taken off academic probation. During his third year, he failed surgery and was notified by the Promotions Committee that he was subject to dismissal and placed on probation. He passed his psychiatry, neurology, and obstetrics clinical rotations. Halfway through his pediatrics clerkship, he was perceived as being weak and told by the clerkship director to improve his academic performance. The pediatrics' faculty met and awarded grades to all students except for this student. The department decided to give him an oral exam due to weakness in his clerkship performance. Although his fund of knowledge was passable, the examiners felt he should repeat the clerkship. The clerkship director, based on all evaluations and the exam results, gave student a failing grade. The Promotions Committee met and reviewed his entire record and recommended dismissal after the student had appeared. The student's record was reviewed by the Dean after meeting with the student and the student was dismissed. His appeal to the university President was denied. The student filed lawsuit alleging the dismissal decision was arbitrary and capricious and lacked procedural due process.	Dismissal upheld

(continued)

Table 5. (continued)

Case and Year Decided	Type of Dismissal	Case Scenario	Outcome
Lack of professionalism			
<i>Abbas v Woleben</i> ⁶ (2013)	Academic	Student was admitted to medical school in 2006. After completion of the first 2 years of school, the school granted student 5 leaves of absence for health and personal reasons from June 2008 until January 2011. Student had been recommended for dismissal in 2009 for not taking the USMLE by Promotions Committee. The recommendation was not upheld by the Dean. In January 2011, he was given notice of an upcoming Promotions Committee meeting. The Promotions Committee met in January 2011 and recommended dismissal for lack of academic progress. The letter did not inform the student of his right to appeal. Further, the school administrators informed him that he could not protest decision. Student was dismissed and filed a lawsuit alleging breach of contract and lack of due process.	Dismissal upheld
<i>Corso v Creighton</i> ²⁵ (1984)	Academic	Student during his first year of medical school was accused of cheating on his first year final examinations. The student was notified of the allegation in writing. The Acting Dean established a committee to investigate the allegation. The committee stated that the student had collaborated with another student. The school's Advancement Committee recommended to the Executive Committee and Dean expulsion. The student was notified in writing and by phone. He was informed he could respond to the charge and respond to the Associate Dean for Student Affairs. Student met with the Associate Dean to discuss the issue denying the cheating. He requested to appear in front of the Executive Committee but that request was denied. The Acting Dean conducted his own investigation interviewing 20-25 students. The Acting Dean met with student and he denied cheating. Several of the other 25 students admitted cheating and implicated student in the cheating and student was expelled. Student filed a lawsuit alleging breach of contract. The lower court stated that student was dismissed for lying, a nonacademic offense, which required certain due process requirements. The appellate court disagreed and stated the offense was cheating, even though student lied about it and it was academic in nature. The appellate court also stated the student handbook is contractual. Based on procedures elaborated in the handbook, they found the school was not in compliance with their own policy that required a university committee, not school committee, to adjudicate serious offenses, expulsion meeting that criterion. The court concluded that the student must be afforded the procedural safeguards to appear before a university committee before the school rendered a decision.	Dismissal reversed pending committee hearing specified in student handbook
<i>Doherty v Nellis</i> ²⁶ (2016)	Nonacademic	Student was a second-year medical student who was alleged to have assaulted a staff member in the student recreational center in June of 2014. Review of the student's record documented going back to November 2012, there had been complaints of inappropriate behavior by female students at school functions against student. During 2013, female student members of the first-year class expressed concern about their safety and inappropriate behavior. The incident was addressed by the university through several meetings and dialogues with student and his attorney. In September 2014, the Student Conduct Board recommended dismissal. Student appealed decision to the university Provost who concurred with decision. Student filed a lawsuit alleging lack of due process, unlawful taking, violation of American with Disabilities Act, and conspiracy claim.	Dismissal upheld
<i>Fernandez v Medical College of Wisconsin</i> ²⁷ (1996)	Academic	Student was admitted in 1987 and entered school's 5 year program. During her second year, she took a semester leave of absence for scheduling issues and a subsequent semester leave of absence for health reasons. Student was warned by school's Academic Standing Committee of her lack of academic progress that could lead to dismissal. Student was informed by school that she needed to complete her biochemistry course, take a full load of second-year courses, and take the NBME	Dismissal upheld

(continued)

Table 5. (continued)

Case and Year Decided	Type of Dismissal	Case Scenario	Outcome
<i>Flairm v Medical College of Ohio</i> ²⁸ (2005)	Nonacademic	<p>exam in June. Due to issues at the school, the June exam was not offered. The school notified all students in a memo they were encouraged to take the exam in September. Student did not take the exam. The school's Academic Standing Committee reviewed student's entire academic record and recommended dismissal based on failure to meet previous mandates and unprofessional behavior. Unprofessional conduct identified was not taking the NBME exam, not taking other examinations, and repeated leaves of absence for personal and academic reasons. The Committee provided her notice and said they would consider other grounds they discovered. Student also received notice that it would consider evidence of unethical conduct (dishonesty) that included misrepresentation regarding loans, reasons for not taking NBME exam, lack of congruency in health insurance application, and false pledges during an alumni phonathon. At student's request, an ad hoc committee was convened to evaluate dishonesty claims. Student appeared with her attorney and was allowed to call witnesses and the session was tape-recorded. The Ad Hoc Hearing Committee found the dishonesty claims credible. The Academic Standing Committee subsequently convened and considered the dishonesty claims as being relevant to student's credibility. The Committee found she failed to demonstrate the required level of professional responsibility in not taking exams in a timely manner, not accepting responsibility for her actions, and disregarding mandates about the NBME exam. After review of her entire record, the Committee recommended dismissal. An Appeals Committee upheld the dismissal. Student filed a lawsuit alleging defamation, infliction of emotional distress, breach of contract, lack of substantive due process, conversion of student loan money, breach of fiduciary duty, and fraud. Student was a third-year medical student arrested and convicted of a felony drug crime. Two days after his arrest, school notified him in writing that he was suspended until an external investigation/hearings were completed. He was also informed of his right for an internal investigation. He declined to appear until criminal charges were adjudicated. After pleading guilty to one charge, he contacted the school and received written notice that he would appear in front of Student Conduct and Ethics Committee. The Committee heard testimony from the arresting officer and was able to review portions of his criminal record. The Committee informed him after the hearing that it would provide the Dean with a written recommendation. The recommendation was never generated. The Dean expelled the student 2 days after the hearing for violation of the institution's code of conduct. Student filed lawsuit alleging lack of due process.</p>	Dismissal upheld
<i>Jenkins v Hutton</i> ²⁹ (1997)	Academic	<p>Student passed the first 2 years of medical school without difficulty. Student failed the NBME Part I exam in June 1990. He also failed to show up for his third-year rotations. A month into the third year he requested a leave of absence to study for NBME exam. His request was granted. Student however did not take the next scheduled NBME exam in June 1991. He was called to a Promotions Board meeting in November 1991 to discuss why he didn't take the NBME exam. He failed to attend. In March 1992, he was requested to meet the Board again. He was informed he must take the exam in June 1992. He again did not take it. The Board sent him notice that he could not start his fourth year until he took the exam. He was also required to complete his final 2 years of coursework in 3 years requiring him to complete all course work by graduation day, June 1994. Student completed his third year during 1991-1992 academic year. He took only one course in order to study for NBME exam during the 1992-1993 academic year. He passed the NBME exam in June 1993. He passed all his fourth-year rotations with high pass or honors. He registered and completed his final rotation after graduation in June 1994. The Board met in June. Student was present and addressed the Board. The Board voted to adhere to its original guidelines of completion of all requirements by graduation day, June 1994 and voted for dismissal. Student appealed the decision. The decision was upheld by the Appeals Board and Dean. Student was dismissed for failure to complete the program in specified time period. Student filed lawsuit-alleging lack of due process.</p>	Dismissal upheld

(continued)

Table 5. (continued)

Case and Year Decided	Type of Dismissal	Case Scenario	Outcome
<i>Lee v University of Michigan-Dearborn</i> ⁷ (2007)	Nonacademic	Student was alleged to have interfered and harassed a university professor through obscene gestures, filming her, stalking her, and sending her slanderous e-mails. Inappropriate comments were present in some assignments. The faculty member filed a complaint against the student. A hearing was conducted by a Non-Academic Conduct Board where the student, university professor, and other witnesses appeared. Evidence indicated that the university professor had obtained a personal protection order against the student. The University's Hearing Board found the student guilty of the following university code violations: "B.3 Interfering with Liana McMillan's University business, ie, studying, teaching, administration; B.5. Harassment, ie, stalking that involved deliberate interference or a deliberate threat to Liana McMillan; B.7. Failing to comply with the directions of University officials and campus safety; B.14. Violating published University policies, including those regarding affirmative action."	Due process claim dismissed
<i>Stathis v University of Kentucky</i> ³⁰ (2005)	Nonacademic	The Hearing Board recommended expulsion. The student appealed the decision to a university Code Appeals Board. The Board found that the student had adequate due process but the sanction of expulsion was too excessive and reduced the penalty to "expulsion in abeyance" with the condition of no further contact (verbal, written, electronic, or other contact) with the professor and the student pursue counseling. Violation of this condition would lead to expulsion and the student was allowed to continue classes. While the student was appealing the Code Appeals Board's decision in the Michigan Court of Claims, she was expelled for violating the no-contact provision for sending an e-mail where the professor along with others were contacted. See text Case 5.	Dismissal upheld

Abbreviation: LCME, The Liaison Committee on Medical Education.

case, the student had received adequate notice to discuss her learning disability with the Promotions Committee and to appeal the decision. Adequate procedural due process was provided.

Addressing potential substantive due process rights and relying on *Horowitz*, the court stated, “Where there is an academic dismissal, as in the present case, it has been held that ‘courts are ill-equipped to review the largely subjective academic appraisals of the faculty.’”¹⁰ Citing *Ewing*, the Court stated judges, when they are “asked to review the substance of a genuinely academic decision, they should show great respect for the faculty’s professional judgment.”¹⁰ Courts lack the knowledge to understand the decision by academic faculty and therefore are not suited to “override an academic decision of the school authorities unless the decision is such a substantial departure from accepted academic norms so as to demonstrate that the persons responsible for the decision did not actually exercise professional judgment.”¹⁰ Given that Temple followed its student handbook and that termination of students with grades analogous to Leacock’s grades is consistent with good academic decision-making, there were no substantive due process issues.¹⁰

Failure of USMLE Step Exams

As previously discussed in *Ewing*, the Supreme Court stated dismissal for failing the NBME exam was an academic decision. It would not overrule an institutional academic decision where the institution provided procedural due process. In contrast, where academic decisions appear arbitrary and capricious, the courts may take a different approach even if purely academic.³¹

In a related case, *University of Mississippi Medical Center v Hughes*, a student with a poor academic record who failed the NBME examination 3 times, was dismissed.¹⁵ Procedural due process had been provided. An argument raised by the student was that when he was admitted, there was no requirement to pass Step 1 of the USMLE. The student stated the policies outlined in the student handbook were contractual. The Supreme Court of Mississippi concluded there was a contractual obligation, however, the university’s right to modify educational requirements is implicit in its contract with students. The implementation of a new grading requirement was not arbitrary and applied to all students and there was a rational basis for the change. There was no due process issue. In this case, the State of Mississippi had a requirement to pass USMLE Step exams for state licensure. Further, their student handbook stated policies could be modified.¹⁵

The student handbook issue has been raised in many cases. Many courts uphold the creation of a contractual relationship between the school and student.^{12,15,22,25} In *Abbas*, where a student was recommended for dismissal for lack of academic progress by a student Promotions Committee, and the student raised the point that the handbook created a contractual obligation, the court held “university handbooks and catalogs do not form a contract where the terms bind the university,” where there is a disclaimer that the university may change its terms at

any time or the handbook states “it is a useful guide” and “proposed modifications are always welcome.”⁶

Failure of Clerkships

Failure of clerkships, where student knowledge, clinical skills, and professionalism are assessed, is also addressed in *Horowitz*.¹ More recent cases support that clerkship failures are academic decisions (Table 5). In *Bain*, a Howard student failed several NBME (subject) clerkship exams that were a requirement for passing the clerkship. His entire record was reviewed by a Promotions Committee that allowed him to repeat the third year, but established in writing that failure of any clerkships in the third year would lead to dismissal. During his repeat third year, he failed 3 clerkships and was dismissed. The DC Court upheld the contractual nature of the student–university relationship. Given that the student had received procedural due process, that the policy to dismiss him had been outlined in the student handbook, and that the NBME exams were not graded locally, Howards’ dismissal decision was not arbitrary.¹²

Case 4

Philip Hill, a medical student at the University of Kentucky, had a poor academic record failing several courses that he remediated as well as failing USMLE Step 1 twice before passing it on the third attempt after a prolonged leave of absence to prepare for it. During this time, the student had received notice and had his academic record reviewed by a Promotions Committee as well as appeals to the Dean. During his third-year surgery clerkship, the student did not meet the grading requirements specified in the syllabus. The syllabus also included the phrase “The Department of Surgery reserves the right to assign an unsatisfactory grade for the entire clerkship if the student performs in an unsatisfactory manner in terms of professional behavior, interactions with patients, or on examinations.” Based on a number of incidents, including 6 absences of which 2 were excused, choosing patients with the same disease for examination in conflict with the syllabus and changing his on-call night schedule without notifying other students, the student received a failing grade. Specifically, the clerkship director stated that the failing grade was based on “several episodes of intellectual dishonesty, unsatisfactory ratings from both the students and myself, and a deficit in performance in areas such as self-responsibility for learning, relationships with peers and faculty, and attendance.” The student appealed the grade to the clerkship director and then to the Dean. The failing grade was upheld. The school’s Promotions Committee reviewed the clerkship performance and the student’s entire academic record and recommended dismissal. Subsequent appeals upheld the Committee’s decision with the Dean affirming the decision after reviewing the student’s seven-and-a-half-year association with the school. The student filed a lawsuit for being dismissed arguing violation of his “substantive and procedural due process rights.”¹⁹

The United States Court of Appeals for the Sixth Circuit cited *Ewing* using the following standard. “When judges are asked to review the substance of a genuinely academic decision . . . [such as in *Ewing*], they should show great respect for the faculty’s professional judgment. Plainly, they may not override it unless it is such a substantial departure from accepted academic norms as to demonstrate that the person or committee responsible did not actually exercise professional judgment.”^{2,19} The decision to award a failing grade for the surgery clerkship was not arbitrary nor capricious, and not inconsistent with academic norms. The dismissal decision was upheld.

The Court relied on the factors cited by Dr Schwartz, the “six absences with only 2 being excused; 18 unsatisfactory peer evaluations; “virtual absence” in attending operating room procedures during the first 10 weeks of the class; switching the on-call night without informing the other members of his rotation group; and the repeated use of identical material in patient writeups” in upholding the dismissal. The documented findings that were part of the legal transcript were found persuasive. Given that the student had notice, the opportunity to appeal, and have legal representation, the student was provided adequate due process. The school’s decision was careful and deliberate.¹⁹

Lack of Professionalism

Professionalism is a competency demanded by one’s profession and the public. Specifically, “professional competence is the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and community being served.”³² Each institution has its own guidelines on what constitutes unprofessional behavior. In student dismissal cases for unprofessional behavior, due process arguments are held to a higher standard.

In *Corso*, a Creighton University student was accused of cheating on his final examinations. Creighton considered the incident as an academic disciplinary issue.²⁵ His case was reviewed by a special School of Medicine committee. The Advancement Committee’s recommendation to the Executive Committee and Dean was for dismissal. The student was notified in writing of the charges and provided with evidence by the Associate Dean for Student Affairs. The student’s request to appear in front of the Executive Committee to present evidence was rejected and he was informed meeting with the Dean of the School of Medicine would not change the decision. Nonetheless, the Dean met with Corso and conducted his own investigation. The dismissal was upheld, and Corso began litigation against Creighton.

Upon reviewing the case, the District Court held the incident was nonacademic given the student lied about his cheating, and the university did not follow its procedures for nonacademic offenses. Following the decision, the Court of Appeals held it was an academic issue, but agreed that there was a contractual obligation between the school and the student. The student handbook stated “that a University Committee hearing may

be requested in *all* cases involving a *serious* penalty,” with the right to appeal to the President of the university. Relying on the student handbook as the basis of the contract, the Court held that Creighton breached its contract by not allowing the student to appeal to the University’s Committee on Student Dismissal, a university committee outside the School of Medicine. The Court stated that the appropriate procedures specified in the student handbook needed to be followed before the student could be dismissed.²⁵

In *Lee*, a student was dismissed for interference and harassment of a university professor.⁷ The dismissal was considered nonacademic. The legal transcript documented that the student received written notice and was given the opportunity to appear at a hearing also attended by the university professor. The hearing board recommended expulsion, which Lee appealed. The final decision given was “expulsion in abeyance” where the student would be expelled if she further contacted the professor. Subsequently in a multisender e-mail, the professor was contacted and the student expelled for violating a no-contact provision. The student filed litigation claiming lack of procedural and substantive due process when the school upheld the appeal board’s decision. The court found that the student had no clearly established constitutional right to due process based upon her expectation of continued enrollment and that the due process provided was adequate.⁷

Case 5

Michael Stathis was a student at the University of Kentucky. He completed his first 2 years of medical school with distinction. During his clinical OB/GYN rotation, he was found to have made hostile threats against a fellow student. An investigation was performed that documented violations of the school’s Health Sciences Student Professions Professional Behavior Code. A hearing, that Stathis elected, determined that Stathis physically threatened a fellow student while engaged in clinical activities. Similar incidents of hostile behavior directed toward others were also documented. A psychiatric report documented the type of behavior Stathis had was difficult to treat. Based on the totality of the evidence and the school’s responsibility to maintain a “safe and nonthreatening clinical environment,” he was recommended for dismissal without the possibility of readmission. The Dean in writing upheld the Hearing Committee’s decision. An appeal to the university Chancellor upheld the Dean’s decision. Litigation was subsequently instituted claiming gender, racial discrimination, breach of contract, and lack of due process. Regarding the due process claim, the court stated, relying on *Horowitz*, “This case was, of course, a disciplinary proceeding. It seems to us that Stathis was given reasonable notice of the charges against him and the opportunity to respond to those charges. Further, he was afforded a hearing on the charges, and while not permitted to cross-examine witnesses, he was presented with the opportunity to submit questions to the witnesses in advance of the hearing, and those questions were, in fact, so submitted. As such, we cannot conclude, in this regard, that due process was lacking.”³⁰

Amount of Due Process for Academic Dismissals Is Notice and Opportunity to Be Heard

In *Horowitz*, the court stated “the determination whether to dismiss a student for academic reasons requires an expert evaluation of cumulative information and is not readily adapted to the procedural tools of judicial or administrative decision-making.”¹ This tenet is reinforced in *Ewing* where the court states that “[w]hen judges are asked to review the substance of a genuinely academic decision, [such as in *Ewing*], they should show great respect for the faculty’s professional judgment. Plainly, they may not override it unless it is such a substantial departure from accepted academic norms as to demonstrate that the person or committee responsible did not actually exercise professional judgment.”²

In *Horowitz*, the student was proficient in basic science course work but deficient in the clinical curriculum. The Supreme Court commented that “competence in clinical courses is as much of a prerequisite to graduation as satisfactory grades” in the traditional basic science curriculum. Performance in the clinical curriculum is also considered “an ‘academic’ judgment because it involves observation of her skills and techniques in actual conditions of practice.”¹ In a concurring opinion in *Ewing*, Justice Powell stated “Judicial review of academic decisions, including those with respect to the admission or dismissal of students, is rarely appropriate, particularly where orderly administrative procedures are followed.”²

However, the Supreme Court argues in nonacademic cases that procedural due process requires that a “student be given oral or written notice of the charges against him, and if he denies them, an explanation of the evidence the authorities have and an opportunity to present his side of the story.”³³

Due Process in Graduate Medical Education

Failure to provide due process is also considered in cases of residents being dismissed from training programs or not having their contract renewed (Table 6).³⁴⁻⁴³ Inadequate knowledge of basic concepts, lack of clinical skills, failure of in-service exams, and professionalism apply to GME in a similar fashion to UME.

Graduate medical education differs from UME based on residents being students as well as hospital employees. Residents have renewable 1-year contracts based on performance. Where residents are dismissed or do not receive a renewed contract, questions about what level of due process is owed to them, given their simultaneous student and employee status, are raised.

Case 6

Dr Hernandez was an internal medicine resident. During her second year of residency, her contract was terminated based on

observations from the Chief Resident and Program Director that she lacked the clinical judgment required of a second-year resident, failing to offer leadership and guidance to interns, lack of professionalism when dealing with staff, and weakness in clinical decision-making, assessment, and patient follow-up. Following her termination, Dr Hernandez filed an appeal in accordance with the House Officer’s manual for judgment that her dismissal was arbitrary or capricious and not based on documented evaluations. An Appeal Board meeting was scheduled. Dr Hernandez demanded her attorney be allowed to appear and participate in the process and various documents including patient records be provided to her. Initially, Overlook Hospital denied the requests. In order to avoid litigation, Overlook agreed to allow Dr Hernandez’s attorney to attend and provide advice to Dr Hernandez and review relevant documents except for patient records. Overlook refused the attorney from presenting evidence and having a shorthand reporter transcribe the meeting. Dr Hernandez rejected the offer stating that her attorney should be allowed to attend and present evidence, the incident should be transcribed, and she needed to review patient records which served as the basis for the termination. Dr Hernandez brought legal action, the trial court agreed with Dr Hernandez that she be allowed to have her attorney present and participate in the proceedings offering evidence and presenting arguments on her behalf as well as allowing the proceedings to be transcribed. Based on their ruling, an Appeal Board hearing was held pursuant to the trial court order where Dr Hernandez’s attorney was present and the session transcribed. The Appeal Board upheld its decision to terminate Dr Hernandez. Subsequently, the Supreme Court of New Jersey reviewed the case and held that a resident does not have the right to counsel at a private academic hearing and there is no requirement that it be transcribed.³⁶

Case 7

Dr Allahverdi entered a Family Practice residency at the University of New Mexico. Four months after the start of his residency, the Program Director sent him a letter placing him on administrative leave for inappropriate and threatening comments while on duty and for inappropriate communications with coworkers. A psychiatric evaluation was also requested. During the examination, Dr Allahverdi admitted a problem using foul language. The psychiatric evaluation also commented that Dr Allahverdi’s “personality defenses rationalized his behavior and minimize his own blame.” Five months into the residency, the Family Practice Residency Competence Committee notified him in writing, which he acknowledged receipt, that he was being fired for the following conduct: repeatedly calling women derogatory terms in violation of the University’s sexual harassment policy, and Code of Professional Conduct, threatening those individuals who complained about his inappropriate language in violation of University policy against campus violence and falsification of his residency application for failing to disclose a prior residency program he had been enrolled in. Their decision was based on University staff, rotation evaluations, faculty supervisors, his prior undisclosed

Table 6. Graduate Medical Education Dismissal Cases That Raised Lack of Due Process.

Case and Year Decided	Type of Dismissal	Type of Residency	Reason for Dismissal	Outcome
Failure of in-service exams				
<i>Brown v Hamot Medical</i> ³⁴ (2008)	Academic	Orthopedics	Dr Brown was an orthopedic resident in an ACGME-approved residency at Hamot Medical Center. Her program was 5 years in duration with yearly renewable contracts. During her residency, she performed poorly on the orthopedic-in-training examination placing in the bottom 2% during her third year of residency. Issues in clinical judgment were also raised throughout the program. Dr Brown was counseled by her Program Director that she needed to improve her medical knowledge and clinical performance. During her third year, she was notified that her contract would not be renewed. Dr Brown's case was reviewed by a grievance committee, who supported nonrenewal of the contract, which was affirmed by the Medical Education Committee, the Medical Staff Executive Committee, and upheld by the Board of Directors. Dr Brown filed a lawsuit alleging discrimination, breach of contract, and due process concerns.	Nonrenewal of contract upheld
<i>Schaefer v Brookdale University Hospital</i> ³⁵ (2008)	Academic	Urology	Dr Schaefer was a urology resident in a 6-year ACGME-approved residency that consisted of PGY-1 and PGY-2 years in general surgery and the PGY-3 to PGY-6 years in urology. During his PGY-3 year, he scored in the lowest 6 percentile on the urology-in-service examination and had his clinical skills rated below acceptable performance. His annual performance evaluation noted his skills needed to be improved and that his technical skills and hand dexterity were lacking. Despite the above findings, he was promoted to a PGY-4 year to improve his performance. During his PGY-4 year, his in-service-exam score was in the lowest third percentile and his clinical skills were lacking. He was advised to consider a different specialty. He was allowed to enter his PGY-5 year where his in-service exam score was still in the lowest third percentile and his clinical skills did not match his level of training. During a midyear conference with faculty, he was informed he would not be promoted to the PGY-6 year and his contract would not be renewed and that he had no further recourse. Dr Schaefer subsequently filed a lawsuit alleging breach of contract, defamation, tortious interference with a business relationship, and due process concerns.	Nonrenewal of contract upheld
Lack of clinical skills and judgment				
<i>Hernandez v Overlook Hospital</i> ³⁶ (1997)	Academic	Internal medicine	See text Case 6.	Dismissal upheld
<i>Samper v University of Rochester</i> ³⁷ (1987)	Academic	Anesthesiology	Dr Samper was an anesthesiology resident who claimed to have received unsatisfactory academic evaluations during her residency. She filed a lawsuit claiming sex discrimination, defamation, intentional infliction of emotional distress, breach of contract, and violation of her due process rights based in part on inadequate notice of a meeting to discuss her performance and being denied the right to have an attorney present.	Due process claim dismissed
<i>Shaboon v Duncan</i> ³⁸ (2001)	Academic	Internal medicine	Dr Shaboon was a PGY-2 internal medicine resident who presented with mental health issues after working an alleged 108-hour workweek. She was found to be suffering from depression and from psychological and physical exhaustion and had deprived herself of sleep, a normal appetite, and relaxation. She was treated in a mental health facility and left under her own volition before her treatment had been completed. Her Program Director would not allow her to see patients without approval from her treating psychiatrist and she was directed to report to the department conference room to read medical literature. She was subsequently put on probation for mental health reasons and	Due process claim dismissed

(continued)

Table 6. (continued)

Case and Year Decided	Type of Dismissal	Type of Residency	Reason for Dismissal	Outcome
Ross v University of Minnesota ³⁹ (1989)	Academic	Psychiatry	<p>failure to cooperate with mental health practitioners. Several committees that reviewed her case requested access to her medical and psychiatric records in order to reinstate her clinical privileges, which she refused. She was continued on probation and received notice of potential termination due to failure to meet academic requirements and was eventually dismissed. She subsequently filed a lawsuit alleging due process issues and other claims.</p> <p>Dr Ross was a psychiatry resident. From the start, the faculty were concerned about his performance due to anxiety, preoccupation, slurred speech, and difficulty remembering things. He was treated for depression and able to complete his rotations. Midyear, he was notified by the Program Director in writing that the Progress Committee was concerned about interpersonal issues to include failure to respond to pages, slurred speech, and incomplete notes. He was placed on probation due to difficulty to prioritize tasks, work efficiently, work rapidly, and lack of flexibility to manage various tasks. He was evaluated and found to have attention deficit disorder, treated with Ritalin, with some improvement. The Progress Committee recommended he repeat his PGY-2 year to gain more experience in patient care and emergency room management. He was offered a new 1-year contract. During his repeat PGY-2 year, he received mixed evaluations with 1 faculty member commenting that he had serious problems that would affect his ability to function as a psychiatrist. He was told his contract would not be renewed and to look for a new position. In spite of some positive research on tardive dyskinesia, his subsequent evaluations were mixed and he was dismissed. He subsequently filed a lawsuit arguing due process concerns and defamation.</p>	Nonrenewal of contract upheld
Lack of professionalism				
Allahverdi v Regents of University of New Mexico ⁴⁰ (2006)	Academic	Family medicine	See text Case 7.	Due process claim dismissed
Easaw v St. Barnabas ⁴¹ (1989)	Nonacademic	Internal medicine	<p>Dr Easaw was a PGY-2 internal medicine resident whose academic record was positive. His final clinical evaluations during his PGY-2 year were good to excellent. He was offered and signed a contract for a PGY-3 year. After missing work in May of his PGY-2 year, his record was reviewed demonstrating he had the highest absentee record of any Intensive Care Unit (ICU) intern. He was found to have prefabricated having chickenpox. The Hospital Director of Medical Education found this a serious offense and brought it up to the Medical Education committee who terminated him. Dr Easaw alleged he had limited notice of the meeting, limited time to present his version of the facts, and was not notified of his termination until June 29 of his PGY-2 year. He subsequently filed a lawsuit for failure to provide procedural due process for not complying with ACGME requirements and the institution's own policies.</p>	Dismissal deferred. Court required medical center to comply with ACGME criteria and its own internal policy

(continued)

Table 6. (continued)

Case and Year Decided	Type of Dismissal	Type of Residency	Reason for Dismissal	Outcome
<i>Fenje v Feld</i> ² (2005)	Academic	Emergency medicine	Dr Fenje was dismissed from an emergency medicine residency 12 days into the program for his lack of competency to deliver patient care in Scotland. He filed a lawsuit against the Scotland hospital for breach of contract. He subsequently applied for an anesthesiology residency in the United States. Prior to his acceptance into the program, he was interviewed by the Program Director and asked if there were any issues the program needed to be aware about regarding his application, including work in previous training programs and whether he had any "skeletons in his closet." Dr Fenje did not address the prior training in Scotland. He was admitted into the residency after an interview with an executed contract. Several days after execution of the contract, the Program Director received an anonymous phone call disclosing the Scotland residency and difficulties encountered which were confirmed in a phone call with the Scotland Program Director. Dr Fenje was confronted with this information and stated the incident was due to a clash in personalities. The Anesthesiology Department subsequently terminated Dr Fenje's residency for dishonesty in the application and interview process. Dr Fenje filed lawsuit alleging violation of his due process and equal protection rights.	Dismissal upheld
<i>Marmion v Mercy Hospital</i> ³ (1983)	Academic	OB/GYN	Dr Marmion was a PGY-4 OB/GYN resident. During his final year, the Program Director discussed administrative and medical deficiencies in his performance that needed to be addressed for him to be promoted to chief resident and complete the program. His performance improved. As Chief Resident, he confronted the Program Director about a change in the institution's anesthesia policy and that he would not comply with it. He was informed by the Program Director that he might be terminated for not complying with hospital policies. Dr Marmion met with the Program Director and Associate Program Director and was orally notified he was being put on probation and had a number of conditions to comply with. Subsequently, the Director of Medical Education met with Dr Marmion and informed him of the dissatisfaction and grievances the hospital had with him. Dr Marmion followed the conversation by filing a formal grievance according to the hospital policy manual. The Program Director provided Dr Marmion with written notice he was suspended and to vacate the premises until the OB/GYN Residency Review Committee met. The Committee recommended dismissal. The decision was upheld by the Medical Education Committee. Reasons for termination included the inability or willingness to function within the department structure, insubordination, and failure to comply with hospital policies. Litigation followed where due process concerns were raised.	Dismissal upheld

Abbreviation: ACGME, Accreditation Council for Graduate Medical Education.

residency program, and the psychiatrist's evaluation. Dr Allahverdi appealed the decision by filing a grievance. A university GME committee reviewed the record and found "just cause" to support the dismissal but that he should be reinstated and placed on probation subject to several conditions to include zero tolerance for any behavioral difficulties. Dr Allahverdi was notified in writing of the GME committee's constraints which he acknowledged by signing it. A new residency agreement was instituted in early March. Later that month, he received a letter from the Program Director placing him on administrative leave for allegations of misconduct. The Family Practice Committee met and recommended dismissal for violation of his probation based on derogatory language to a hospital employee, failure to complete accurate and timely checkouts, making misrepresentations, and inability to perform all duties of first-year house officers in a satisfactory manner due to inadequate medical knowledge and clinical skills. Dr Allahverdi was notified in writing that he could appeal the decision. Subsequently, Dr Allahverdi challenged the dismissal and raised numerous procedural issues. He subsequently filed a grievance with the University's GME committee. He explained the allegations were unwarranted and requested all documentation made against him. The GME committee met. Dr Allahverdi and his attorney were present. He was allowed to make a statement, answer, and ask questions. The GME committee subsequently interviewed witnesses and ultimately upheld the dismissal. After several procedural challenges, the Dean of the School of Medicine upheld the termination leading Dr Allahverdi to pursue litigation alleging his due process rights were violated.⁴⁰

The Supreme Court of New Jersey in *Hernandez* held that residents are treated as students and therefore subject to the academic requirements of a program.³⁶ Given that Hernandez's dismissal "only involved issues of academic and medical judgment," the relief sought by Hernandez "would diminish the Program Director's ability to exercise academic judgment and deny the Appeal Board the opportunity to apply the procedures that it deems necessary to attain appropriate levels of performance from its residents. As such, Overlook's interest in academic freedom predominates because the relief sought by plaintiff will result in an "appreciable interference" with the Appeal Board's academic judgment." They further commented, "A graduate or professional school is, after all, the best judge of its students' academic performance and their ability to master the required curriculum." Imposition of legal proceedings for purely academic issues would limit academic deliberations.³⁶

Further, "If academic termination hearings are transformed into proceedings that involve legal procedures, the academic hearing would become an adversarial and litigious contest. The panel of doctors would no longer be acting as academics reviewing medical decisions, but rather as judges, ruling on legal issues that they are not trained or qualified to evaluate. The procedure would become complicated, legalistic, and time-consuming and expeditious review of academic judgments would be severely hindered."³⁶ Additionally, "candid

input and evaluations from attending physicians and senior residents regarding the residents' academic performance could be discouraged, raising a concern that residents may escape critical review of poor academic and practical performance. Those evaluations ensure that residents are performing at acceptable levels of competency and professionalism. Without such input, the integrity of the program and the public interest is at stake."³⁶ Given Hernandez's "unique status as a doctor-in-training and considering the strong public policy of ensuring that only qualified physicians serve the public, we find that Overlook is qualified, both substantively and procedurally, to pass judgment on whether plaintiff is fit to practice medicine in its programs. To hold otherwise and not afford great deference to a program's expertise in this area would, in effect, threaten the autonomy of such a program to determine the academic standards by which residents are to be educated, trained, and judged."³⁶

Regarding what is fair procedure, the Court held a fair procedure "includes the right to adequate notice of deficiencies, an opportunity to examine the evidence of those deficiencies used by the hospital to make its academic decision, and the right to present a case to the decision-making authority." The Court continued "a resident also may bring a peer or other physician, including a professor to the hearing. Such a person could consult with the resident and provide a sympathetic ear during the hearings. However, such a person could not act as an adversarial advocate. Those mandates not only accord great weight to the institution's judgment as to a resident's competence but also ensure that all of the relevant evidence is considered and protect against the risk of arbitrary or capricious decisionmaking."³⁶

In *Allaverdi*, the US District Court for the District of New Mexico held the dismissal was academic.⁴⁰ They stated "An academic dismissal is where a student's scholarship or conduct reflects on the personal qualities necessary to succeed in the field in which he or she is studying, and can be based on an at least partially subjective appraisal of those qualities." Based on documentation from the Second Family Practice Committee that outlined 4 reasons for dismissal including, (1) the inability of Dr Allaverdi to follow procedures in patient handoffs, (2) medical knowledge below that expected of first-year house officers (not knowing about cardiac risk factors in a patient with chest pain, not knowing about urine protein content in nephrotic syndrome, and lack of knowledge that one of the patients he managed had a Foley catheter in place), (3) "failure to truthfully report [his] behavior with respect to patient care duties," and (4) "use of unacceptable language in reference to the staff of UNM HSC during the course of patient care activities," the court held the dismissal was academic. Although, as the Court stated, the latter 2 findings may seem disciplinary involving Dr Allaverdi's conduct, however relying on *Horowitz* and other court opinions, they stated that "conduct is academic when it reflects on the personal qualities necessary to succeed in the field in which he or she is studying." Lack of professionalism, lying, and inappropriate language may be viewed as nonacademic "disciplinary" issues; however, the court reasoned that their absence in Allaverdi reflects on the

Table 7. Due Process Considerations in Student Dismissal Cases.

- Due process is a constitutional right that has been incorporated into case law and accrediting body standards.
- Both UME and GME institutions need well-defined criteria that outline academic and professionalism standards and the consequences of not meeting their standards.
- Documentation by faculty is critical if litigation is initiated. Courts will look to the written record in making determinations.^{19,35}
- At the UME level, it is worth having a faculty committee review the performance of students at the end of a clerkship, where the grade is both objective and subjective in nature in contrast to courses or licensing exams that are objective in nature, to preclude complaints that grading decisions are arbitrary and capricious.
- At the GME level, departmental review of resident performance annually, before new contracts are signed or when resident performance does not meet department standards, diminishes substantive due process claims.
- Residents for the most part are treated as students versus employees.
- Framing the dismissal as an academic decision limits the amount of due process needed in contrast to nonacademic (disciplinary action) decisions.
- Written notice, with the consequences of committee action, to students with acknowledgment of receipt of the notice by the student and the opportunity to meet diminishes procedural due process claims for academic dismissals.
- Due process requires that institutional guidelines are followed. In rendering a decision at a departmental or institutional level, the totality of a student's record should be reviewed. The appeal process should be outlined in the institutional policy.
- The Courts recognize that institutions have the right to modify their educational requirements.
- The Courts recognize that disparities may arise in dealing with students on a case-by-case basis given that promotion decisions are made by committee consensus and based on review of the totality of a student's record.⁵⁰
- Implicit in the student's contract with the university upon matriculation is the student's agreement to comply with the university's rules and regulations, which the university is entitled to modify to exercise properly its educational responsibility.
- Student handbooks and catalogs should include the phrase that policies are subject to modification and apply to accepted and current students.

Abbreviations: GME, graduate medical education; UME, undergraduate medical education.

individual's ability to deal in a professional manner with patients and other health-care professionals. Given that Dr Allaverdi's dismissal was academic, the court argued that a hearing was not necessary, all that was required "was the academically dismissed student must have prior notice of faculty dissatisfaction with his or her performance and of the possibility of dismissal, and the decision to dismiss the student must be careful and deliberate."⁴⁰

The initial question the courts address, as outlined above in *Hernandez* and *Allaverdi*, are whether residents are employees or students. Although there is some disagreement, the preponderant opinion by the courts is that residents are treated as students not employees when it comes to dismissal for academic reasons.

In dismissal of an anesthesiology resident for not disclosing information on a residency application that he had been terminated from a previous residency for competency-related issues, the court considered it an academic dismissal based on the nexus between "dishonesty in the application process as undermining his future credibility as a source of information concerning the care of seriously ill patients." The Program Director's "professional judgment that a doctor-in-training who has demonstrated a willingness to withhold damaging information when it serves his purposes cannot be fully trusted to convey all information crucial to the health of the patients committed to his care." This is clearly an academic decision by school officials who possess expertise on the subjective evaluation of medical doctors.⁴² Failure to perform adequately on in-service exams,^{34,35} lack of clinical judgment and skills,³⁴⁻³⁹ pass USMLE Step 3⁴⁴ were also considered academic dismissals. Therefore, the due process afforded academic dismissals

was the guiding principle. In contrast, disruptive behavior and absenteeism in *Easaw*, a resident who was progressing satisfactorily, were considered nonacademic.⁴¹ In *Easaw*, the court treated the resident as an employee with a nonacademic issue resulting in the need for greater due process. Absenteeism, alternatively, if it affected academic performance could be considered as a reason for academic dismissal.⁴¹

Academic Versus Nonacademic Dismissal

The distinction between an academic and nonacademic case is important in determining the due process owed. Tables 5 and 6 outline numerous cases that were treated as academic dismissals and several that were treated as nonacademic (disciplinary) in nature. In the disciplinary cases, students were suspended or terminated for breaking specific "rules of conduct" and insubordinate behavior versus academic dismissals where students lacked the professional qualities required by a profession based on faculty judgment that is subjective in nature.^{40,42}

Nondue Process Claims

Students dismissed for failure of basic science courses,⁴⁵⁻⁴⁷ clerkships,^{45,48,49} Step 3,⁴⁴ and lack of professionalism,⁵⁰ where due process was adequate, have raised equal protection, breach of contract, disability, and discrimination causes of action. Courts have deferred to the standards from *Horowitz* and *Ewing* even where due process was not an issue in adjudicating these causes of action.^{1,2}

Professionalism

Professionalism is also an UME and GME accreditation standard.^{51,52} Each institution sets its own standards consistent with its accrediting body. Failure to comply with institutional standards has led to student dismissal. Although academics are important, professional behavior toward patients, peers, and faculty is just as critical.¹ Failure to show up on time for clinical rotations,¹ not meeting clerkship objectives,¹⁹ deceit in an application,^{40,42} drug conviction,²⁸ or abusive behavior toward a peer^{30, 40} are deemed unprofessional behavior. Tables 5 and 6 outline several cases where professionalism was an issue. In adjudicating student dismissal cases for unprofessionalism, the courts utilized the standards outlined above on whether the issue was academic or nonacademic in determining the amount of due process owed the student.

Lapses in professional judgment are sometimes difficult to “prosecute” as compared to purely academic issues. They are often difficult to address with students, residents, and even faculty. These lapses may eventually lead to disciplinary actions by state medical licensing boards.⁵³ These failures are at times ignored or passed up the chain of command when there were findings to terminate the student or resident earlier in the educational continuum.⁵⁴ The courts will look to the judgment of the faculty on whether the individual in question met the institution’s standards provided due process was adequate.² In dealing with these type of cases, documentation is critical. With adequate documentation, promotions committees and residency review committees have a record they can use in reviewing the totality of a student’s record to render a decision.

Conclusion

Inherent in any academic enterprise are students who lack the academic ability or have unprofessional attributes in their behavior. Academic institutions have a responsibility to protect the public and may need to remediate or dismiss students. Student dismissal has the potential to lead to litigation by deprivation of potential liberty or property interests without due process. Due process considerations in student remediation/dismissal are summarized in Table 7.

Noteworthy is that in several UME and GME cases, committees that evaluated the entire student or resident’s record recommended dismissal. On appeal to a dean or other administrator, the committee’s decision was not upheld. As documented above, many of these cases continued on to litigation creating more work for faculty and potentially compromising patient care at the GME level.

As outlined in *Horowitz*, the courts will usually uphold a school’s decision to dismiss a student where the entire student record has been reviewed, due process provided, and the institution complied with its own policies that were made available to students on matriculation.^{1,2} For nonacademic decisions, more due process is required. As Justice Powell commented in *Ewing*, “Judicial review of academic decisions, including those with respect to the admission or dismissal of students,

is rarely appropriate, particularly where orderly administrative procedures are followed.”²

Authors’ Note

The opinions expressed are those of the authors and do not reflect the official positions of the Uniformed Services University, the US Army, Navy, Air Force, or DoD.

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The Johns Hopkins Department of Pathology Novel Organizational Model: A 25-Year-Old Ongoing Experiment

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Abstract

In 1993, the present Department of Pathology at Johns Hopkins was established with the leadership of a new chair (ie, referred to as department director at Hopkins) and upon the integration of 3 separate and independent departments at the Johns Hopkins School of Medicine (Pathology) and the Johns Hopkins Hospital (Pathology, Laboratory Medicine). This new department was organized into 17 divisions, each of which was expected to develop and maintain significant clinical, educational, and research programs of excellence. To facilitate performance and alignment across missions and parent organizations, a novel professional and administrative structure was created. Professionally, vice-chairs (ie, deputy directors) for research, teaching, and patient care were appointed to oversee and coordinate these activities across all units of the department. Likewise, to focus and enhance expertise, individual administrators were appointed for academic, clinical, and business affairs. A departmental executive committee was created consisting of the vice-chairs and administrators, which was presided over by the chair. Simultaneously, substantial effort was put into measuring and improving the organizational culture using evidence-based methods. Significant improvements were documented by the year 2000 in departmental performance in research, education, clinical service, culture, and finances. Under 2 successive leaders, the department has maintained its eminence across missions and financial performance. This 25-year experience supports the tenet that innovative and strategic organizational structures and functional alignments can provide sustainable competitive advantages in performance.

Keywords

Department of Pathology, organizational structure, performance, culture, outcomes, strategic priorities

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Introduction

Clinical departments must balance competing priorities of their missions (ie, clinical service, education, and research) while aligning priorities with those of their parent organizations (ie, university, health system, physician practice).¹ For pathology, there is also complexity related to perceived and real divisions between “anatomic pathology” (AP) and “laboratory medicine” (LM) or “clinical pathology” (CP). AP and LM/CP are often separate operational and administrative units within

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Table 1. Mission and Organizational Alignments.

Missions (Organizational Units)	Business Models	Culture	Performance Measures
Research (schools, hospitals)	Return on investment	Innovation	Funding Papers Impact
Education (schools, hospitals)	Service	Academic	Student quality Job placement Rankings
Health care (hospitals, practices)	Profit and loss	Command-control	Clinical quality Revenue Net income

departments of pathology and, in some cases, are even distinct medical school departments.

Across academic health centers (AHCs) in the United States, the organization of pathology and LM departments varies greatly. Some departments of pathology are based entirely in a school of medicine, while others in academically oriented hospitals and usually associated with departments in an affiliated medical school. Most, however, span both the medical school and hospital of an AHC. In some cases, other disciplines, notably immunology, microbiology, and anatomy, are also included in pathology departments.

Developing structural integration and functional alignment across the missions and organizational units of an academic department or medical center is difficult in part because of differences in measures of performance, as well as differences among each component's business model and behavioral norms and expectations (ie, culture; Table 1). The value of proper alignment was demonstrated in a recent study of 85 AHCs, which showed that their structural integration across organizational units was associated with functional alignment, which in turn was associated with measures of performance across missions.²

Adding to the complexity of aligning structure and function to mission is the relationship of performance to culture. Organizational performance has been shown to be associated with its culture in both businesses³⁻⁵ and AHCs.^{6,7} Specifically, "constructive" styles of organizational culture (eg, humanistic-encouraging, affiliative, self-actualizing, and achievement) are strongly associated with higher performance than passive/defensive or aggressive/defensive cultures.⁸ The ability to sustain high performance in a competitive environment is tied to many factors, the most important of which is developing signature organizational structures, functions, and cultures that are hard for others to duplicate.⁹

Here we present an "experiment" conducted in a large, multidisciplinary academic pathology department demonstrating that novel organizational structural and functional changes designed to enhance performance across missions and to promote a constructive culture can result in rapid short-term improvement in performance across missions and operations. With 25 years of follow-up, we also show an enduring trajectory of high performance.

Methodology

Departmental Structures and Functions Prior to 1993

Prior to 1993, the Johns Hopkins Hospital (JHH) had 2 independent departments: pathology (AP) and LM (CP), while the School of Medicine (SoM) had a separate academic department of pathology (Figure 1). Historically, the chair of the academic department in the SoM was also the chair of pathology (AP) in the hospital. With the retirement of Dr Robert Heptinstall as chair of the JHH and SoM departments of pathology in 1988, 2 interim directors, Drs John Boitnott and John Yardley were appointed to chair the 2 respective entities. The Department of Laboratory Medicine in JHH continued to be chaired independently by Dr Robert Rock. From the perspective of organizational structure and function, these 3 departments were independent, with separate budgets and reporting relationships, as well as different priorities and measures of success.

The lack of functional alignment was evident in reporting structures. While the academic department of pathology reported to the dean, the 2 hospital departments reported to the JHH chief financial officer, a clear sign that the mission of those departments was focused more on revenue than on clinical research and quality of clinical service. For individual faculty, structural features exacerbated problems aligning missions. All physicians performing clinical services in JHH were required to have a faculty appointment in the SoM. While virtually all faculty in JHH Pathology had their primary faculty appointment in the SoM pathology department, most (but not all) physicians in the JHH Department of Laboratory Medicine had appointments in the Department of Medicine. Leaders were given responsibility for departmental performance, but not commensurate authority over personnel and resource allocation. Many diagnostic labs at Hopkins were physically dispersed in other departments in JHH and in the SoM with no accountability to LM or pathology.

This structure also had a negative impact on research and education, as the JHH departments provided no direct incentives for these activities. Although JHH provided limited funds through a "joint agreement" to the SoM department, which could be used to support faculty research and educational activities, there were no funds made available for these activities in the 2 JHH departments. Because the Johns Hopkins University (JHU) SoM has only a single tenure-track for all Hopkins faculty, it became difficult for those faculty engaged primarily in hospital activities to earn promotion. Graduate and fellowship training positions were relatively limited, and the ability to recruit residents suffered from a lack of AP-CP integration. There were independent residency programs in AP and CP administered by the JHH Department of Pathology and Laboratory Medicine, respectively. Applicants to one program were not guaranteed combined AP-CP training nor permission to complete rotations in the other program.

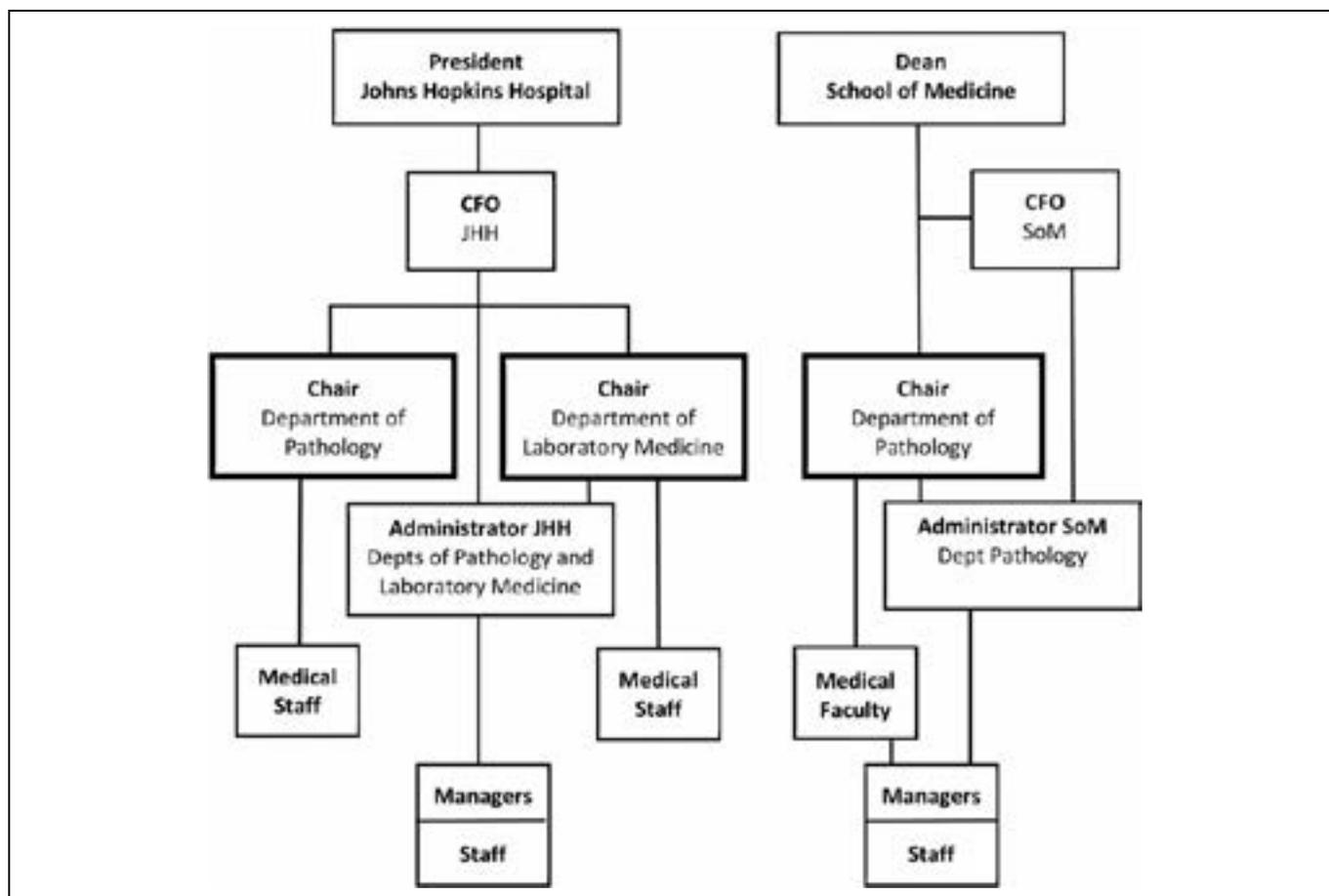


Figure 1. Three independent Departments of Pathology and Laboratory Medicine, prior to 1993. Left: Two distinct clinical departments of Pathology and Laboratory Medicine were led by chairs reporting to the Johns Hopkins Hospital chief financial officer (CFO). Right: The academic Pathology department chair reported to the dean of the School of Medicine and the School of Medicine CFO.

Rationale and Process of Creating a Unified Department: Johns Hopkins Pathology

Despite the lack of functional synergy among the 3 departments prior to 1993, both JHH and SoM had a long history of valuing pathology as a basic and clinical science. The founding dean of Johns Hopkins, Dr William Henry Welch, was also chair of the pathology department, so it is not surprising that the inaugural chairs of other departments all highly valued pathology. The first chair of medicine, Dr William Osler, remarked often on the importance of pathology and that the quality of pathology set the tone for the quality of the institution.¹⁰

The importance of pathology was still recognized by institutional leadership into the early 1990s, and there was a strong desire to enhance the stature of pathology and its contributions to both Johns Hopkins Health System (JHHS) and JHU SoM. A failed national search for a new director following the retirement of Dr Heptinstall in 1988 was largely due to the lack of resources available at the time. After the new Ross Research Building was opened in 1992, with 2 floors allocated to pathology, and with increased funds appropriated for recruitment, the SoM Dean Dr Michael Johns and the newly appointed CEO of JHHS, Dr James Block, reinitiated a chair search.

In 1992, Dr Fred Sanfilippo offered a vision for a unified department and was recruited as both the department chair (JHU SoM) and pathologist-in-chief (JHH and JHHS). It was agreed with both Drs Johns and Block that the 3 departments would be completely integrated into a new single department of pathology, that is, Johns Hopkins Pathology (JHP). It was also agreed that the new chair would have full authority over operational, financial, and personnel matters of the previously 3 independent departments, including “hire-and-fire” authority over JHH and SoM staff employees. The new chair of the integrated department reported directly to the CEO of JHH and the dean of JHU SoM (Figure 2).

Dr Sanfilippo was also given responsibility for the quality of laboratory and pathology services throughout the JHH and JHU SoM, regardless of the department in which the services were provided. As stated in the agreement letter of September 30, 1992, signed by Drs Block, Johns, and Sanfilippo,

Consistent with the concept of a unified Department of Pathology, we agree that all Pathology services in the Johns Hopkins Hospital that are not directly under the Department of Pathology should operate with the concurrence of the

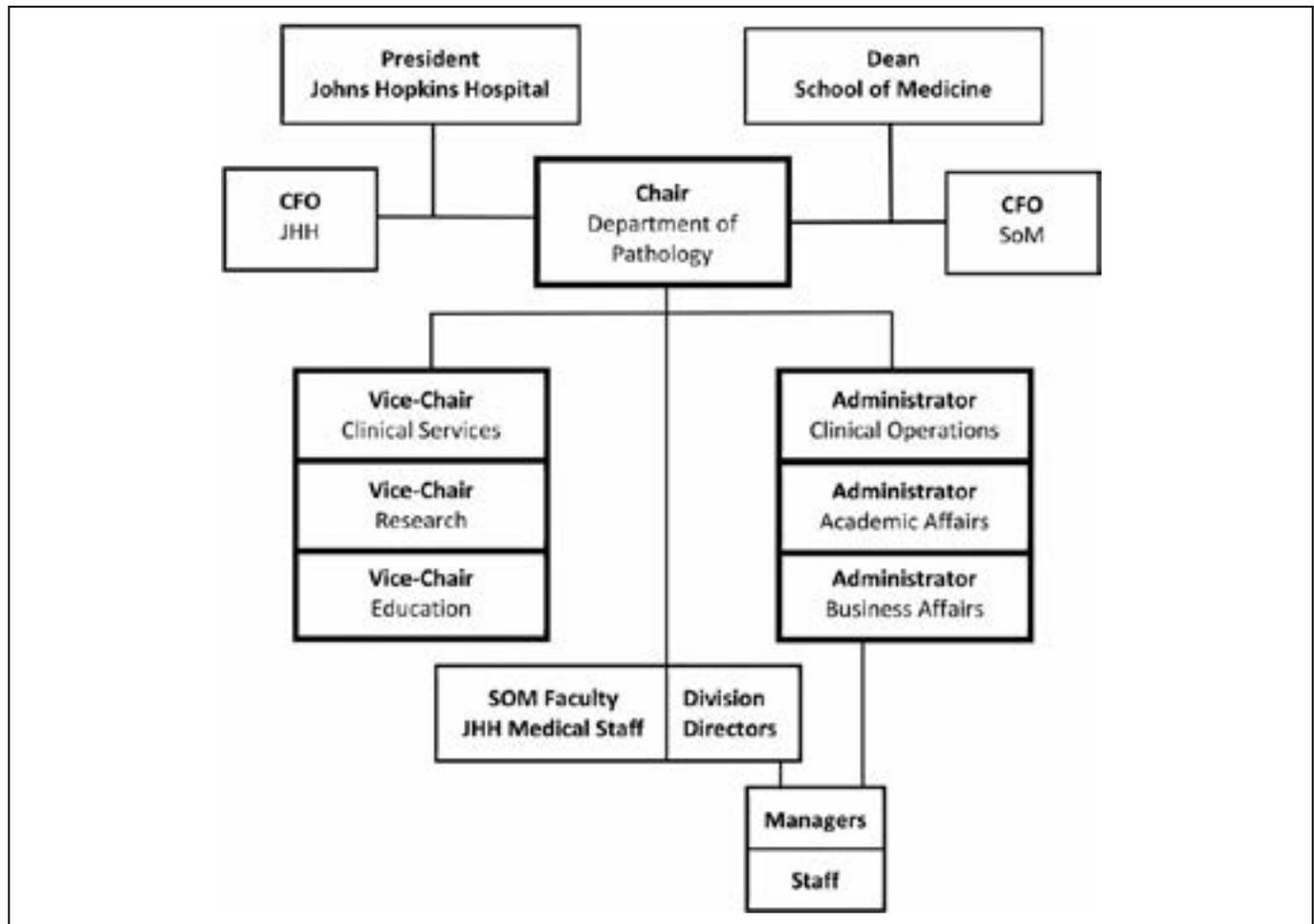


Figure 2. Unified JHP department organizational structure, established in 1993. A single chair led the unified department, with reporting responsibilities to both the president of the Hospital and the dean of the School of Medicine. Three vice-chairs were delegated responsibilities in the areas of clinical services, research, and education, and three administrators were appointed for clinical operations, academic affairs, and business affairs. JHP indicates Johns Hopkins Pathology.

Pathologist-in-Chief who will be responsible for the overall quality of the service.

Consistent with the concept of a unified Department of Pathology and the development of a reference laboratory, we are supportive of the goal of having all “University labs” and the laboratories of the Cancer Center that undertake specialized and routine diagnostic testing operate with the concurrence of the Pathologist-in-Chief who will have overall responsibility for the quality of these services.

The Johns Hopkins Pathology Experiment

In return for the structural changes in the department and the delegation of significant authority and resources to the chair, institutional leadership had high expectations for improvements across all missions. To meet these expectations, Dr Sanfilippo and the department leadership team engaged faculty and staff to effect the changes needed to achieve specific goals. Their primary focus was to align the structure and function of operational units to optimize not each individual component but performance of the department as a whole. The process was

framed at the time as “The Johns Hopkins Pathology (JHP) Experiment.” Tables 2, 3, and 4 outline the formal hypotheses, specific aims, and methods of the experiment, respectively. Academic, financial, and cultural outcomes were planned to be measured regularly to determine success.

Hypotheses. The first hypothesis (Table 2) was that integrating clinical services offered by pathology and lab medicine (ie, AP, CP) would improve quality. To reinforce the notion of a single entity providing diagnostic services, Dr Sanfilippo requested that the new unified department be named Pathology rather than Pathology and Laboratory Medicine. The second hypothesis was that diagnostic pathology is a consultative physician specialty, not a “hospital-based” service. Pathologists performing clinical services brought professional clinical expertise and were to be viewed similarly to other academic physicians, not just as staff overseeing services for the hospital. The third hypothesis was that integrating faculty clinical and research activities would improve overall productivity, opportunity, and achievement. The final hypothesis was that organizational (ie,

Table 2. The JHP Experiment: Hypotheses (1992).*

Structure–function relationships
<ul style="list-style-type: none"> • Integrated “AP” and “CP” clinical services improve value to patients, physicians, trainees, and staff. • Diagnostic pathology is a consultative physician specialty, not a hospital service. • Integration of the clinical and research activities of faculty improves overall productivity, opportunity, and achievement in each. • Departmental values and culture impact faculty and staff productivity and satisfaction.

Abbreviations: AP, anatomic pathology; CP, clinical pathology; JHP, Johns Hopkins Pathology.

*Original hypotheses as stated in 1992.

Table 3. The JHP Experiment: Specific Aims (1993).*

Clinical
Focus on high quality
<ul style="list-style-type: none"> • Demonstrate added value, cost-effectiveness • Esoteric, specialty, second opinion services
Leverage services with research and education
<ul style="list-style-type: none"> • Biotech and informatics R&D, assessment • Tech transfer, outcomes studies, CME
Enhance infrastructure, unit cost
<ul style="list-style-type: none"> • Billing, regulatory expertise • Optimal volume growth, partnerships • Consolidate, coordinate services: Johns Hopkins Medical Labs
Research
<ul style="list-style-type: none"> • Support physician-scientists: opportunity, flexibility • Expand basic research to complement clinical service • Access best trainees for basic and clinical research • Improve research infrastructure and resources • Enhance technology and translational research • Develop corporate sponsorship • Priorities: immunology, cardiovascular, micro-HIV
Education
<ul style="list-style-type: none"> • Improve quality of residency: service, research • Enhance medical student teaching: core, electives • Expand fellowship programs: basic, clinical • Develop graduate student program: virtual, actual • Enhance allied health programs • Improve infrastructure: resources, organization • Market educational products: CME, text

Abbreviations: CME, continuing medical education; JHP, Johns Hopkins Pathology.

*Original specific aims as stated in 1993.

Table 4. The JHP Experiment: Methods (1993).*

Performance change
<ul style="list-style-type: none"> • Develop consensus on mission, values, goals • Create a departmental structure to facilitate function • Develop decision and resource allocation methodology • Create linkage of all departmental resources • Drive and promote changes as experiments • Assess, change organizational culture: incentive and achievement versus entitlement

Abbreviation: JHP, Johns Hopkins Pathology.

*Original methods as stated in 1993.

departmental) values and culture would have a significant impact on employee (ie, faculty and staff) productivity and satisfaction.³⁻⁷ There was strong support for testing all 4 of these hypotheses, with the sense that the process would significantly enhance departmental performance.

Specific aims. The specific aims of the JHP Experiment were broken down by clinical, research, and education missions as shown in Table 3, and they included anticipated tactics to achieve the strategic priorities of each aim.

Clinical specific aims focused on improving the quality, scope, and value of services. Tactics identified included expanding esoteric, specialty, and second opinion services; improving billing and regulatory processes; developing commercial partnerships; and forming a consolidated reference service lab (Johns Hopkins Medical Labs [JHML]) to provide a portal for outside consumers to access all diagnostic services at JHH and JHU SoM.

Research specific aims included supporting physician-scientists, enhancing technology and translational research, and recruiting and engaging the best basic and clinical research trainees. Priority was given to particular areas of investigation based on perceived opportunities. Tactics included leveraging research programs to complement clinical services, improving research infrastructure and resources, and obtaining corporate sponsorship for suitable research and development projects.

The top specific aim in education was to improve the quality of the residency program. This was to be accomplished by integrating AP and CP training, providing residents with more research and broader service opportunities, creating more research and clinical fellowships for training beyond residency, and improving infrastructure supporting the residency program. Other educational specific aims were to enhance the medical student experience in the pathology core course and expand electives, enhance allied health programs, and develop a pathobiology PhD graduate program. Tactics included increasing resources for educational initiatives and administration of departmental educational programs and developing educational products and services such as textbooks and continuing medical education (CME) courses.

Methods

The methods proposed to test the hypotheses, achieve the specific aims, and drive performance change are shown in Table 4. The key approach was to first develop consensus on the new department's mission, values, and goals and subsequently to create a departmental structure to reflect these priorities and meet these goals. This involved defining operational units (ie, divisions and programs) and leadership positions (ie, division directors, vice-chairs or deputy directors, and administrators).

Several additional processes were proposed to achieve department goals, including developing decision and resource allocation methodologies, linking and aligning all departmental resources, driving and promoting changes as experiments, improving organizational culture and achievement by

Table 5. JHP Department Faculty/Staff Engagement.

Annual one-on-one faculty-director meetings
– Summary of achievements
– Review expectations for coming year
– Career planning, promotion
Development of a new department faculty compensation plan ¹¹
– Part A: standardized for rank and years at rank
– Part B: roles and responsibilities
– Part C: incentive for performance expectation for each mission area
Establishment of department-wide meetings
– Regular faculty meetings to review resources, update performance
– Weekly Pathology Grand Rounds: faculty and trainees
– Monthly CPC with other departments
– Annual off-site retreats to discuss strategy, tactics, performance (Table 7)
Restructure of department leadership
– Division directors with line authority, responsibility; direct report to director
– Deputy directors for research, education, clinical services to coordinate activities across divisions without line authority; direct report to director
– Administrators for academic, clinical, and business affairs
– Executive Committee (Pathology Operations Group, POG) of deputy directors and administrators with operational authority, responsibility
Provide resources to promote productivity
– Resource allocation transparency based on strategic priorities
– Departmental professional development and tech transfer director
– Research Advisory Committee: review, advise, assist extramural grant submissions

Abbreviations: CPC, Clinical-Pathological Conference; JHP, Johns Hopkins Pathology.

providing incentives, and continuously assessing outcomes and performance.

Faculty/Staff Engagement

A major priority of the JHP Experiment was to enhance faculty and staff engagement. Table 5 lists the activities used to achieve this goal. The department was among the first to institute annual one-on-one meetings between each faculty member and the chair to review performance across each mission, to assign administrative responsibilities, and to agree on expectations for the coming year. A priority of the review was to ensure that appropriate resources to support each faculty member's productivity were provided to enable their eventual promotion to full professor with tenure under Hopkins' rigorous single-track promotion system. In addition, a new department faculty compensation plan¹¹ was developed that comprised 3 components: academic rank and years in rank (part A), administrative roles and responsibilities (part B), and bonus based on performance relative to expectations (part C). The annual review, by designating time to discuss responsibilities and performance, provided every faculty member the opportunity to understand the basis for his or her compensation.

Table 6. Off-Site JHP Department Faculty and Staff Retreats.

Date	Topic
January 1994	Changing the Paradigm, Culture
March 1994	Follow-Up to January '94 Retreat
November 1994	Collective Academic Mission
April 1995	Teaching/Education
December 1995	Department Structure, Policies, Processes
April 1996	Improving Efficiency and Effectiveness
November 1997	New & Alternative Revenue Sources
November 1998	Opportunities to Prioritize Future Growth
March 2000	Defining the Cutting Edge

Abbreviation: JHP, Johns Hopkins Pathology.

To communicate changes to the faculty, and to engage them in the reorganization process, a 2-day off-site retreat was held in January 1994, with a second retreat to follow up on issues raised 2 months later. The success of these retreats led to a series of regular, mostly 1-day off-site retreats (Table 6), held at frequencies to match the pace of change. Subsequent retreats focused on specific topics agreed upon by department leadership, with different faculty members assigned to design programs and lead discussion, with the goals of addressing critical issues as well as engaging a variety of faculty in the process. To provide transparency, each retreat began with an introduction of new faculty, a description of any administrative changes, and an update on departmental financial performance.

Culture Inventory Assessment

As a component of the JHP Experiment, surveys of all full-time faculty and senior administrative staff were conducted to assess organizational culture. A commercially available culture assessment, the *Organizational Culture Inventory* (OCI; Human Synergistics)¹² was used to measure culture. The results are displayed as percentile scores on a circumplex with 12 cultural norms grouped into 3 clusters.⁷ The OCI surveys of participants were coded to maintain anonymity and were taken longitudinally in years 1 (1993), 4 (1996), and 7 (1999) of the JHP Experiment. During this period (1993-1999), several faculty left the department, and other new faculty were recruited into the department. It should therefore be noted that there was some, but not complete overlap in the study participants.

Outcome Tracking and Follow-Up

Outcome measures were identified for research, education, clinical service, faculty, and financial performance. Measures were tracked annually from 1992 through 2001 and presented at faculty and staff meetings and annual retreats.

Results

Changes in Departmental Structure and Administration

The initiating event of the JHP Experiment was the consolidation of 3 pathology and LM departments (Figures 1 and 2). This

Table 7. JHP Department Divisions Established in 1993.

Divisions	Associated Labs/Clinical Services
Autopsy pathology	Autopsy service
Cardiovascular pathology	
Clinical chemistry	General chemistry lab Toxicology lab Special chemistry lab
Comparative pathology	
Cytopathology	Cytopath lab
Gastrointestinal-liver pathology	GI path lab
Gynecologic pathology	GYN path lab
Hematopathology	Coagulation/special hematology lab Flow cytometry lab
Immunopathology	Diagnostic immunology lab Immunopathology lab
Informatics	Image analysis Path data systems (PDS) Photography lab/graphic services
Kidney/genitourologic pathology	
Medical microbiology	Bacteriology lab Microimmunology lab Special microbiology lab Mycology lab Virology lab Parasitology lab Mycobacteriology lab
Molecular pathology	Molecular One lab
Neuropathology	Neuropathology lab
Pediatric pathology	
Surgical pathology	Electron microscopy Histology labs
Transfusion medicine	Blood bank

Abbreviations: GI, gastrointestinal; GYN, gynecologic; JHP, Johns Hopkins Pathology.

facilitated other changes in department function, culture, and performance. In the context of this restructuring, 17 divisions were created, each of which was expected to have substantial and high-performing activities in clinical service, research, and education (Table 7). Directors were appointed to lead each division and reported directly to the chair.

This novel divisional structure was created to fully integrate the traditional pathology department divisions and operational units of AP, CP, and experimental pathology. For example, the new Division of Hematologic Pathology included what traditionally had been tissue hematopathology in the department of pathology (AP) and clinical hematology in the department of LM (CP). The new Division of Neuropathology combined the research division in the SoM Department of Pathology with the AP services in the JHH department. The new Division of Informatics was created in anticipation of its future importance, and this quickly became a hub of health services and outcomes research with substantial research funding, while at the same time operating the laboratory information system for the JHH.

New department-level leadership positions were created to enhance alignment, improve operational efficiency, and help

decentralize decision-making (Figure 3). Two vice-chair (deputy director) positions were created initially to oversee clinical services and administrative activities, which were filled by Drs Patricia Charache and John Boitnott, respectively. Shortly thereafter, the vice-chair position for administration was split into vice-chairs for research and education. Drs Donald Price and Michael Borowitz were appointed, respectively, providing a total of 3 vice-chairs to oversee the 3 mission activities of clinical services, research, and education. Dr Brooks Jackson was subsequently recruited as vice-chair for clinical affairs. While division directors had full delegated authority for decisions within their divisions and reported directly to the chair, they also had dotted-line reporting responsibility to the vice-chairs as appropriate. Issues beyond a division could be resolved when the appropriate division chief(s) and vice-chair(s) agreed. In cases where there was no agreement, issues were brought to the Pathology Operations Group (POG; see below) for resolution.

Three new administrator positions, responsible for academic, clinical, and business affairs, also were created to span all divisions and activities across the new department. Mabel Smith, the previous administrator for the pathology department in the SoM, was appointed administrator for academic affairs, and James Creech, the previous administrator for the JHH pathology and lab medicine departments, was appointed administrator for clinical operations. Edward Pigo, an expert in business, finance, and the reimbursement system in the state of Maryland, was recruited to the position of administrator for business affairs. New job descriptions for each of these positions were intended to focus their activities, avoid overlap, and promote collaboration. A departmental executive committee, the POG, was appointed consisting of the vice-chairs and administrators, which met weekly to review progress and deal with operational as well as strategic matters.

Change in Departmental Organizational Culture

Results of the baseline OCI survey made in 1993 are shown in Figure 4. These demonstrated a low-performance culture characterized by tendencies toward “aggressive/defensive” styles and low “constructive” styles. Concurrent with changes in departmental organization and the methods used to engage faculty and staff as described above (Tables 5-7), departmental OCI surveys showed desirable changes in 11 of 12 styles by 1996 (Figure 4). These encompassed gains in all 4 subcategories of constructive styles (achievement, self-actualizing, humanistic-encouraging, and affiliative) and reductions in aggressive/defensive and passive/defensive styles. By 1999, all 12 styles had changed in a desirable direction (Figure 4). The most notable changes were the large increases in constructive styles, showing a mean increase from the 38.5th to 68.0th percentile ($P < .001$). Desired decreases were also seen in all passive/defensive styles (mean 44.3-22.8, $P < .039$) and all 4 aggressive/defensive styles (mean 67.0-54.0, $P < .10$).

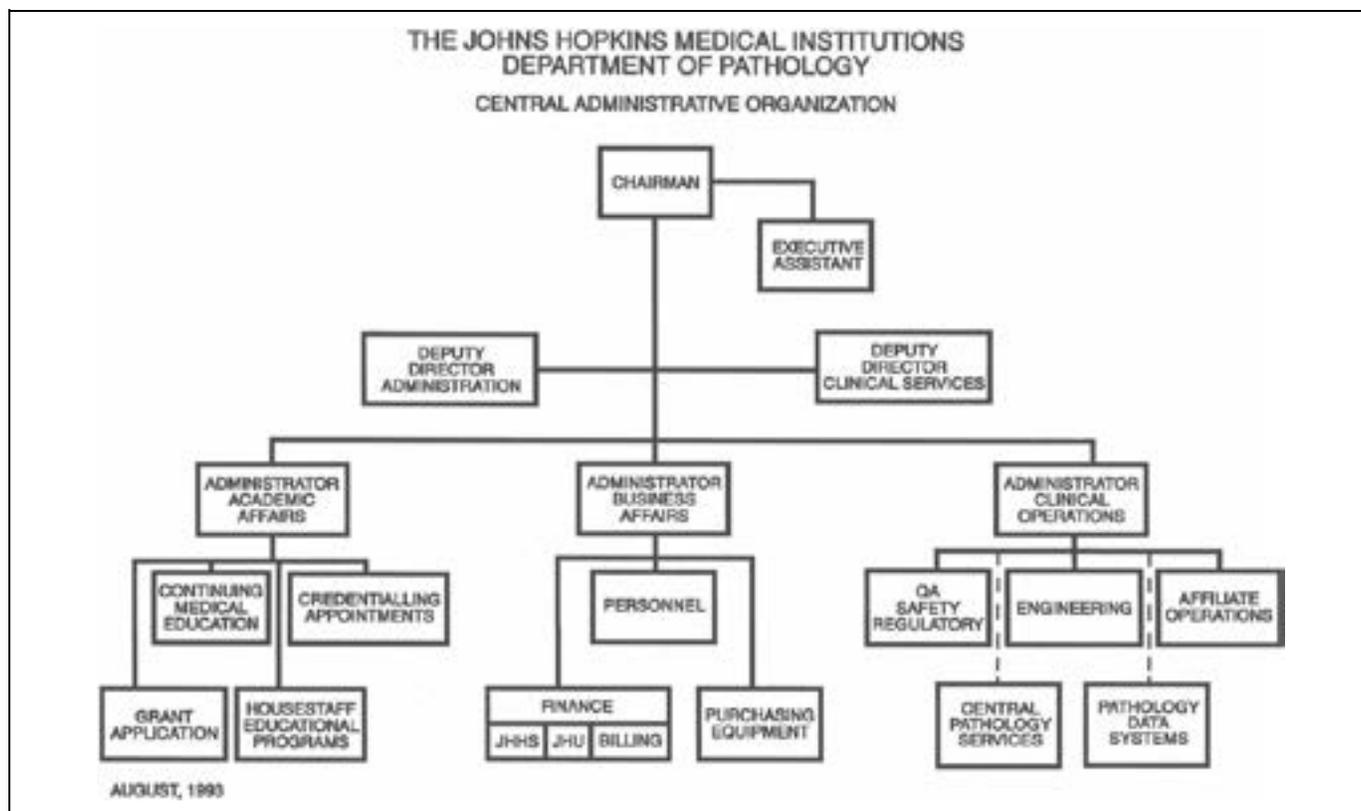


Figure 3. The JHP administrative organization, original chart from 1993. Three administrators led department operations in the areas of academic affairs, business affairs, and clinical operations. Note the deputy director (vice-chair) position for administration was divided into vice-chairs for research and education by late 1993. JHP indicates Johns Hopkins Pathology.

Performance Improvement 1992 to 2000

Clinical services. Immediately prior to the consolidation in 1992, there were more labs outside the 3 pathology-lab medicine departments (18) than were within the 3 departments (17), and these had inferior performance based on Joint Commission on Accreditation of Healthcare Organizations (JCAHO) survey data. The outside labs were responsible for all 24 serious type 1 deficiencies (Table 8). To address this situation, the vice-chair for clinical affairs was delegated authority to inspect all labs across the institutions, and a full-time expert in quality assurance was hired to help perform the detailed reviews. Outside labs unable to meet quality standards set by the Department of Pathology were closed with the concurrence of their department chairs. As a result of these changes, 1995 and 1998 inspections identified no type 1 deficiencies (Table 8).

Improvement in service quality was accompanied by improved cost performance. Prior to 1993, JHH lab services costs ranked in the top 20 of 47 hospitals in the state based on the Maryland Health Services Cost Review Commission at \$0.91/RVU. By 1999, JHH ranked as the third lowest in lab services cost (45 of 47) with direct expenses of \$0.54/RVU compared to the Maryland state and Baltimore city averages of both \$0.73/RVU (Table 8).

To further enhance and expand services, a commercial reference laboratory, designated the JHML, was created to offer

specialized laboratory tests and consultative pathology services. In providing a single portal for these services across Hopkins, it helped to rapidly grow these activities and their associated revenue.

Research. Between 1992 and 2001, the department saw a 4-fold increase in the number of grant awards, from 30 to 117, and a commensurate increase in extramural-sponsored funding (total costs) from \$5.9 million to over \$25 million (Table 8). National Institutes of Health (NIH) R01 grants increased 5-fold from 5 to 27 with a doubling of funding from \$2.8 million to \$5.6 million. This increase in research and development activity led to an increase in technology transfer activity, which increased significantly from an annual average of 19 inventions, patents, licenses, and agreements to 89, with a revenue increase from \$3000 to \$147,000.

A major factor contributing to the success of research activities was the recruitment of new research faculty members and an increase in the number of clinically oriented faculty engaged in research. Also contributing was an improved infrastructure for faculty engaged in research. This included the creation of a departmental Research Advisory Committee under the vice-chair for research, which helped individuals in the grant writing and submission process, as well as hiring a full-time expert in technology transfer and fund-raising.

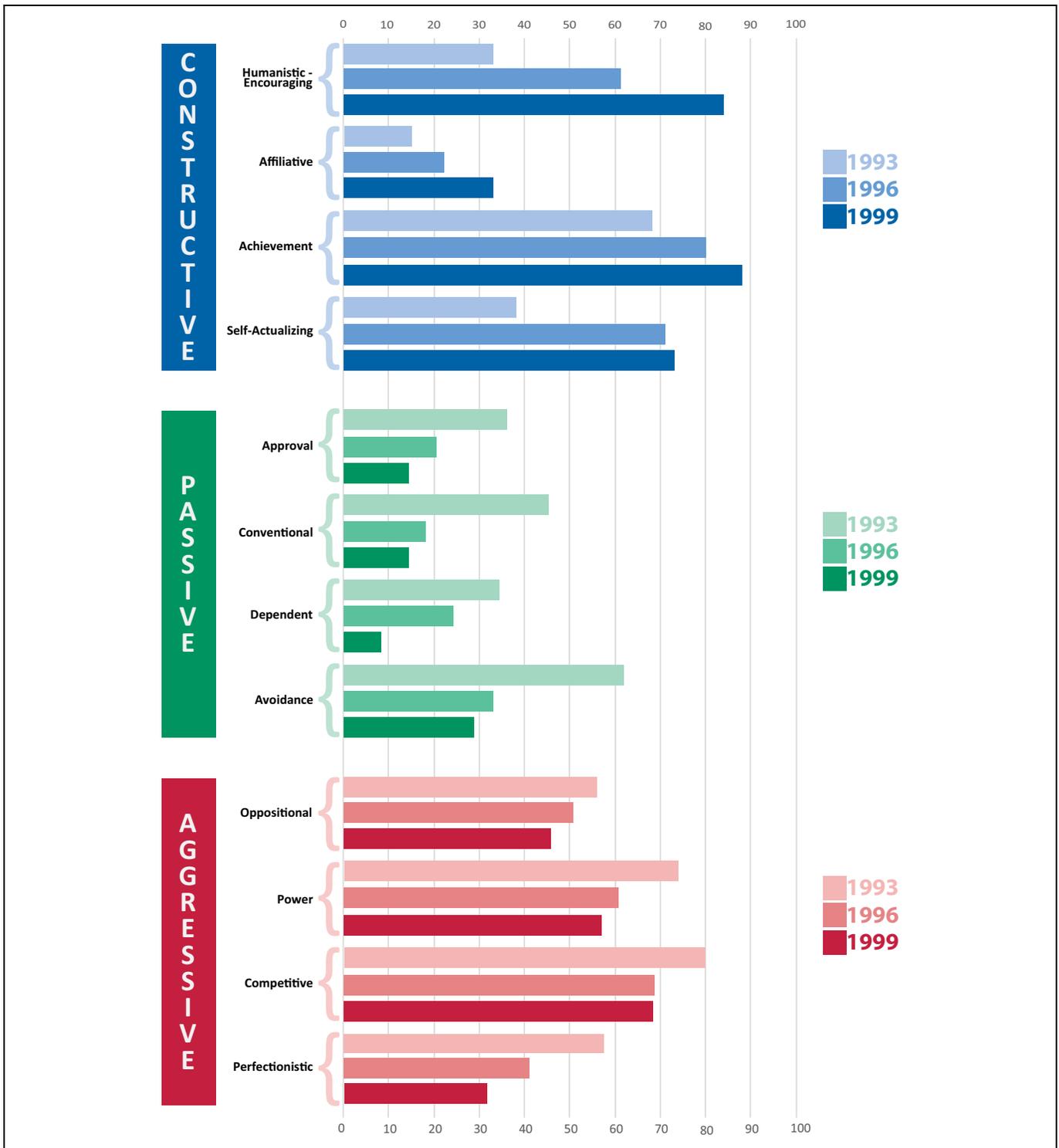


Figure 4. The JHP department *Organizational Culture Inventory* changes. Results are shown from 3 successive surveys in 1993, 1996, and 1999. Trends show gains in all constructive styles (blue), including humanistic-encouraging (33%-84%, +151%), affiliative (15%-38%, +153%), achievement (68%-88%, +29%), and self-actualizing (38%-73%, +92%). There were concurrent decreases in aggressive/defensive (red) and passive/defensive (green) styles. JHP indicates Johns Hopkins Pathology.

Education. The integration of the AP and CP residency programs gave JHP residents flexibility to enroll in AP or CP or AP-CP programs and to move from one program to another during their training. Two chief residents were selected

annually by the chair to assist with program administration and serve as liaisons between residents and department leadership. A large, centrally located residents' room was constructed. Each resident was provided support to attend one national

Table 8. JHP Department Short- and Long-Term Performance Changes.

	1992-1993	2000-2001	2016-2017
Clinical			
Quality: JCAHO type I deficiencies (all labs)	24*	0	0 [†]
Quality: JCAHO total deficiencies (all labs)	55	10	6 [†]
Scale: Number of department (all) lab services	17 (35)	38 (63)	22 (39)
Efficiency: Lab services unit cost (HSCRC rank)	<20/47	45/47	NA [‡]
Efficiency: Lab services unit cost (\$/RVU)	0.91	0.54	0.97
Research			
Grants/contracts (annual total number)	30	117	182
Extramural-sponsored funding (annual total cost)	\$5.9 million	\$25.4 million	\$67.7 million
NIH R01 grants (annual total number)	5	27	19 [§]
NIH research grants (annual direct cost)	\$2.8 million	\$5.6 million	\$53.7 million [§]
Technology transfer (inventions, patents, agreements)	19	89	111
Technology transfer (royalty revenue)	\$3000	\$147 000	\$716 000
Education			
Postdoctoral fellows (clinical, research)	25	90	139
Predoctoral graduate students	17	32	49
Resident national presentations	10	25	36
NIH training grants direct costs (total #)	\$6000 (6)	\$681 000 (12)	NA [‡]
CME program funding (number)	\$51 000 (1)	\$183 000 (10)	\$15 000 (1)
Faculty (FT tenure track)			
Primary faculty (instructor to professor)	50	88	96
Primary MD-PhD faculty	1	22	31
Secondary faculty (assistant professor to professor)	8	40	94
Total JHP primary and secondary faculty	58	128	190
Financial			
Annual JHP net revenue (JHU SoM general funds)	\$0.9 million	\$1.0 million	\$1.6 million
Annual JHP net revenue (JHH, Joint Agreement)	\$2.2 million	\$4.3 million	\$7.1 million
Annual JHP professional fee revenue (JHU CPA)	\$2.3 million	\$11.7 million	\$26.1 million
Annual JHP total net revenue (SoM + JHH + CPA)	\$5.4 million	\$17.0 million	\$34.8 million
JHP fund balance (starting UEF \$\$)	\$1.2 million	\$5.5 million	NA [‡]

Abbreviations: CME, continuing medical education; CPA, Clinical Practice Association; FT, full-time; HSCRC, Health Services Cost Review Commission; JCAHO, Joint Commission on Accreditation of Healthcare Organizations; JHH, Johns Hopkins Hospital; JHP, Johns Hopkins Pathology; JHU, Johns Hopkins University; NA, not applicable; NIH, National Institutes of Health; SoM, School of Medicine.

*All type I deficiencies in labs outside the 3 departments of pathology and lab medicine.

[†]Although the CAP terminology is different, the 2017 CAP inspection identified 0 "phase I" and 6 "phase II" deficiencies out of 4127 total checklist requirements.

[‡]No longer published or tracked.

[§]Based on Blue Ridge Institute for Medical Research.¹⁴

meeting a year of their choice, as well as any others for which they had an accepted presentation. By 1998, the number of publications involving residents increased from less than 70 to over 100, national presentations by residents more than doubled, and the number of postdoctoral clinical and research fellows more than tripled (Table 8).

A novel Pathobiology PhD Graduate Program was also created. This drew from faculty both within and outside the department and significantly increased the number of graduate students in the department (Table 8). The number of NIH training grants that included pathology faculty doubled from 6 to 12 along with associated funding (Table 8). The number of CME programs involving pathology faculty increased from 1 to 10 per year, also with an increase in revenue from tuition (Table 8).

The preclinical medical student pathology course was restructured to include clinical exposure to pathology services, and each medical student was assigned a resident mentor during their preclinical pathology course. A new weekly Pathology

Grand Rounds series was organized, each session made to include a short case report by a resident and a faculty seminar. At least quarterly, visiting speakers nationally recognized for their expertise in pathology were invited to present at Grand Rounds and spend time with faculty and trainees. These individuals also often provided advice to the chair on a variety of departmental issues.

Faculty. To achieve the significant growth in clinical service, research, and education, a considerable expansion of the faculty was initiated. The recruitment of the new chair included financial support for 6 new faculty. With the rapidly successful financial performance of the department, 75 new primary tenure-track faculty were recruited between 1993 and 2000 with a net increase of 38 faculty from 50 to 88 (Table 8). Efforts to recruit and retain physician-scientists were particularly successful, with an increase in MD-PhD faculty from 1 to 22 (Table 8).

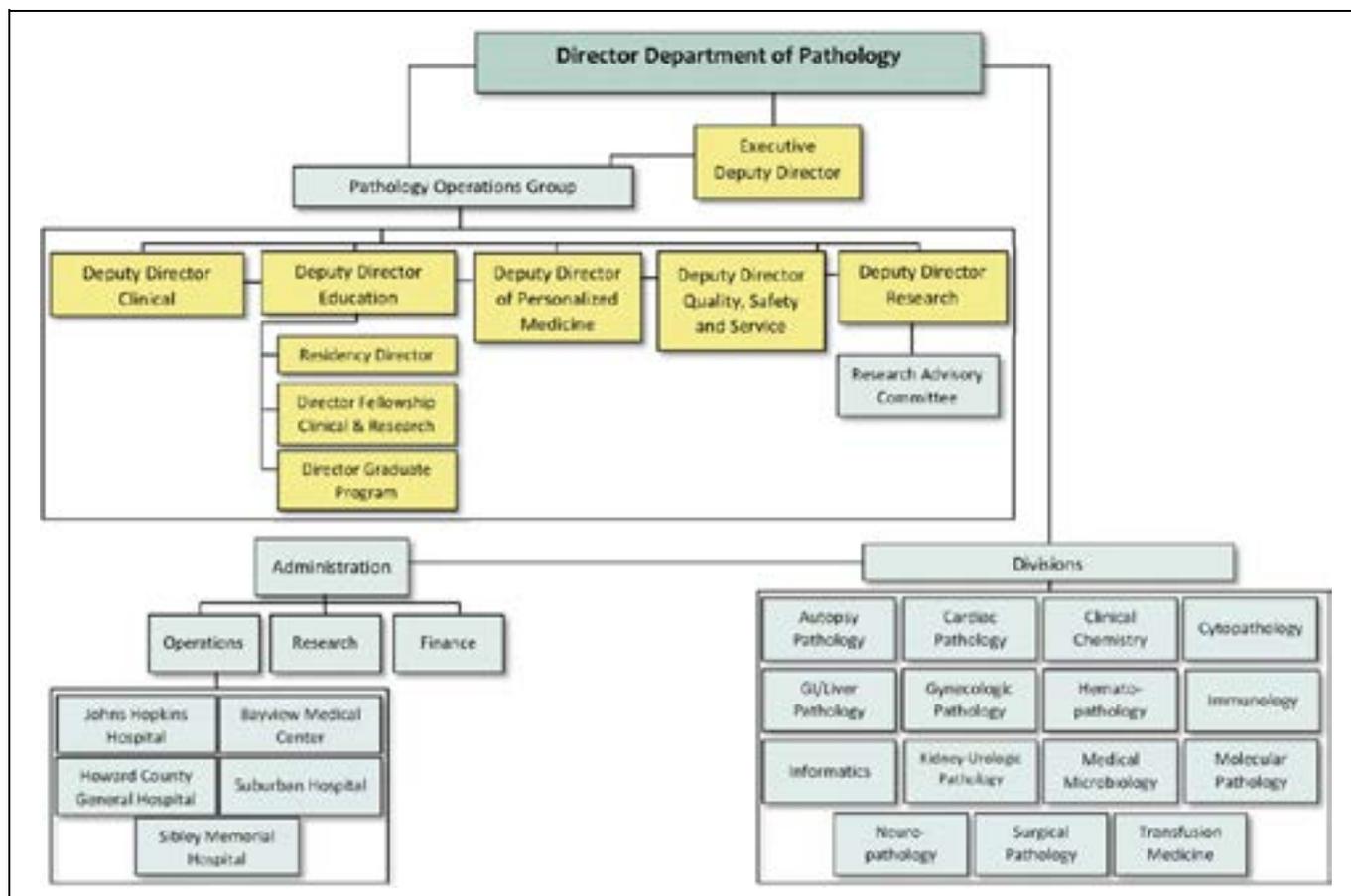


Figure 5. The JHP organizational structure 25 years after restructuring, 2018. JHP indicates Johns Hopkins Pathology.

In addition, there was a concerted effort to provide secondary appointments in pathology to appropriate faculty in other departments. There was a 5-fold increase in faculty with secondary appointments in pathology (from 8 to 40), contributing significantly to total faculty in the department, which more than doubled from 58 to 128 (Table 8). As a result, the new department of pathology was more visible and well integrated within the institution.

Financial. Sources of funding for the department included direct funding from JHH for operating the hospital-based services and funds transferred from JHH to JHU SoM under the “joint agreement” to support faculty activities; direct funding from the SoM for teaching, research, administrative, and other activities; professional fee revenue through the SoM Clinical Practice Association (CPA); and funds generated through CME, tech transfer, and fund-raising. Aggregate net revenue increased 3-fold from \$5.7 million to \$17.0 million from 1992 to 2000, and the JHP fund balance (reserves) increased almost 5-fold from \$1.2 million to \$5.5 million (Table 8). The major increases in revenue came from clinical professional fee revenue, which also increased almost 5-fold. By 2000, JHP had the highest annual net margin of all clinical departments in the CPA, almost double that of the next highest department.

Sustained Development of the Department

Structure. The rapid growth realized from restructuring JHP 25 years ago remains sustained today (Figure 5). The fundamental organizational structure codified then has lasted through 2 changes in departmental directors, both of whom were internal candidates named after rigorous national searches. Today there are 15 divisions and essentially all encompass both academic and clinical activities related to a specialty within pathology. There no longer are divisions of comparative pathology or of pediatric pathology; comparative pathology is now a stand-alone department (Department of Molecular and Comparative Biology), and Johns Hopkins has acquired All Children’s Hospital, providing rich pediatric pathology research and training opportunities in that entity. The department leadership team, the POG, continues to meet regularly with the chair. Three new vice-chair (deputy director) positions have been recently added to the POG. Two of these positions, the deputy director for Personalized Medicine and deputy director for Quality, Safety and Service, reflect emerging areas of focus for Johns Hopkins. The third, creation of an executive deputy director, reflects the need for more administrative depth in an increasingly complex department and recognizes the value of continuity of senior leadership. The POG includes a mix of mid-career and senior faculty.

Clinical. Clinical and quality metrics continue to be sustained and evolve. With the addition of a vice-chair for Quality, Safety and Service, the department has an impactful continuous quality improvement effort.¹³ For the 2017 College of American Pathologists (CAP) inspection cycle, JHP had a total of 6 CAP phase II deficiencies out of 4127 total checklist requirements (that includes both phases I and II) with an overall deficiency rate of just 0.15% (Table 8).

Research. The Department has been ranked first in NIH funding among pathology departments for 9 of the past 10 years, and total extramural research spending in 2016 to 2017 amounted to \$67.7 million (Table 8). In 2016 to 2017, the faculty held 50 NIH grants, including 2 training grants, and 2 very large NIH contracts. Based on the Blue Ridge Institute for Medical Research,¹⁴ the department's total NIH funding for 2016 to 2017 was \$53.7 million (Table 8). This represents 8.8% of all NIH academic pathology funding (\$613 million) and is more than 15 times the median amount (\$3.5 million) of NIH funding for departments of pathology in the United States.

Education. The 139 fellows in the department in 2016 to 2017 included 15 clinical fellows and 124 research fellows. There were 34 residents and 42 graduate students in our Pathobiology PhD Program (Table 8).

Faculty. As shown in Table 8, for the 2016 to 2017 academic year, there were 98 full-time tenure-track faculty, 9 assistants, and 9 research associates in the department. Of the 98, 36 were MD only, 30 PhD only, 31 MD, PhD, and 1 held 2 master's degrees. The faculty compensation plan has been recently modified but retains the basic structure developed in 1993.¹²

Financial. The total revenue for the department was \$34.8 million (Table 8).

Discussion

Twenty-five years ago, the 3 pathology and LM departments in the JHH and SoM were consolidated and fundamentally reorganized through a process internally called "The Johns Hopkins Pathology (JHP) Experiment." The structural changes initiating the JHP Experiment facilitated subsequent functional and cultural changes, with improved overall performance across all missions and metrics. Although there have continued to be modifications in response to the changing academic and clinical environment, the basic structures instituted at that time endure today and continue to be a successful model for departmental operation.

A fundamental premise of the JHP Experiment was that a single pathology department that integrated research, laboratory services, and AP diagnostics would be more productive in meeting all aspects of the Hopkins mission. The new chair and departmental leadership structured JHP internally to optimize activities across the department by creating 17 discipline-based divisions and an overarching supportive administrative organization. With this arrangement, the departmental leadership was

able to focus on optimizing the performance of the department as a whole.

The unique features of the reorganization that were put in place as part of the JHP Experiment included: (1) elimination of traditional AP/LM/experimental pathology lines of authority, replacing them with divisions whose directors all had direct reports to the department chair; (2) creation of a mission-based leadership team of faculty vice-chairs and administrators; (3) initiation of a culture change process to improve faculty and staff engagement and performance; and (4) a focus on process and quality improvement to increase productivity and generate resources. As a result of these changes, and an extensive recruiting effort that more than doubled the size of the department in 8 years, the department evolved into one of the most successful pathology departments in the country in terms of its clinical, research, and education programs, as well as reputation.

To our knowledge, the structure of the Pathology Department at Johns Hopkins has remained unique, although indeed it is difficult to find any 2 large, research-oriented pathology departments that are organized the same way anywhere in the country. Although there are still a few institutions that have separate academic departments of pathology and LM, the great majority now have a single, unified department. However, most unified departments have separate vice-chairs or directors for AP and CP with faculty reporting through them for operational and often financial and academic issues. Most institutions also still maintain an experimental or research pathology division, often with a specific focus such as immunology or neurobiology or both, largely related to their historical successes in those areas.

One of the strengths of the JHP structure is the integration of basic and translational research with clinical services within divisions, each of which is expected to provide the full spectrum of research, education, and clinical service. This structure facilitated academic productivity among all faculty, something that was necessary given that Hopkins does not have separate tracks for promotion.¹⁵ In fact, the single tenure-track system at Hopkins helped drive the process of integration and alignment across missions in JHP by necessity to ensure all faculty had the opportunity for scholarship. The successes of the department—financially and academically—have allowed even primarily clinical faculty substantial protected time for scholarship and a rich environment for collaboration.

An important part of the JHP Experiment was to enhance the organizational culture. The ability to change culture to more constructive styles has been well demonstrated in business organizations and shown to be associated with changes in performance, productivity, and job satisfaction.³⁻⁵ Although the culture of medical schools and departments within university medical centers is commonly cited as a distinguishing characteristic, virtually no quantitative measures of organizational culture had been reported for any clinical specialty until 1993.⁶ The JHP Experiment demonstrated significant short-term shifts toward a more constructive culture that paralleled significant changes in performance and productivity of faculty

and staff, confirming the prior results seen in industry and providing the basis for a subsequent medical center-wide study at Ohio State University.⁷

In addition to the impacts of the JHP Experiment on mission performance and culture, the financial successes for the department and both parent institutions were important factors in sustaining the change. In particular, consolidation of the 3 departments into JHP significantly increased the contribution margins of pathology to both JHH and JHU SoM. The rapid turn-around from a deficit spending department to one that had the highest contribution margins for JHH and JHU SoM also provided significant latitude for the department to operate with flexibility. This included being allowed to create a novel incentive-based compensation plan,¹¹ hire a tech transfer and development officer, create and operate an institution-wide reference lab (JHML), develop a new graduate program, and on average hire 10 new faculty a year during the first 7 years of the experiment.

In summary, in 1993, JHH and JHU SoM embarked on a transformative experiment by consolidating its 3 departments of pathology and LM under a single chair who was given significant authority and responsibilities. In turn, faculty and staff leadership of JHP shaped new departmental structures and fostered a culture of experimentation to discover best practices. Cultural inventories showed significant increases in faculty and staff tendencies to work responsibly toward goals, think creatively, respond positively to criticism and conflict, and cooperate with colleagues. Clinical services saw significant improvement in quality, scope, and cost. Research achievement and funding increased. Educational programs grew and gained status. These changes rapidly transformed JHP into one of the premier departments of pathology in the world. Now 25 years later, the basic structure and functions of the organization remain largely intact as does the level of departmental achievement and recognition. This ongoing JHP Experiment supports the premise that novel organizational structures and leadership behaviors can provide sustainable competitive advantage, which may become even more important in the future with the increasing challenges facing academic medicine across all its missions.

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A Difficult Challenge for the Clinical Laboratory: Accessing and Interpreting Manufacturer Cross-Reactivity Data for Immunoassays Used in Urine Drug Testing

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Abstract

Urine drug testing by immunoassay is widely used to detect nonmedical drug use and to monitor patients prescribed controlled substances. A key attribute of urine drug testing immunoassays is cross-reactivity, namely the response of various compounds compared to the target of the assay. In this report, we analyzed the variability in how manufacturer cross-reactivity data are summarized in package inserts for commercially available amphetamines, benzodiazepines, and opiates immunoassays, 3 broad drug classes commonly included in routine drug testing panels. Specifically, we determined the number of compounds tested for cross-reactivity, manner in which cross-reactivity is measured, concentration units used, how often compounds known to be cross-reactive with marketed urine drug testing immunoassays prior to 2010 were tested, availability of the package insert online, and how often cross-reactivity on “designer drugs” was found in the package inserts. There was wide variability in the number of compounds tested (both positive and negative), with the highest number of tested compounds generally found in point-of-care urine drug testing applications. Most package inserts used ng/mL as the concentration units and expressed cross-reactivity in terms of equivalent concentrations to the assay calibrator. Approximately 50% of package inserts were directly available online. Cross-reactivity data were sparse with respect to “off-target” drugs known to be cross-reactive prior to 2010 (an example being quinolone antibiotics and opiates immunoassays) and designer drugs. The present study indicates lack of consistency in cross-reactivity information in package inserts, complicating the interpretation of urine drug testing results. We use 3 example clinical cases to illustrate practical challenges accessing and interpreting cross-reactivity data.

Keywords

amphetamines, benzodiazepines, designer drugs, false positives, immunoassay, opiates

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Introduction

Substance abuse continues to be a significant medical and public health issue in the United States and other countries.^{1,2} An ongoing epidemic of nonmedical use of prescription drugs has added to the existing challenges associated with abuse of cocaine, heroin, methamphetamine, and other “street drugs.”^{3–6} Drug testing in patients serves as a diagnostic and monitoring tool in the management of substance abuse.^{7–11}

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In the clinical setting, urine drug testing (UDT) is commonly used to detect nonmedical drug use and to monitor adherence of patients prescribed controlled substances.^{7,9-13} Many drugs and drug metabolites are excreted in urine, allowing for windows of detection range from hours to days (or occasionally weeks) for commonly targeted drugs with standard testing techniques.^{12,13} Immunoassays (antibody-based assays) are currently the most common methodology for UDT, frequently used as “drug screens.”^{9,11} Clinical laboratories based in hospitals or other larger care facilities often perform UDT immunoassays on automated or semiautomated clinical chemistry platforms. Point-of-care (POC) devices (eg, urine cups or strips) for UDT allow for testing with rapid turnaround time without the need for laboratory equipment in a variety of settings.

Immunoassays used for UDT can be classified into 2 broad categories: those targeting a class of drugs with multiple clinically relevant compounds (eg, amphetamines, benzodiazepines, or opiates) and those narrowly targeted toward a single drug and/or its unique metabolites (eg, buprenorphine, fentanyl, methadone, or the cocaine metabolite benzoylecgonine).^{9,11,14} A false-negative result occurs when the immunoassay fails to detect a drug or drug metabolite within the targeted class. A common example is that many opiates screening assays poorly detect oxycodone and its metabolites, even though oxycodone is technically an opiate, being a semi-synthetic derivative of opium constituents such as morphine or codeine. A false positive occurs when a positive result is caused by a compound outside of the targeted drug or drug class.¹⁴⁻¹⁶ There are numerous documented examples of false positives, including a metabolite of labetalol (antihypertensive medication) cross-reacting with amphetamines immunoassays¹⁷⁻¹⁹ and quinolone antibiotics cross-reacting with some opiate immunoassays.²⁰

A key attribute of UDT immunoassays is cross-reactivity, namely the degree to which any given compound (eg, drug, drug metabolite, or endogenous compound) can produce a signal on the assay.^{9,11,14} For UDT immunoassays, this may be expressed as the equivalent concentration of a compound that equals the cutoff concentration of the assay target (eg, the concentration of codeine or hydrocodone that produces the same signal as 300 ng/mL of morphine in an opiates screening assay) or as a percent cross-reactivity compared to a standard such as morphine. During the development of commercially marketed UDT immunoassays, assay manufacturers test drugs, drug metabolites, and endogenous compounds for cross-reactivity and report this data in the assay package insert.¹⁴ In addition to manufacturer information, the published literature contains reports of UDT cross-reactivity in case reports, case series, and sometimes more systematic investigations of multiple compounds.^{9,14-16}

The proliferation of clinical laboratory and POC UDT immunoassays available on the market adds an additional element of complexity.⁹ The UDT immunoassays from different manufacturers vary in assay antibody specificity, calibrators, signal detection, and other factors, all of which can impact cross-reactivity. This is evident when analyzing results of UDT

immunoassay proficiency testing.²¹ For pathologists and other health-care professionals who may be involved in interpreting UDT results, it is important to be able to access and interpret information related to assay cross-reactivity.²² In this report, we analyze the variability in how manufacturer cross-reactivity testing is summarized in package inserts for commercially available amphetamines, benzodiazepines, and opiates immunoassays, 3 broad drug classes commonly included in routinely used UDT panels. Specifically, we determined the number of compounds tested for cross-reactivity, manner in which cross-reactivity is measured, concentration units used, and how often compounds known to be cross-reactive with UDT immunoassays prior to 2010 had information in the various package inserts. We further assessed how often cross-reactivity data for some of the more widely known “designer drugs” (eg, “bath salts” such as mephedrone) were available in the package inserts.²³⁻²⁵ Lastly, we use 3 example clinical cases below to illustrate some of the practical challenges accessing and interpreting cross-reactivity data for UDTs.

Example Case #1

A 26-year-old pregnant woman is referred to a tertiary care medical center for management of preeclampsia. She previously tested presumptive positive for amphetamines on a POC UDT panel ordered by her primary obstetrician. No confirmatory testing was performed. At the medical center, a UDT panel performed in the central clinical laboratory also yielded a presumptive positive for amphetamines. The woman has no known history of nonmedical drug use. Her only known prescription medication is labetalol for hypertension during pregnancy. The obstetrician inquires whether the UDT results indicate use of amphetamine or methamphetamine.

Example Case #2

A 33-year-old man with chronic back pain is being monitored by UDT for adherence to therapy with oxycodone. As part of his controlled substance medication contract, he undergoes regular UDT to verify adherence to oxycodone therapy and to also monitor nonmedical drug use. He has had UDT performed at 2 different locations—a commercial laboratory site near his home and the medical center clinical laboratory affiliated with his pain specialist (more distant from the patient’s home). Urine drug testing for this patient has yielded inconsistent results with regard to opiate screens—those at the commercial laboratory are consistently negative for opiates, while those at the medical center laboratory have been consistently presumptive positive for opiates. The pain specialist consults the medical center pathologist-on-call to discuss the discordant results.

Example Case #3

An 18-year-old man is found unconscious during a rave party. He is brought by ambulance to the emergency department, and

a friend accompanying him says the patient purchases “designer drugs” via the “dark web.” The emergency physician calls the clinical laboratory for information on how well the routine UDT panel used at the medical center (consisting of amphetamines, benzodiazepines, cocaine metabolite, opiates, and tetrahydrocannabinol) will detect the types of drugs this patient may have used.

Material and Methods

We compiled information from package inserts from marketed versions of 30 amphetamines, 23 benzodiazepines, and 28 opiates UDT immunoassays. These were chosen as they represent broad specificity immunoassays that have been commonly included on routine drug screening panels for decades, thereby having extensive literature on cross-reactivity.¹⁴ These included assays available as discrete applications for random access chemistry analyzers and also POC UDT panels (which typically require the user to run all assays simultaneously). Some of the assays are used by multiple vendors on different instrument platforms. The difference in numbers of inserts analyzed in this study is mainly due to multiple forms of amphetamines assays being marketed (including by the same manufacturer in varying assay specificities such as “amphetamines,” “amphetamine/methamphetamine,” or “amphetamine/ecstasy”) and that some POC UDT applications do not include a benzodiazepines screen. The package insert versions were obtained by direct access (assay being used within the authors’ health-care system), from publicly accessible web sites, or from contacting the manufacturer. A complete list of the assays is in Supplemental Table 1. Note that some assays have had recent updates (eg, additions to cross-reactivity data of an existing product or a more substantial change to a new assay version involving changes in assay antibodies, calibrators, etc), while others have been unchanged for years. An example of an assay that underwent an update with respect to cross-reactivity testing during the last 5 years is the Roche Diagnostics COBAS Benzodiazepines Plus assay, which added data to the package insert for some of the designer benzodiazepines discussed below.

The following information was extracted from each of the package inserts: concentration units for drugs and metabolites (ng/mL, µg/mL, or both units), whether cross-reactivity data were expressed in concentration equivalents (eg, 450 ng/mL of codeine equaled the reactivity of 300 ng/mL morphine in an opiates assay), whether cross-reactivity data were expressed in percent cross-reactivity (in some cases in addition to the data also being expressed in concentration equivalents), whether information was provided on therapeutically or toxicologically relevant urine concentrations, and whether the assay package insert was directly accessible online without restrictions. The package insert was considered not directly accessible if it was either not available at all online or was only available with special access (eg, online account only to those from institutions who were customers) or by request to vendor.

The package inserts were also analyzed for whether they contained information on cross-reactivity of “designer drugs” related to amphetamines, benzodiazepines, and opiates. Compounds examined included amphetamine-like drugs (cathinone, methcathinone, mephedrone, methylenedioxypyrovalerone [MDPV]), designer benzodiazepines (adinazolam, clonazolam, cloniprazepam, diclazepam, etizolam, flubromazepam, flubromazolam, flutazolam, ketazolam, phenazepam), and designer opioids (acetylfentanyl and other fentanyl analogs, AH-7921, MT-45, U-47700). The inserts were also examined for whether they contained cross-reactivity data for out-of-class compounds known to be cross-reactive with at least some marketed assays prior to 2010 based on a previously published detailed analysis of cross-reactivity data available at that time¹⁴: amphetamines assays (bupropion, ephedrine, labetalol, mexiletine, phenethylamine, phentermine, propylhexedrine), benzodiazepines assays (diazoxide, ketoprofen, lovastatin, modafinil, oxaprozin), and opiates assays (imipramine, meperidine, quinolone antibiotics [ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, ofloxacin], ranitidine, rifampin).

The example patient scenarios in this study are hypothetical and do not identify any particular patient. However, these combine common cross-reactivity issues encountered by the corresponding author throughout years of experience.

Results

Variability of Information in Urine Drug Testing Package Inserts

We analyzed information from package inserts from marketed versions of 30 amphetamines, 23 benzodiazepines, and 28 opiates UDT immunoassays with respect to concentration units used, how cross-reactivity was reported, and whether assay package insert was directly available online. Over 80% of package inserts for all 3 types of assays used ng/mL as the only concentration unit for drugs, drug metabolites, and other compounds tested for cross-reactivity. The remainder of the package inserts used either µg/mL or both ng/mL and µg/mL (Figure 1A). Those that contained both units typically used µg/mL for compounds with weak cross-reactivity (eg, expressing as 200 µg/mL instead of 200 000 ng/mL). Over 90% of the package inserts reported cross-reactivity in concentration equivalents (Figure 1B). Less than 30% reported cross-reactivity as a percentage compared to a standard (Figure 1C), although this calculation can be performed if concentrations equivalents are supplied ($100 \times [\text{concentration of assay target that produces positive signal at intended cutoff}] / [\text{concentration of other compound producing equivalent signal}]$). Only approximately 50% of the package inserts were directly available online (Figure 1D). None of the package inserts analyzed provided information on clinically relevant concentrations of drug or drug metabolites in urine (eg, what concentrations might be expected during therapeutic treatment).

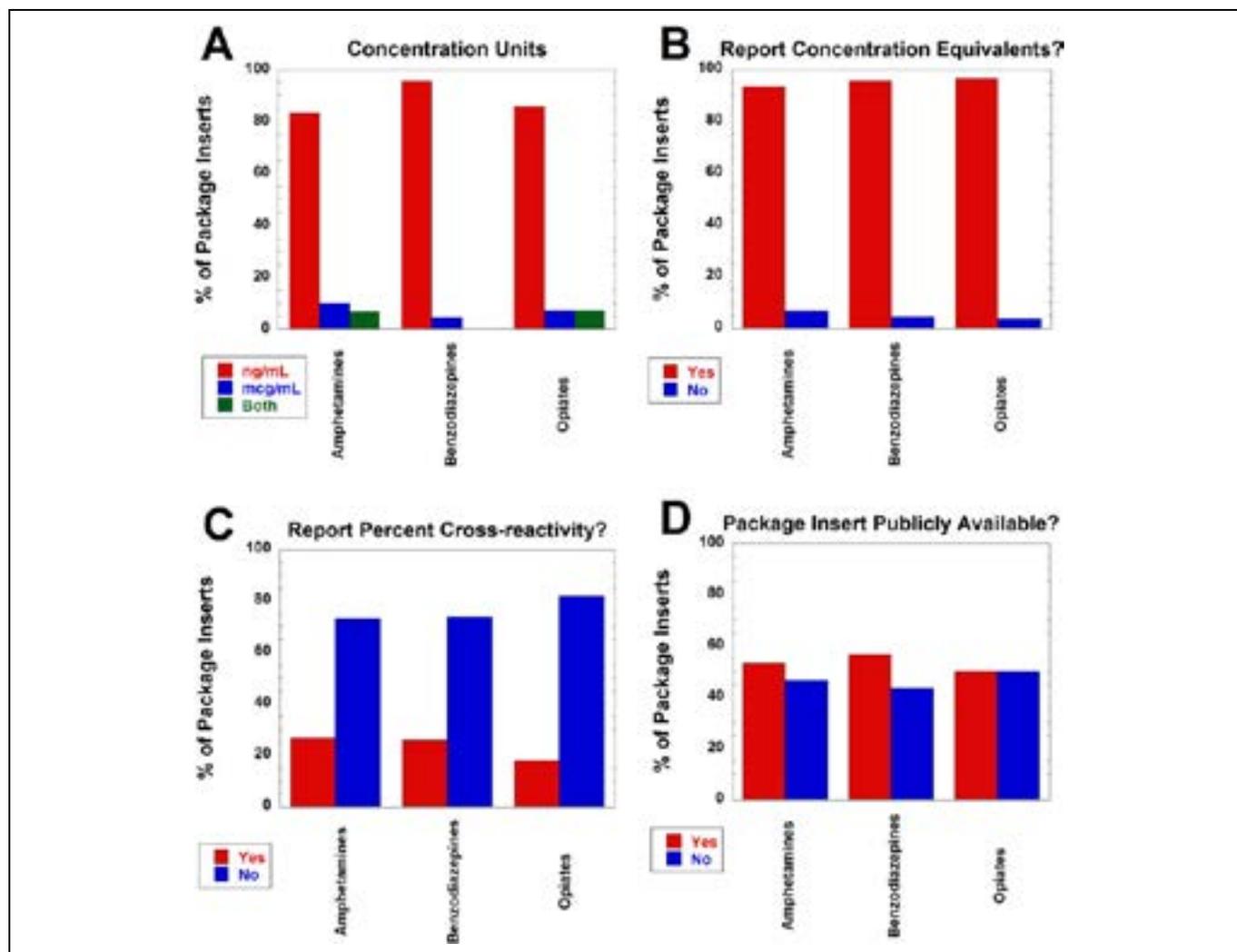


Figure 1. Variability of information in urine drug testing package inserts for amphetamines ($n = 30$), benzodiazepines ($n = 23$), and opiates ($n = 28$) immunoassays. A, Breakdown on concentration units (ng/mL, μ g/mL, or both units) used to describe cross-reactivity data. B, Breakdown of whether package insert reported concentration equivalents for cross-reactivity data. C, Breakdown of whether package insert reported percent cross-reactivity (relative to standard such as morphine for opiates). Note that some package inserts reported in both concentration equivalents and percent cross-reactivity. D, Breakdown of whether package inserts was directly available online. See Methods for more details on definitions.

We next analyzed how many compounds were tested for cross-reactivity in the UDT package inserts (Figure 2). There was wide variability in both number of cross-reactive compounds reported and those with no cross-reactivity. For example, for the amphetamines assays, the range of cross-reactive compounds varied from 4 to 40, while the number of compounds with no reported cross-reactivity ranged from 0 to 221 (Figure 2A). A similar range was seen with both benzodiazepines (Figure 2B) and opiates (Figure 2C) immunoassays. Many of the package inserts with a high number of tested compounds with no cross-reactivity were from POC products that tested the same wide array of compounds on a device that performs multiple UDTs simultaneously.

We next determined whether package inserts contained cross-reactivity data for “designer drugs” and for

compounds with cross-reactivity to marketed UDTs known prior to 2010 (Table 1). The latter category includes compounds such as phentermine and the labelalol metabolite 3-amino-1-phenylbutane (APB) that are structurally close to amphetamine and methamphetamine, but not the intended targets of the assay.^{14,19} For the amphetamine UDT package inserts, ephedrine and pseudoephedrine were the compounds whose cross-reactivity data were most frequently found in package inserts (both 83.3%), followed by phentermine (66.7%), phenethylamine (53.3%), and bupropion (40.0%). Cross-reactivity data for labelalol were found in 20.0% of package inserts; however, only 6.7% had data for the metabolite APB that actually produces most of the cross-reactivity.^{14,19} Cross-reactivity data for designer amphetamine-like drugs were either absent in all package inserts (MDPV) or

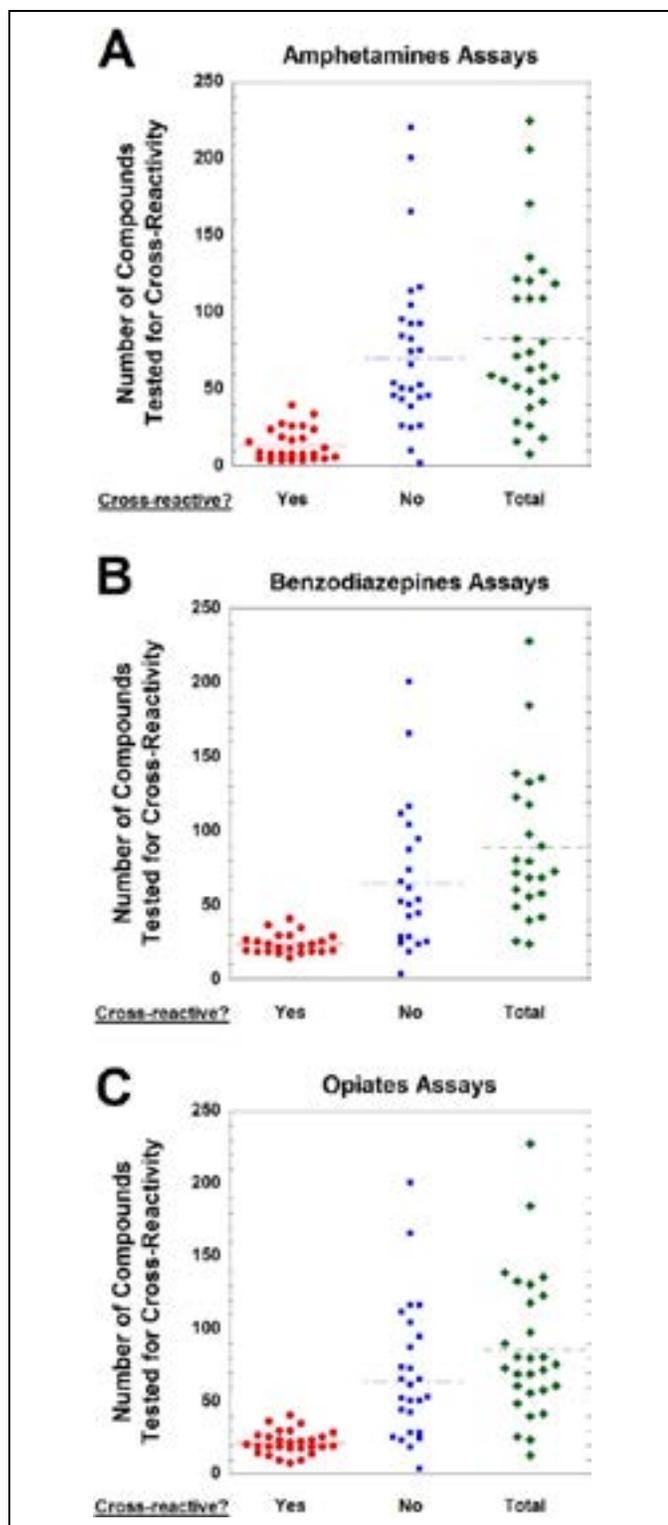


Figure 2. Number of compounds tested for cross-reactivity as reported in urine drug testing package inserts for (A) amphetamines ($n = 30$), (B) benzodiazepines ($n = 23$), and (C) opiates ($n = 28$) immunoassays. Data are broken down into compounds showing measurable cross-reactivity and those reported as having no cross-reactivity (at least within limits of concentrations tested by the manufacturer).

Table 1. Data on Compound Cross-Reactivity for Amphetamines Urine Drug Testing (UDT Immunoassays).

Compound	Category	Cross-Reactivity Data to Amphetamines Documented Before 2010*	Number and Percent of Package Inserts With Cross-Reactivity Data ($n = 30$)
Bupropion	Psychiatric medication	Yes	40.0%
Cathinone	Cathinone (found in khat)	No	3.3%
Ephedrine	Stimulant (substituted amphetamine)	Yes	83.3%
Labetalol	Antihypertensive	No	20.0%
Labetalol metabolite [†]	Metabolite of labetalol	Yes	6.7%
MDPV	Designer drug (cathinone)	No	0.0%
Mephedrone	Designer drug (cathinone)	No	6.7%
Methcathinone	Designer drug (cathinone)	Yes	3.3%
Mexiletine	Antiarrhythmic medication	Yes	3.3%
Phenethylamine	Backbone of amphetamine structure	Yes	53.3%
Phentermine	Stimulant (substituted amphetamine)	Yes	66.7%
Propylhexedrine	Stimulant (substituted amphetamine)	Yes	10.0%
Pseudoephedrine	Stimulant (substituted amphetamine)	Yes	83.3%

Abbreviation: MDPV, methylenedioxypropylvalerone.

*Whether cross-reactivity data for amphetamines UDTs were available in package inserts and/or published literature prior to 2010. For those who were available prior to 2010, all except labetalol (parent drug) have shown cross-reactivity with at least one marketed amphetamines UDT immunoassay.

[†]3-amino-1-phenylbutane (APB).

found in only 3.3% (cathinone, methcathinone) or 6.7% (mephedrone) of the inserts.

For the benzodiazepines UDT package inserts (Table 2), cross-reactivity data were mostly absent for 5 nonbenzodiazepine compounds known to be cross-reactive with some benzodiazepine UDTs prior to 2010 (diazoxide, ketoprofen, lovastatin, modafinil, oxaprozin). Of these compounds, cross-reactivity data were only present in package inserts for ketoprofen (26.1%), oxaprozin (17.4%), and diazoxide (8.7%). Cross-reactivity data were absent in all 23 package inserts for 4 of 10 designer benzodiazepines examined and only present in 4.3% (1 insert) or 8.7% (2 inserts) for the other 6 designer benzodiazepines: clonazepam (4.3%), diclazepam (4.3%),

Table 2. Data on Compound Cross-Reactivity for Benzodiazepines Urine Drug Testing (UDT Immunoassays).

Compound	Category	Cross-Reactivity Data to Benzodiazepines UDTs Documented Before 2010*	Number and Percent of Package Inserts With Cross-Reactivity Data (n = 23)
Adinazolam	Designer benzodiazepine	No	0.0%
Clonazolam	Designer benzodiazepine	No	4.3%
Cloniprazepam	Designer benzodiazepine	No	0.0%
Diazoxide	Antihypertensive	Yes	8.7%
Diclazepam	Designer benzodiazepine	No	4.3%
Etizolam	Designer benzodiazepine	No	4.3%
Flubromazepam	Designer benzodiazepine	No	4.3%
Flubromazolam	Designer benzodiazepine	No	4.3%
Flutazolam	Designer benzodiazepine	No	0.0%
Ketazolam	Designer benzodiazepine	No	8.7%
Ketoprofen	Nonsteroidal anti-inflammatory drug	Yes	26.1%
Lovastatin	Lipid-lowering agent	Yes	0.0%
Modafinil	Medication for excessive sleepiness	Yes	0.0%
Oxaprozin	Nonsteroidal anti-inflammatory drug	Yes	17.4%
Phenazepam	Designer benzodiazepine	No	0.0%

Abbreviation: UDT, urine drug testing.

*Whether cross-reactivity data for benzodiazepines UDTs were available in package inserts and/or published literature prior to 2010. For those who were available prior to 2010, all have shown cross-reactivity with at least one marketed benzodiazepines UDT immunoassay.

etizolam (4.3%), flubromazepam (4.3%), flubromazolam (4.3%), and ketazolam (8.7%).

For the opiate UDT package inserts (Table 3), the compounds most frequently included for cross-reactivity data were meperidine (82.1%), imipramine (53.6%), and fentanyl (35.7%). Cross-reactivity data for 5 quinolone antibiotics (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, and ofloxacin) were low throughout, with data for only ciprofloxacin and norfloxacin included in 7.1% of inserts. Of the 4 designer opioids examined (fentanyl analogs, AH-7921,

Table 3. Data on Compound Cross-Reactivity for Opiates Urine Drug Testing (UDT Immunoassays).

Compound	Category	Cross-Reactivity to Amphetamines UDTs Documented Before 2010*	Number and Percent of Package Inserts With Cross-Reactivity Data (n = 28)
Ciprofloxacin	Quinolone antibiotic	Yes	7.1%
AH-7921	Designer opioid	No	0.0%
Fentanyl	Synthetic opioid (nonopiate)	Yes	35.7%
Fentanyl analog	Designer opioid	No	3.6%
Imipramine	Tricyclic antidepressant	Yes	53.6%
Levofloxacin	Quinolone antibiotic	Yes	0.0%
Meperidine	Synthetic opioid (non-opiate)	Yes	82.1%
Moxifloxacin	Quinolone antibiotic	Yes	0.0%
MT-45	Designer opioid	No	0.0%
Norfloxacin	Quinolone antibiotic	Yes	7.1%
Ofloxacin	Quinolone antibiotic	Yes	0.0%
U-47700	Designer opioid	No	0.0%

Abbreviation: UDT, urine drug testing.

*Whether cross-reactivity data for opiates UDTs were available in package inserts and/or published literature prior to 2010. For those who were available prior to 2010, all have shown cross-reactivity with at least one marketed opiates UDT immunoassay.

MT-45, U-47700), data were universally absent except for a single package insert (3.6%) with data for a fentanyl analog (acetylfentanyl).

Resolution of Case #1

Labetalol is now well established to produce cross-reactivity on multiple marketed amphetamine UDTs mainly due to its metabolite APB, which has a chemical structure close to that of amphetamine.¹⁷⁻¹⁹ The shift toward labetalol as a preferred medication for managing hypertension in pregnancy means that cross-reactivity to amphetamines UDTs presents a special challenge within obstetrics. As indicated above, very few of the amphetamines UDT package inserts provide cross-reactivity data on the metabolite, although some do provide data on the parent drug (usually reporting as having no cross-reactivity). Thus, an examination of package inserts alone could easily lead to the conclusion that labetalol cross-reactivity would not be an explanation for the presumptive positive screens for this patient, which may lead to erroneous assignment of nonmedical drug use. This is a situation where literature search would be more insightful than package insert information. Confirmatory testing may also be indicated. If labetalol is the cause of the presumptive positive amphetamine UDT screens, standard

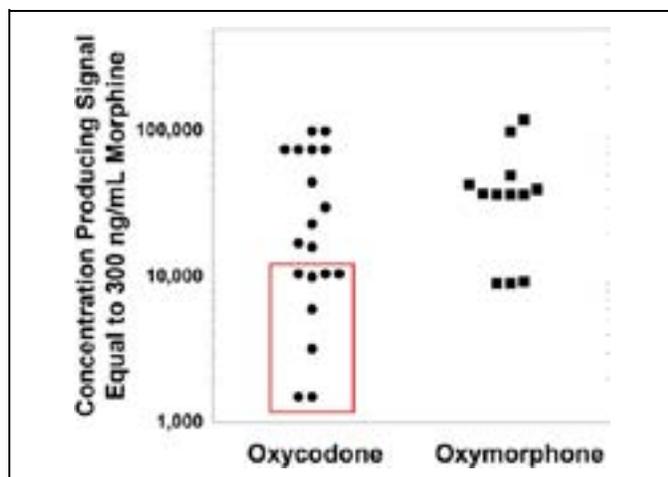


Figure 3. Concentrations of oxycodone and oxymorphone (oxycodone metabolite) producing equivalent signal to 300 ng/mL for morphine urine immunoassays, as reported in package inserts analyzed in this study. The oxycodone concentrations outlined by the red box are within the range of concentrations seen in a detailed pharmacokinetic study of 20 mg oxycodone administered to healthy adult volunteers.²⁶ The 4 data points plotted at 75 000 ng/mL for the oxycodone concentration were reported in the package inserts as >75 000 ng/mL.

amphetamines confirmatory testing would be expected to be negative.

Resolution of Case #2

Variable cross-reactivity of traditional opiate UDTs to oxycodone has been well established, with most marketed assays having low cross-reactivity.^{14,16,21} This can be confusing, since oxycodone is a semisynthetic opiate sharing the core chemical structure of codeine and morphine. Using a 300 ng/mL positive cutoff (morphine as calibrator), the equivalent cross-reactive concentration of oxycodone varies from approximately 2500 to >75 000 ng/mL according to the package insert data analyzed in the present study. Figure 3 plots the concentrations of oxycodone and oxymorphone (main metabolite) that are reported in opiates package inserts to produce cross-reactivity equivalent to that of 300 ng/mL morphine (using package inserts analyzed in the present study). The oxycodone concentrations outlined by the red box in Figure 3 are within the range of concentrations seen in a detailed pharmacokinetic study of 20 mg oxycodone administered to healthy adult volunteers.²⁶ As can be seen, 11 of the oxycodone assays plotted in Figure 3 have cutoffs for oxycodone higher than the upper limit of the concentrations observed in the pharmacokinetic study. The generally poor cross-reactivity of opiates UDT immunoassays to oxycodone has led to the development of oxycodone-specific immunoassays that provide sensitive and targeted detection of oxycodone and its metabolites.^{9,21,27} In the case scenario, use of an oxycodone immunoassay and/or confirmatory testing would provide more reliable assessment of adherence to therapy.

Resolution of Case #3

This is a challenging and increasingly common question with the proliferation of designer drugs. Compounds misleadingly labeled “bath salts” are often amphetamine-like compounds such as mephedrone or MDPV.^{24,28,29} There are a wide array of other amphetamine-like drugs such as the cathinones and the 2C series. The abuse of designer benzodiazepines is a somewhat more recent development in the United States, although the drugs themselves often have long histories, developed by pharmaceutical companies in the 1960s and 1970s and then either abandoned for the clinical market or marketed in a limited number of countries.³⁰⁻³² Synthetic opioids (including fentanyl analogs and other drugs such as U-47700) have also recently emerged as designer drugs of abuse.^{3,31,33,34} For the case scenario, the data in the present study should emphasize that package inserts are unlikely to contain data on these designer drugs. A literature search is more likely to reveal any information, if available. For example, a recent report contains data on how well multiple marketed benzodiazepines UDT immunoassay detect designer benzodiazepines, of which some do cross-react well with UDTs.³⁵

Discussion

Interpretation of drug testing can be challenging yet have significant consequences for the patient.^{7,9,11,12,22} Some of the complications arise with the different purposes for which drug testing is used. In the context of emergency medicine, identification of drug overdoses may often be the primary consideration. In substance abuse programs and pain management, verification that a patient is actually adhering to therapy with a controlled substance may be as important as detecting non-medical use of other substances.^{10,13,36} An additional challenge is that the downstream consequences of drug testing can involve a variety of personnel including nurses, pharmacists, social workers, probation officers, and medical review officers. The clinical laboratory may thus interact with personnel of diverse backgrounds seeking to understand UDT results. The multitude of vendors offering drug testing, including proliferation of many POC immunoassays, further complicates interpretation, as can be highlighted when discrepant results are seen for the same patient.²²

Immunoassays are currently the most widely used method for UDT.²² In addition to immunoassays, mass spectrometry (MS)-based analytical methods such as gas chromatography/MS or liquid chromatography/tandem mass spectrometry (LC/MS/MS) provide specific identification of drugs and drug metabolites.^{7,11} Mass spectrometry-based methods are often used for confirmation of positive immunoassay screening results or for detection of drugs or drug metabolites undetectable or poorly detectable by immunoassays. An emerging but currently less common application of MS-based methods is as the direct method for UDT, bypassing initial screening by immunoassays.³⁷ Although an increasing number of clinical laboratories are utilizing MS-based assays for UDT testing,

relatively few hospital- or physician office-based laboratories have the capability to perform this testing and even fewer with rapid turnaround time.

The main barriers for adoption of MS-based technology by clinical laboratories include high cost of instrumentation (eg, LC/MS/MS analyzers often have capital purchase prices exceeding US\$200 000), technical complexity of operation, and labor-intensive sample preparation and results analysis.³⁸⁻⁴⁰ There are relatively few FDA-cleared MS-based assays available in the United States for urine drug of abuse testing, requiring laboratories to validate their own “laboratory-developed tests” that would be high complexity under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.⁴¹ In contrast, most marketed immunoassays for drug analysis are in the CLIA moderate or waived complexity categories that have less stringent constraints than high-complexity tests.¹¹

Although urine as a specimen offers a number of advantages for drug testing, there are a number of challenges with UDT immunoassays.^{9,14,15} These include variation in antibodies, assay format, vulnerability to interference, calibrators, and chosen cutoff concentration. Variability in drug metabolism and UDT assay cross-reactivity for metabolites add another complicated variable.

Shifting trends in drug use can influence how manufacturers design UDT immunoassays.¹⁶ For example, diazepam was the most commonly prescribed benzodiazepine of the 1970s and 1980s in the United States and was the overall most prescribed drug for some of those years. Not surprisingly, benzodiazepine UDTs developed in that era tended to target diazepam and/or diazepam metabolites such as nordiazepam or oxazepam. However, there has been a shift in benzodiazepine prescription patterns and 3 other benzodiazepines (alprazolam, clonazepam, and lorazepam) steadily increased in prescription volumes until all 3 overtook diazepam in frequency of prescriptions in the United States by 2002 (drug prescription trends compiled and analyzed in detail by Krasowski et al¹⁶; see especially supplemental data in that publication). This trend has continued to the present, as evidenced by data on outpatient prescription volumes.⁴² As a consequence, some manufacturers have redesigned benzodiazepine UDT immunoassays to better detect these historically “newer” benzodiazepines.

Cross-reactivity is an important aspect of UDT immunoassays.^{9,14,15} Even though interpretation can be complicated (eg, drugs with cross-reactive metabolites), cross-reactivity data can help explain results of testing. As the results in the present study show, there is wide variability in how manufacturers present cross-reactivity data (see Table 4 for summary), including units of concentration, manner in which cross-reactivity is expressed (percent cross-reactivity vs equivalent concentrations), number of compounds tested for cross-reactivity, and whether the package insert is directly available on the Internet. In our analysis of the number of compounds tested for cross-reactivity, there were as few as 4 positively cross-reactive compounds reported for one assay. Four UDT package inserts reported no compounds negative for cross-reactivity. On the

Table 4. Limitations of Cross-Reactivity Data in Package Inserts.

Limitation	Comments
Variable number of compounds tested	<ul style="list-style-type: none"> Currently no clearly defined regulations on which specific compounds to test
Limited data on drug metabolites	<ul style="list-style-type: none"> Exceptions are metabolites that are themselves also parent drugs or represent the main target of testing (eg, heroin metabolite 6-acetylmorphine) Literature search may be informative
Sparse data on designer drugs	<ul style="list-style-type: none"> Literature search more likely to be informative Metabolism of designer drugs may be poorly defined
Use of different concentration units	<ul style="list-style-type: none"> Pay attention to units to avoid misinterpretation (eg, confusing ng/mL and µg/mL)
Variable availability of package inserts online	<ul style="list-style-type: none"> Lack of online access can delay troubleshooting questions on assays (eg, patient with discordant results on assays performed at different sites)

other extreme, some package inserts reported cross-reactivity data for over 200 compounds.

High variability in data was also noted with cross-reactivity of compounds previously identified over 8 years ago to be cross-reactive on specific UDT immunoassays. Perhaps the best example of this is cross-reactivity of quinolone antibiotics to opiates immunoassays, a finding published in a high-impact general medical journal (*JAMA*) 17 years ago.²⁰ Only 2 of 28 opiate immunoassay package inserts analyzed in the present study contained any information on quinolone antibiotic cross-reactivity. Similar low rates were seen for other compounds previously shown to be cross-reactive. The paucity of data makes it challenging to interpret UDT results. For the quinolone antibiotics, a literature search would reveal the 2001 publication that had analyzed 11 different quinolone antibiotics for cross-reactivity. However, without data on how more recent versions of UDT assays cross-react, it is not possible to predict cross-reactivity.

A general trend throughout package inserts is that they often do not contain cross-reactivity data on drug metabolites (unless the metabolites of one drug are themselves also a parent drug) and designer drugs.^{14,43} There are practical challenges in that metabolism of designer drugs may be poorly understood. Further, reference standards for drug metabolites and designer drugs may be difficult and costly to obtain. Labetalol is a good example of a drug whose metabolite has higher cross-reactivity to UDT immunoassays than the parent compound. The labetalol metabolite APB cross-reacts well with amphetamine UDT immunoassays (first reported in 1995), while the parent drug has much weaker or no cross-reactivity, as demonstrated in multiple publications.¹⁷⁻¹⁹ Yet in our analysis, data for the

metabolite were found in only 2 of 30 current amphetamines UDT package inserts (both from the same manufacturer). The low amount of cross-reactivity data for designer drugs is not surprising, since some have only recently emerged as drugs of abuse.¹⁷⁻¹⁹ For designer drugs, published literature often provides more information, as illustrated with a recent publication on designer benzodiazepine cross-reactivity with UDT immunoassays.³⁵

One regulatory challenge is that there are no established guidelines for which and how many compounds to test for cross-reactivity,¹⁴ although there are publications such as Guidance Document C-52 from the Clinical and Laboratory Standards Institute that can guide how to perform and report such testing once compounds are selected.⁴⁴ Many package inserts utilize language such as “structurally related” compounds, although it is not clear how this is defined, either by manufacturers or the FDA. The FDA guidance does state that labeling of drug of abuse assays should include information on cross-reactivity/interferences, with cross-reactivity defined as how much the assay antibodies cross-react with “similar” drugs/metabolites/compounds.⁴⁵ For the amphetamines, for example, ephedrine, phentermine, and pseudoephedrine show obvious similarity in chemical structure. Structural resemblance is less obvious with other compounds known to be cross-reactive (eg, quinolone antibiotics compared to morphine).

One systematic computational approach to this problem is molecular similarity, a computational technique that quantifies chemical similarity of one compound to the other. This approach has been used to rationalize and predict cross-reactivity of immunoassays used in UDT,^{14,16,43,46} therapeutic drug monitoring,⁴⁷ and endocrinology.⁴⁸ Regardless of approach, it would help to have more consistency in cross-reactivity testing, placing priority on compounds known to be cross-reactive in at least some assays and those with higher structural similarity to the target of the assay. This is an area of potential improvement for both regulators and manufacturers.

Overall, pathologists and other health-care professionals should be aware of the limitations of manufacturer information for UDT immunoassays. This can be especially challenging when managing patients who have had testing performed at other institutions or laboratories or in health-care systems utilizing a variety of different UDTs. Ideally, the number of different UDT systems should be minimized where feasible. In working up discrepant or confusing results, it can be time-consuming to determine which exact assays were used and attempt to obtain package inserts. For package inserts that are not readily available online, faxing or scanning the primary document can be challenging due to irregular sizes and small font. Literature searches for publications on cross-reactivity play an important role, particularly for designer drugs or other compounds that are unlikely to have been tested by the manufacturer for cross-reactivity. Confirmatory testing using MS should be considered when the clinical question cannot be answered by immunoassay screen alone. Lastly, pathologists

and the clinical laboratory can play a helpful consultative role in drug test interpretation and assay selection.

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Impact of Daily Electronic Laboratory Alerting on Early Detection and Clinical Documentation of Acute Kidney Injury in Hospital Settings

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Abstract

Acute kidney injury, especially early-stage disease, is a common hospital comorbidity requiring timely recognition and treatment. We investigated the effect of daily laboratory alerting of patients at risk for acute kidney injury as measured by documented *International Classification of Diseases* diagnoses. A quasi-experimental study was conducted at 8 New York hospitals between January 1, 2014, and June 30, 2017. Education of clinical documentation improvement specialists, physicians, and nurses was conducted from July 1, 2014, to December 31, 2014, prior to initiating daily hospital-wide laboratory acute kidney injury alerting on January 1, 2015. Incidence based on documented *International Classification of Diseases* diagnosis of acute kidney injury and acute tubular necrosis during the intervention periods (3 periods of 6 months each: January 1 to June 30 of 2015, 2016, and 2017) were compared to one preintervention period (January 1, 2014, to June 30, 2014). The sample consisted of 269 607 adult hospital discharges, among which there were 39 071 episodes based on laboratory estimates and 27 660 episodes of documented *International Classification of Diseases* diagnoses of acute kidney injury or acute tubular necrosis. Documented incidence improved significantly from the 2014 preintervention period (5.70%; 95% confidence interval: 5.52%-5.88%) to intervention periods in 2015 (9.89%; 95% confidence interval, 9.66%-10.12%; risk ratio = 1.73, $P < .001$), 2016 (12.76%; 95% confidence interval, 12.51%-13.01%; risk ratio = 2.24, $P < .001$), and 2017 (12.49%; 95% confidence interval, 12.24%-12.74%; risk ratio = 2.19, $P < .001$). A multifactorial intervention comprising daily laboratory alerting and education of physicians, nurses, and clinical documentation improvement specialists led to increased recognition and clinical documentation of acute kidney injury.

Keywords

acute kidney injury, clinical documentation, KDIGO: Kidney Disease Improving Global Outcomes, clinical decision support, electronic laboratory alerting

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Introduction

Acute kidney injury (AKI) is a common comorbidity and affects up to 20% of all hospitalized patients.¹ The KDIGO (Kidney Disease: Improving Global Outcomes) guidelines are the most widely accepted evidence-based diagnostic criteria for AKI. The diagnosis and assessment of AKI severity is dependent on incremental rise in serum creatinine (SCr) above the patient's baseline value within a specified duration.¹ Increasing

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severity of AKI is associated with longer length of stay (LOS), costs of care, resource utilization, and in-hospital mortality.²⁻⁴ Hence, it is imperative to diagnose and manage AKI at the earliest possible stage during an inpatient admission. Since AKI can occur on virtually every hospital service, this comorbidity must be recognized by practitioners across a broad array of clinical specialties.

Although nephrologists are well-versed with KDIGO criteria, most AKI diagnoses, especially early-stage disease, are made by nonspecialist physicians.³ Physician recognition of AKI remains poor because of inability to apply KDIGO criteria consistently in routine hospital settings, limited clinical awareness among non-nephrologists, and lack of effective clinical decision support (CDS) tools in the electronic health record (EHR).^{5,6} A recent study confirmed lack of recognition of early AKI by nurses.⁷ While the implementation of EHR alerts in bringing AKI to the attention of providers has come under intense scrutiny,^{6,8} the impact of such alerts has not yet been shown to be of value.^{9,10} Automated AKI detection algorithms using delta-checking criteria have increasingly been embedded in Laboratory Information Systems (LIS) of biochemistry laboratories,¹¹⁻¹⁴ but the clinical value of LIS-generated alerts also remains unproven.

Incidence estimates based on hospital billing codes are more specific but less sensitive when compared to incidence estimates based on laboratory SCr criteria.^{15,16} However, billing codes tend to capture only the more severe cases of AKI (stage 2 and 3), which account for less than 30% of all AKI episodes.¹⁷ Hence, compared to laboratory data, billing codes underestimate the true disease burden and economic impact of AKI, especially early-stage disease.^{16,17}

This study was conducted as part of a quality improvement project to standardize detection of AKI within an integrated health system in New York. The clinical aim was to introduce into routine hospital practice, especially in nonspecialist settings, a comprehensive electronic laboratory AKI alerting system based on KDIGO criteria. Besides standardizing early AKI detection, we aimed to reduce variability in diagnosis by embedding this alerting system into daily clinical workflow.^{18,19} The laboratory-triggered AKI alert was distributed in a patient-specific fashion to all inpatient units, with the requirement that such patients be evaluated promptly. Clinical documentation of AKI, through the *International Classification of Diseases (ICD)* coding system, was used as the primary end point and laboratory estimates of AKI severity were assessed as secondary end points to evaluate the effectiveness of daily laboratory alerting.

Methods

Study Design, Setting, and Population

We performed a quasi-experimental study with a pre-post study design and interrupted time-series analysis.²⁰ The study was conducted at 8 adult hospitals within the Northwell Health System between January 1, 2014, and June 30, 2017. Although

the alerting program ran in continuity, data were collected and analyzed for four 6-month intervals during this study period so as to avoid potential seasonality as a confounding factor: January 1 to June 30, 2014; January 1 to June 30, 2015; January 1 to June 30, 2016; and January 1 to June 30, 2017. For these 4 time periods; there were 65 831 discharges in 2014, 66 364 discharges in 2015, 68 889 discharges in 2016, and 68 523 discharges in 2017 at the 8 hospital sites collectively. With one exception, all sites shared the same LIS, Cerner Millennium and EHR, Sunrise Clinical Manager (Allscripts Corp, Raleigh, North Carolina). The exception was one study site which was not yet on the Cerner Millennium LIS in January to June 2014, but was by the January to June 2015 time period. This study was limited to inpatient adult medical and surgical patients greater than 18 years of age.

A health system executive committee comprising senior clinical leadership from the Department of Pathology and Laboratory Medicine, the Division of Nephrology, and the system Clinical Quality program endorsed the policy to standardize AKI detection through daily alerts.

Acute Kidney Injury Criteria and Baseline Creatinine

The KDIGO criteria rely on the ability to detect an incremental increase in SCr, compared to a baseline value, of 0.3 mg/dL within 48 hours and/or a 50% increase (1.5 times) within 7 days.¹ The KDIGO definition also suggests comparing the high inpatient SCr value to a prior stable baseline, usually an outpatient SCr measurement in a patient's normal state of health.¹ But, there is no consensus on what the baseline should be, and investigators have used different surrogates.²¹⁻²³ If no reliable estimate of baseline SCr can be made, the KDIGO guidelines recommend using the lowest SCr during hospitalization as the baseline.¹ Although there may be risk of dilutional artefact in SCr measurements if blood samples are drawn from an intravenous line, our hospital quality metrics indicate that test cancellations due to "improper collection" are rare. The most common causes of test cancellations are clotted sample (44%) or quantity not sufficient (36%); among remaining causes, "improper collection" (wrong tube type or wrong collection methodology, including dilutional artefact) were only 6% of cancelled tests, or 0.006% of total tests (data not shown). We therefore felt that use of the lowest SCr during hospitalization as the baseline was appropriate.

Laboratory Electronic Alerting for Acute Kidney Injury

We developed a real-time alerting system based on a structured query language algorithm run on all laboratory SCr values generated during an inpatient encounter (Figure 1). Our algorithm used the delta-checking functionality within Cerner. Because of inconsistent access to prior outpatient SCr values for all hospitalized patients, the minimum inpatient SCr value was used as the baseline for this algorithm, as per KDIGO guidelines.¹ Initial SCr at the time of admission was included as a potential baseline value. If the baseline value decreased

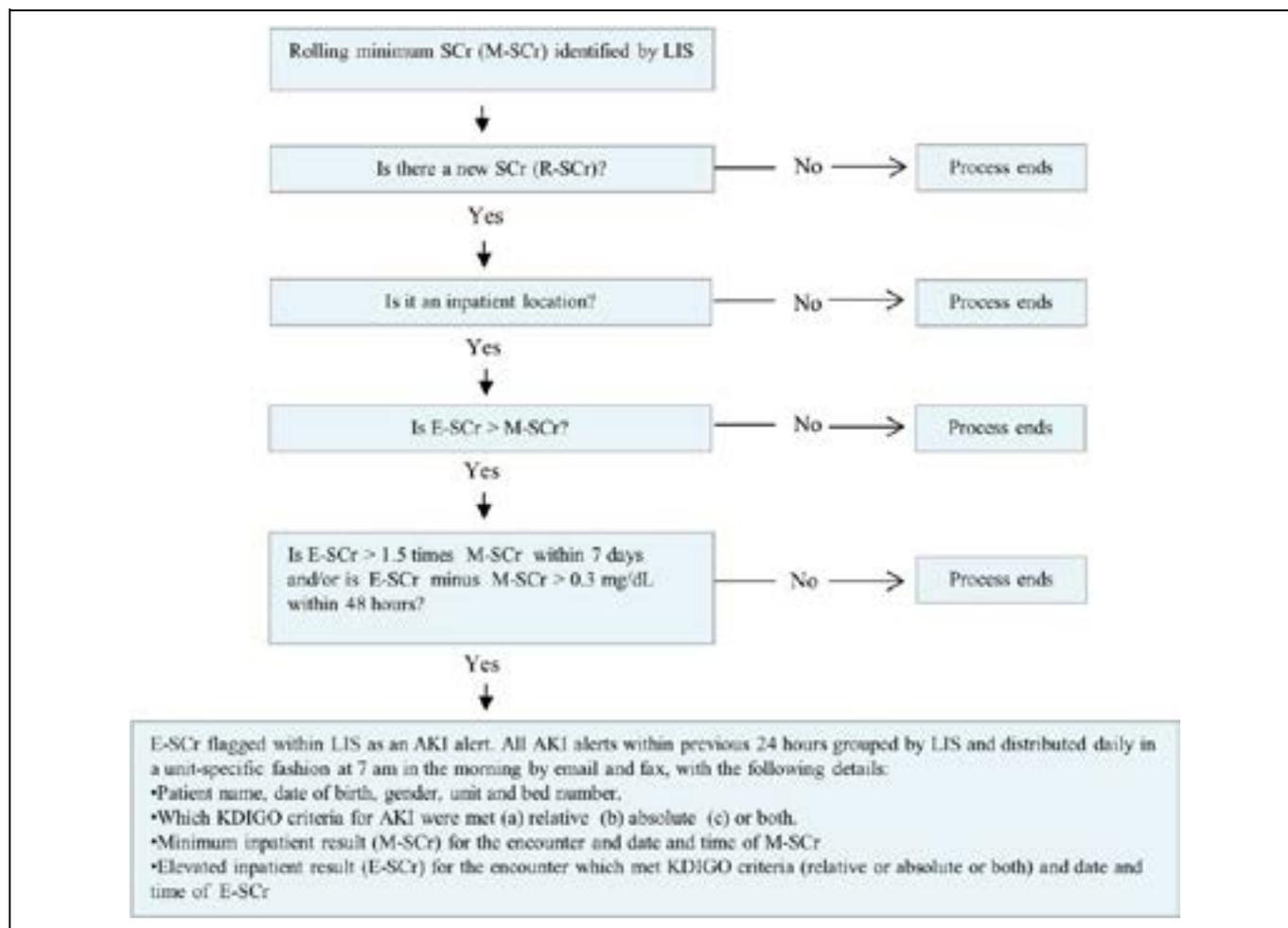


Figure 1. Electronic reporting algorithm for AKI using serum creatinine measurements. AKI, acute kidney injury; E-SCr, elevated serum creatinine; KDIGO, kidney disease improving global outcomes; LIS, laboratory information system; M-SCr, minimum serum creatinine;

during admission, then the new minimum SCr became the rolling baseline. If there was a clinically significant rise consistent with KDIGO criteria, then an alert was generated and the elevated SCr result was flagged. Patients who only had a single SCr measurement during the encounter or did not meet the KDIGO criteria were not flagged.

All SCr measurements from emergency departments, admission units, intensive care units, or any other inpatient location were included. All SCr values throughout the study period were measured using Roche Cobas automated analyzers, based on the modified Jaffe Method. The coefficient of variation of the SCr assay ranged from 2.5% to 5% (normal creatinine range, 0.5-1.2 mg/dL).

Development of Acute Kidney Injury Rounding Report and Validation of Alerting System

To create the daily report, the project team programmed the LIS to generate an electronic report of all AKI alerts within the previous 24 hours. A unit-specific consolidated report, with patient room and bed location, was faxed and e-mailed to

clinical and nursing leads of all units at 7:00 AM in the morning. This “rounding” report was then discussed at morning ward rounds to ensure all members of the clinical team were aware of their patients at risk for AKI. We validated the algorithm and reporting workflow at one hospital (pilot site) from January 1, 2014, to June 30, 2014. The chief medical officer (CMO) of the pilot hospital (G.B.) conducted a provider alert awareness campaign from November to December 2013, prior to the introduction of alerting system.

Intervention

Despite daily AKI alerting at the pilot site for the first 6 months of 2014, preliminary analysis of billing data showed only a minimal improvement in provider documentation of AKI (Supplemental Figure 1). Starting in July 2014, and with the approval of the CMOs of the respective system hospitals, the Clinical Documentation Improvement (CDI) team and Department of Pathology and Laboratory Medicine created a system-wide partnership. At the pilot site, through July to December 2014, in addition to issuance of the rounding report to clinical

units, a copy of the daily AKI rounding report was sent to the CDI specialists who received instructions to query physicians in case of inconsistent documentation of AKI. Supplemental Figure 1 shows that clinical documentation of AKI at the pilot site then began to increase. During this same time period (July to December 2014), physicians and nurses at all 8 hospitals received presentations regarding accurate clinical documentation of AKI based on KDIGO criteria, severity, etiology, and treatments. An awareness campaign for CDI specialists and medical coders at all 8 hospitals also was conducted from July to December 2014.

Data Collection and Statistical Analysis

We analyzed billing data for every hospital episode with a primary or secondary diagnosis-related groups (DRGs) diagnosis of AKI or acute tubular necrosis (ATN), which in turn are based on the 9th and 10th iterations of the *ICD Clinical Modification (ICD-9CM, ICD-10-CM)*. We analyzed laboratory data on AKI alerts generated by our algorithm from the LIS database, noting that a single hospital admission can result in multiple AKI alerts. Accordingly, every hospital episode was categorized into KDIGO stages 1 to 3, as follows—stage 1: SCr increase by ≥ 0.3 mg/dL from baseline or SCr increase by 1.5 to 1.9 times baseline; stage 2: SCr increase by 2.0 to 2.9 times baseline; stage 3: SCr increase by 3.0 times baseline or SCr ≥ 4 mg/dL. Only the most severe AKI alert for each hospital episode was used for classifying laboratory data into stages 1 to 3.

Data points collected (deidentified) were age, gender, encounter number, baseline SCr result, SCr result which met the KDIGO criteria of (a) absolute rise of 0.3 mg/dL within 48 hours, (b) relative rise of 50% within 7 days, or (c) both. The institutional review board waived the need for informed patient consent because the data were collected as part of an ongoing quality improvement project.

For all hospitals, we only compared data from January 1, 2014, to June 30, 2014 (1 preintervention period) with data from January 1, 2015, to June 30, 2015, January 1, 2016 to June 30, 2016, and January 1, 2017, to June 30, 2017 (3 post-intervention periods), to avoid the potential confounding effect of our educational intervention (July 1, 2014, to December 31, 2014) on data from the pilot site and to minimize the effect of seasonal variation.

All incidence estimates for billing and laboratory data were calculated using cumulative incidence methodology. The total number of hospital discharges were the denominators for incidence calculations. As noted earlier, Cerner LIS was in use at 7 of the hospitals for the full study period but was implemented in the latter half of 2014 at one of our hospitals (which was not the 2014 pilot hospital). Hence, the denominator for aggregate AKI incidence calculations from January to June 2014 for laboratory data (7 hospitals) was lower compared to billing data (8 hospitals).

The 95% confidence interval (CI) for incidence estimates was calculated assuming a normal distribution. We grouped laboratory-identified stage 1 and stage 2 AKI episodes as “early

AKI” and stage 3 episodes as “late AKI.” Analysis of variance was used to assess the statistical significance of data variation of the 4 study years (2014-2017). For comparisons of individual years, risk ratio (RR) and absolute risk difference (RD) were used to compare pre- and postintervention incidence estimates. For all statistical tests, $P < .05$ was considered statistically significant; numerical P values are given down to $P < .001$. Microsoft Excel (version 2013) and Minitab (version 14) were used for all analyses.

Results

Incidence of Acute Kidney Injury Episodes

Clinical documentation. Preliminary analysis of coded *ICD* data for the pilot hospital site for the preintervention period (January 1, 2014, to June 30, 2014) showed that the incidence of AKI/ATN combined was 5.52% (509 episodes in 9213 discharges). After our definitive educational intervention (July 1, 2014, to December 31, 2014), incidence for documented AKI and ATN diagnosis improved steadily at the pilot site during the remainder of 2014, reaching 13.1% in December (1245 episodes in 9502 discharges). The monthly incidence rates in 2014 at the pilot site are shown in Supplemental Figure 1, documenting the steady rise in the second half of the calendar year, concurrent with the ongoing educational campaign.

For the 8 hospital sites, the study population consisted of a total of 269 607 adult hospital discharges (65 831 in 2014; 66 364 in 2015; 68 889 in 2016, and 68 523 in 2017). The episode counts for AKI, ATN, and AKI/ATN combined for all hospitals over the study period are given in Table 1. When compared to preintervention period of 2014 (2965 AKI and 789 ATN episodes), the number of coded AKI and ATN episodes increased over the postintervention periods of 2015 (5523 AKI and 1040 ATN episodes), 2016 (7589 AKI and 1198 ATN episodes), and 2017 (7383 AKI and 1173 ATN episodes). The proportion of episodes coded as AKI (versus ATN) also increased: from 79.0% in 2014, to 84.2% in 2015, 86.4% in 2016, and 86.3% in 2017; corresponding proportions for ATN were 21.0% in 2014, 15.8% in 2015, 13.6% in 2016, and 13.7% in 2017. This supports the premise that a large proportion of the increased count of documented episodes was because of better detection and treatment of early-stage AKI.

The denominator for incidence calculations was the number of hospital discharges. For all 8 hospitals combined during the preintervention period (January to June, 2014), the incidence of AKI was 4.5% (2965 episodes in 65 831 discharges), the incidence of ATN was 1.2 % (789 episodes in 65 831 discharges), and incidence of AKI and ATN combined was 5.7% (3754 episodes in 65 831 discharges).

Beginning in January 2015, clinically documented incidence rates of AKI and ATN at all hospitals steadily increased. Documented incidence of AKI increased to 8.32% in 2015, 11.02% in 2016, and 10.77% in 2017 ($P = .002$). Similarly, documented incidence of ATN increased from 1.2% in 2014 to 1.57% in 2015, 1.74 % in 2016, and 1.71% in 2017 ($P = .013$).

Table 1. Study Characteristics and Incidence of AKI Episodes by Laboratory Data and Administrative (ICD) Data for 8 Hospitals by Study Period.

Characteristic	Preintervention Period	Postintervention Periods			P Value [‡]
	January 1, 2014, to June 30, 2014*	January 1, 2015, to June 30, 2015	January 1, 2016, to June 30, 2016	January 1, 2017, to June 30, 2017	
Episodes as per clinical documentation (ICD) data					
Discharges, count	65 831	66 364	68 889	68 523	NA
Episodes coded as AKI, count	2965	5523	7589	7383	NA
Proportion of episodes coded as AKI (%)	2965/3754 (79.0)	5523/6563 (84.2)	7589/8787 (86.4)	7383/8556 (86.3)	NA
Episodes coded as ATN, count	789	1040	1198	1173	NA
Proportion of episodes coded as ATN (%)	789/3754 (21.0)	1040/6563 (15.8)	1198/8787 (13.6)	1173/8556 (13.7)	NA
Episodes coded as AKI or ATN, count	3754	6563	8787	8556	NA
Incidence (95% CI) of coded AKI episodes per 100 discharges	4.50 (4.34-4.66)	8.32 (8.11-8.53)	11.02 (10.79-11.25)	10.77 (10.54-11.0)	.002
Incidence (95% CI) of coded ATN episodes per 100 discharges	1.20 (1.12-1.28)	1.57 (1.48-1.66)	1.74 (1.64-1.84)	1.71 (1.61-1.81)	.0130
Incidence (95% CI) of total coded AKI and ATN episodes per 100 discharges	5.7 (5.52-5.88)	9.89 (9.66-10.12)	12.76 (12.51-13.01)	12.49 (12.24-12.74)	.001
Episodes as per laboratory data					
Discharges, count	55 559 [‡]	66 364	68 889	68 523	NA
Stage 1 AKI episodes, count	9061	10 062	10 891	11 115	NA
Stage 2 AKI episodes, count	2103	2381	2369	2656	NA
Stage 1 and 2 AKI episodes combined (early AKI), count	11 164	12 443	13 260	13 771	NA
Proportion of early AKI episodes (%)	11 164/11 821 (94.4)	12 443/13 227 (94.1)	13 260/14 023 (94.6)	13 771/14 450 (95.3)	NA
Stage 3 AKI episodes (late AKI), count	657	784	763	679	NA
Proportion of late AKI episodes (%)	657/11 821 (5.6)	784/13 227 (5.9)	763/14 023 (5.4)	679/14 450 (4.7)	NA
All stages AKI episodes, count	11 821	13 227	14 023	14 450	NA
Incidence (95% CI) of AKI stage 1 episodes per 100 discharges	16.31 (16.0-16.62)	15.16 (14.89-15.43)	15.81 (15.54-16.08)	16.22 (15.94-16.5)	.903
Incidence (95% CI) of AKI stage 2 episodes per 100 discharges	3.79 (3.63-3.95)	3.59 (3.45-3.73)	3.44 (3.3-3.58)	3.88 (3.74-4.02)	.514
Incidence (95% CI) of AKI stage 1 and 2 episodes combined (early AKI) per 100 discharges	20.1 (19.77-20.43)	18.75 (18.46-19.04)	19.25 (18.96-19.54)	20.1 (19.8-20.4)	.832
Incidence (95% CI) of AKI stage 3 (late AKI) episodes per 100 discharges	1.18 (1.09-1.27)	1.18 (1.09-1.27)	1.11 (1.03-1.19)	0.99 (0.92-1.06)	.438
Incidence (95% CI) of AKI all stages combined per 100 discharges	21.28 (20.94-21.62)	19.93 (19.63-20.23)	20.36 (20.06-20.66)	21.09 (20.79-21.39)	.404

Abbreviations: AKI, acute kidney injury; ATN, acute tubular necrosis; CI, confidence interval; ICD, *International Classification of Diseases*; LIS, Laboratory Information Systems; NA, not applicable.

*All comparisons of postintervention periods (2015, 2016, and 2017) are made with the preintervention period of 2014.

[‡]Analysis of variance was used to assess the statistical significance of data variation of the 4 study years (2014-2017).

[‡]The denominator for incidence calculations for laboratory data was lower for 2014 because of incomplete data: 7 of the 8 study hospitals were on the Cerner LIS at the time. For 2015 to 2017, all 8 study hospitals were on Cerner LIS.

In aggregate (AKI and ATN), the incidence based on documented diagnoses increased significantly from 5.7% (95% CI: 5.52%-5.88%) in 2014 to 9.89% (95% CI: 9.66%-10.12%) in 2015, 12.76% (95% CI: 12.51%-13.01%) in 2016, and 12.49% (95% CI: 12.24% to 12.74%) in 2017 ($P = .001$).

Laboratory data. For analysis of laboratory data, we categorized all hospital episodes into KDIGO stages 1 to 3 based on the most severe laboratory AKI alert for each episode. For comparison, we grouped laboratory-identified stage 1 and 2 AKI

episodes as *early* AKI and stage 3 episodes as *late* AKI. Although there is no 1:1 concordance between clinical severity of AKI cases based on KDIGO criteria, with the severity of documented ICD diagnosis of AKI or ATN, we hypothesized that most if not all stage 3 AKI episodes would be documented as ATN based on ICD coding. This distinction also allowed us to compare laboratory KDIGO criteria versus ICD coding criteria for AKI or ATN.

Table 1 shows that, compared to 2014, and allowing for capturing laboratory data for only 7 hospitals in 2014, there

Table 2. Comparison of Incidence Estimates Between Preintervention and Postintervention Periods.

Variable	Postintervention Period From January 1, 2015, to June 30, 2015		Postintervention Period From January 1, 2016, to June 30, 2016		Postintervention Period From January 1, 2017, to June 30, 2017	
	RR (95% CI)	P Value*	RR (95% CI)	P Value†	RR (95% CI)	P Value‡
Episodes as per clinical documentation (ICD) data						
Documentation of AKI	1.86 (1.78-1.94)	<.001	2.46 (2.35-2.55)	<.001	2.39 (2.30-2.49)	<.001
Documentation of ATN	1.31 (1.19-1.43)	<.001	1.45 (1.33-1.59)	<.001	1.43 (1.31-1.56)	<.001
Documentation of AKI and ATN combined	1.73 (1.67-1.80)	<.001	2.24 (2.16-2.32)	<.001	2.19 (2.11-2.27)	<.001
Episodes as per laboratory data						
Laboratory episodes, AKI stage 1	0.93 (0.91-0.95)	<.001	0.97 (0.95-0.99)	.017	0.99 (0.97-1.02)	.6763
Laboratory episodes, AKI stage 2	0.95 (0.89-1.0)	.0682	0.91 (0.86-0.96)	.0011	1.02 (0.97-1.08)	.4071
Laboratory episodes, AKI stage 1 and 2 (early AKI)	0.93 (0.91-0.95)	<.001	0.96 (0.94-0.98)	.0002	1.00 (0.98-1.02)	.9897
Laboratory episodes, AKI stage 3 (late AKI)	1.0 (0.9-1.11)	.9851	0.94 (0.84-1.04)	.216	0.838 (0.75-0.93)	.0012
Laboratory episodes, AKI all stages	0.94 (0.92-0.96)	<.001	0.96 (0.94-0.98)	<.001	0.99 (0.97-1.02)	.4185

Abbreviations: AKI, acute kidney injury; ATN, acute tubular necrosis; CI, confidence interval; ICD, *International Classification of Diseases*; RR, risk ratio.

*Comparison between the postintervention period of 2015 with preintervention period of 2014.

†Comparison between the postintervention period of 2016 with preintervention period of 2014.

‡Comparison between the postintervention period of 2017 with preintervention period of 2014.

was no change in the distribution of laboratory-identified stages of AKI in 2015, 2016, and 2017. Specifically, stage 1 and 2 “early” AKI contributed to 94% to 95% of all laboratory-detected episodes in all 4 years (2014-2017), with only 4% to 5% being stage 3 “late” AKI episodes.

In the preintervention, baseline period (2014), the incidence of AKI by stages was 16.31 % for stage 1, 3.79 % for stage 2, 20.1% for stage 1 and 2 combined (early AKI), 1.18 % for stage 3 (late AKI), and 21.28% for all AKI stages. The incidence of stage 1 AKI episodes decreased from 16.31% (95% CI: 16.0%-16.62%) in 2014 to 15.16% (95% CI: 14.89%-15.43%) in 2015. However, the incidence for stage 1 episodes increased to 15.81% (95% CI: 15.54%-16.08%) in 2016 and 16.22% (95% CI: 15.94%-16.5%) in 2017 ($P = .903$). Similarly, stage 2 AKI episodes slightly reduced in incidence from 3.79% (95% CI: 3.63%-3.95%) in 2014 to 3.59% (95% CI: 3.45%-3.73%) in 2015 and 3.44% (95% CI: 3.3%-3.58%) in 2016. Similar to stage 1, the incidence of stage 2 episodes rebounded to 3.88% (95% CI: 3.74%-4.02%) in 2017 ($P = .514$). Overall, laboratory-detected early AKI episodes (stage 1 and 2 combined) reduced from 20.1% (95% CI: 19.77%-20.43%) in 2014 to 18.75% (18.46%-19.04%) in 2015. However, incidence of early AKI increased to 19.25% (95% CI: 18.96%-19.54%) in 2016 and back to 20.1% (95% CI: 19.8%-20.4%) in 2017 ($P = .832$).

The incidence of stage 3 (late AKI) remained unchanged from 1.18% (95% CI: 1.09%-1.27%) in 2014 and 2015 to 1.11 % (95% CI: 1.03%-1.19%) in 2016. Stage 3 incidence slightly reduced to 0.99% (95% CI: 0.92%-1.06%) in 2017 ($P = .438$). The total incidence (all stages combined) of laboratory-detected AKI decreased from 21.28% (95% CI: 19.63%-20.23%) in 2014 to 19.93% (95% CI: 19.63%-20.23%) in 2015, but increased again to 20.36% (95% CI: 20.06%-20.66%) in 2016 and 21.09% (95% CI: 20.79%-21.39%) in 2017 ($P = .404$).

Comparison of Incidence Estimates Between Preintervention and Postintervention Periods

For ease of comparison of incidence estimates between preintervention and postintervention periods, we calculated the risk ratio by comparing the postintervention periods of 2015, 2016, and 2017 with the control (preintervention) period of 2014 (Table 2).

Clinical documentation. Compared to the preintervention period, documentation of AKI significantly increased in 2015 (RR = 1.86, $P < .001$), 2016 (RR = 2.46, $P < .001$), and 2017 (RR = 2.39, $P < .001$). Similarly, documentation of ATN significantly increased in 2015 (RR = 1.31, $P < .001$), 2016 (RR = 1.45, $P < .001$), and 2017 (RR = 1.43, $P < .001$). Overall, the documentation of AKI and ATN combined increased significantly and was sustained over the postintervention periods of 2015 (RR = 1.73, $P < .001$), 2016 (RR = 2.24, $P < .001$), and 2017 (RR = 2.19, $P < .001$). These RR ratios corroborate the data shown in Table 2, in which there was a >150% increase in 2015, and >200% increase in 2016 and 2017, of timely clinical documentation of AKI and ATN episodes when compared to 2014.

Laboratory data. Because of laboratory alerting and education of providers, we had hoped to see a reduction in the disease burden of AKI as calculated by laboratory incidence estimates. However, as shown in Table 2, though stage 1 episodes decreased in 2015 (RR = 0.93, $P < .001$) and 2016 (RR = 0.97, $P = .017$), this trend was not sustained in 2017 (RR = 0.99, $P = .6763$). Similarly, stage 2 episodes decreased in 2016 (RR = 0.91, $P < .001$), but this was not preceded by reduction in 2015 (RR = 0.95, $P = .0682$) and also not sustained in 2017 (RR = 1.02, $P = .4071$). The combined stage 1 and stage 2 (early AKI) incidence decreased in 2015 (RR = 0.93, $P < .001$) and 2016 (RR = 0.96, $P = .002$), but this was not sustained in 2017 (RR = 1.0, $P = .9897$). Stage 3 (late AKI) episodes did

Table 3. Comparison of Incidence Estimates of AKI Episodes Between Laboratory Data and Coded (ICD) Data, Preintervention Period, and Postintervention Periods.

Characteristic	Preintervention Period	Postintervention Periods		
	January 1, 2014, to June 30, 2014	January 1, 2015, to June 30, 2015	January 1, 2016, to June 30, 2016	January 1, 2017, to June 30, 2017
Incidence (95% CI) of AKI all stages combined per 100 discharges	21.28 (20.94-21.62)	19.93 (19.63-20.23)	20.36 (20.06-20.66)	21.09 (20.79-21.39)
Incidence (95% CI) of total coded AKI and ATN episodes per 100 discharges	5.7 (5.52-5.88)	9.89 (9.66-10.12)	12.76 (12.51-13.01)	12.49 (12.24-12.74)

Abbreviations: AKI, acute kidney injury; ATN, acute tubular necrosis; CI, confidence interval; ICD, *International Classification of Diseases*.

not decrease in 2015 (RR = 1.0, $P = .9851$) or 2016 (RR = 0.94, $P = .216$), but did decrease in 2017 (RR = 0.838, $P = .0012$), suggesting no consistent effect. Overall, the laboratory incidence for all stages combined decreased in 2015 (RR = 0.94, $P < .001$) and 2016 (RR = 0.96, $P < .001$), but this effect was not sustained through 2017 (RR = 0.99, $P = .4185$). These data do not allow distinction between whether this program was or was not effective in reducing the disease burden of AKI, since we were not examining potential risks for development of AKI in this study.

Comparison of Incidence Estimates of Acute Kidney Injury Episodes Between Laboratory Data and Coded (International Classification of Diseases) Data

Direct comparisons of incidence estimates from laboratory-identified AKI episodes versus administratively documented AKI and ATN episodes are given in Table 3 and Supplemental Figure 2. Before intervention, the incidence of laboratory-detected AKI episodes (21.28 %) was significantly different from coded ICD episodes (5.7%) in 2014 (RD, 15.57%). After intervention, this gap between laboratory incidence and documented incidence narrowed in 2015 (RD, 10.05%), improved further in 2016 (RD, 7.6%) and was sustained in 2017 (RD, 8.6%). We calculate that compared to 2014 preintervention period, an additional 2809, 5033, and 4802 episodes of AKI and ATN were documented in 2015, 2016, and 2017, respectively.

Discussion

To our knowledge, this study is the first to show how inpatient daily laboratory alerting for AKI combined with education of clinical providers (physician and nurses), CDI specialists, and medical coders significantly improved provider recognition and documentation of AKI and ATN. As the 2014 single hospital pilot demonstrated, daily laboratory alerting alone was an insufficient intervention. Communicating the risk of AKI through daily reports in a unit-targeted fashion across the entire hospital, combined with preparatory education for both providers and the administrative teams were important factors in improved recognition and documentation of AKI. A critical factor was the collaboration between the laboratory and the

CDI team. The CDI specialists were the effector arm both for reaching out to the providers regarding patients at risk for AKI and for ensuring compliance with documentation. We also had the all-important support of hospital leadership at each of the 8 hospital sites.

This study presents a workflow innovation for early AKI recognition which can be replicated in other hospital settings. First, KDIGO guidelines are automated into computable CDS, using the delta-checking functionality of the LIS.²⁴ Delta check algorithms are highly sensitive and capture >98% of patients at risk for AKI.^{3,13} Second, alert fatigue is avoided by consolidating daily alerts into a single report for morning rounds.^{18,25,26} Third, there is an educational focus on provider behavioral change in conjunction with implementing the daily AKI alerts.^{9,27,28} Fourth, clinical documentation compliance is promoted by partnering with CDI professionals. Of necessity, clinical documentation demands both clinical diagnosis and appropriate clinical management. Formal AKI documentation has been associated with improved patient survival after adjusting for severity of illness.²⁹ Fifth, linkage of administrative coding data with laboratory data enables examination of the true disease burden of AKI for registry-based clinical studies.^{30,31}

This study has numerous strengths. First, the incidence of AKI based on laboratory estimates is similar to other investigations and confirms the reported gap between laboratory estimates and documented AKI diagnoses.^{4,16} Second, our alerting system is a fully automated, low-cost solution, requiring no manual laboratory intervention.^{15,17} Third, similar to recent reports, we show that laboratory data can be successfully used as a surveillance tool for AKI monitoring in routine hospital settings.^{3,32}

The clinically documented rates of AKI and ATN, our primary outcome of interest, improved significantly from 5.7% in 2014 to 9.89% in 2015, 12.76% in 2016, and 12.49% in 2017. This represented a substantial increase in the assignment of hospital episodes to appropriate DRG categories of AKI (comorbidity) and ATN (major comorbidity). It is reasonable to posit that improved documentation had a significant impact on the calculated case-mix index for the 8 hospitals in the study and on expected LOS and baseline mortality for reporting to regulatory agencies.

Analysis of aggregated laboratory data for all hospitals showed a slight but significant reduction in laboratory-detected AKI incidence from 21.28% in 2014 to 19.93% in 2015 and 20.36% in 2016. However, this reduction was confined to early AKI (stage 1 and 2) and the laboratory-detected AKI incidence increased again to 21.09% in 2017. These data suggest that our intervention had some desirable impact on reducing overall disease burden in 2015 and 2016 but was not sustained through 2017. Consistent sustained reduction in disease burden and progression will require more sophisticated CDS which integrates laboratory with pharmacy data in real time to modulate dosing of nephrotoxic medications, as well as algorithmic treatment approaches and development of novel biomarkers.^{9,33-35}

Our study has limitations. Selection of appropriate baseline SCr is an important determinant of accuracy of AKI detection algorithms. Using minimum inpatient SCr is a sensitive method for AKI detection, but it can lead to false-positives.^{4,36,37} However, our approach was to use laboratory alerting as a screening tool to prompt earlier clinical evaluation rather than provide a diagnosis.⁸ Since we were implementing this system across all units including nonspecialist areas, we accepted the trade-off of high sensitivity over lower specificity. Although some laboratory alerts could have been false-positive, the physicians were required to use their clinical judgment to attribute elevated SCr to AKI. Moreover, to satisfy documentation compliance, the provider needed to document the likely etiology, treatment, and additional nursing time spent in management of the patient. All these provider-driven steps would help ensure that the clinical diagnosis of AKI would have the requisite specificity.

Use of lowest SCr in intensive care settings could lead to overdetection of AKI. However, this has more to do with a lack of consensus on the best estimate for baseline creatinine in the literature.²¹ Investigators have used varying surrogates for baseline SCr, including first inpatient value, minimum inpatient value, average of first 3 values, and an average of outpatient value within 1 year prior to hospitalizations. This lack of consensus makes comparisons difficult and sometimes impractical. According to recent literature, the best value for baseline creatinine is a patient's outpatient SCr value in a normal state of health.^{22,23} However, this outpatient value is not available in most in-patient settings due to lack of interoperability between outpatient and inpatient EHR systems. Consequently, the outpatient SCr value is difficult to obtain and implement consistently in AKI detection algorithms. However, KDIGO guidelines recommend that, if a reliable outpatient SCr value/estimate cannot be obtained, then the next best choice for baseline is the minimum inpatient value.

Acute kidney injury occurs most commonly as a secondary diagnosis in conjunction with other common medical and surgical diagnosis. As this study was based on laboratory and administrative coding data only, we did not assess the impact of our intervention on other clinical outcome variables such as mortality and LOS. We did not have access to granular cost data for hospital episodes. Thus, the impact of our intervention on costs-of-care was not part of this study.^{17,38,39}

Although it can be argued that alerts in the EHR would be the ideal solution, such alerts do not provide a fail-safe for 2 reasons: the ever-present concern about "alert fatigue" and the requisite that a provider interact with the EHR in order to observe such an alert. A founding premise of this program was hospital medical leadership's desire to guarantee medical assessment of potential AKI patients' status at the start of every hospital day. The laboratory-based program provided the foundational data, using delta-checking functionality available within most modern LISs. Indeed, this LIS-based approach for AKI alerting is now in widespread use in the National Health Service in England.¹¹ That being said, institutional efforts to establish real-time AKI alerts within the EHR continue.

A 24-hour rounding report could lead to an alert delay of anywhere between 1 and 23 hours. However, we believe that the enhanced sensitivity of our alerting system offsets the delay in diagnosis resulting from consolidating the alerts from the previous 24 hours into a single report. Specifically, using the minimum inpatient SCr as the baseline allows our alerting algorithm to be extremely sensitive to any significant SCr fluctuations as has been demonstrated in earlier studies.^{3,4} Also, this decision to use a once a day report was taken in conjunction with the CMOs' desire to minimize alert fatigue and optimize provider focus on AKI as a clinical parameter. The fact that clinical recognition of AKI increased, as monitored by coding for this condition, provides assurance that the chosen strategy was of value.

Although the total laboratory incidence of AKI/ATN declined in 2015 and 2016, there was rebound in laboratory disease burden in 2017. This possibly could have been due to unanticipated and unwelcome provider behavioral change of not paying attention to laboratory values over the course of a day and depending solely on the daily alert. However, many studies indicate that isolated laboratory or EHR alerting is not sufficient factor to reduce inpatient AKI morbidity.^{27,33,40} A comprehensive approach involving algorithmic, step-wise treatment plans including proper fluid management and medication reconciliation is necessary for treatment of AKI and prevention of progression to severe stage 3 injury.

In our study, there was a reduction in severe stage 3 episodes in 2017. This leads us to believe that providers did benefit from the daily notification, countering the argument that provider inattention may have been a consequence of this alerting program. Although severe stage 3 AKI episodes can lead to chronic kidney disease (CKD) postdischarge, we do not currently have longitudinal postdischarge data to evaluate whether long-term CKD has been reduced, owing to the current lack of an electronic master patient index in our LIS and EHR systems. This prohibited accurate linkage of inpatient to outpatient laboratory data for longitudinal follow-up of patients. Patients who suffer AKI in hospitals have a much higher risk of developing long-term CKD. Similarly, patients with preexisting CKD are more likely to develop AKI when admitted to hospitals.⁴⁰ In the latter instance, our data did not identify patients with preexisting CKD who may have a higher baseline SCr and may thus have been misclassified on the basis of their

admission SCr values. However, it is now increasingly believed that AKI and CKD are not separate conditions but a spectrum of disorders.⁴⁰ Also, there are inherent limitations in the current definitions of AKI and CKD, which categorize patients into distinct categories, when they can be superimposed on each other.

Conclusions

Laboratory data remain an underutilized resource for detection of AKI in routine hospital settings. We show how laboratory reporting of AKI can be used to augment administrative coding data in the detection of AKI and demonstrate the impact of laboratory reporting on improved clinical documentation. Simultaneously, we demonstrate the importance of linking a laboratory-based program with education of clinical providers and their administrative support personnel to achieve a sustained and significant increase in the recognition and clinical documentation of AKI.

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Supplemental Material

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The following abstracts were accepted by the Association of Pathology Chairs, without modification, for poster presentation at the 2018 APC Annual Meeting. This content was not peer reviewed by *Academic Pathology*.

Presenting authors' names are bolded throughout.

APC-18-0001PC. Pathology's Role in Biospecimen Science: A Study of Preanalytic Variables' Impact on Thrombosis Biomarkers

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Objectives: Some cancers and cancer treatments significantly increase the risk of venous thromboembolism with associated increased mortality and morbidity. Biomarkers of thrombosis may be predictive, but few have been adopted in pathology and laboratory medicine due to lack of standardization. This pilot study was designed to identify steps during biospecimen procurement, handling, and processing for optimal specimen preservation and accurate marker detection. The objective is to provide guidance for measuring thrombosis biomarkers in patients with cancer. **Methods:** Blood samples are collected from adult patients with cancer at diagnosis, pretreatment, and noncancer donors using rigorous standard operating procedures (SOPs). The impact of preanalytical variables (PAVs) in a clinical setting (delay to fractionation, delay to assay, and freeze–thaw cycles) is measured on markers of coagulation (factor VIII activity, F8; prothrombin fragment 1 + 2, F1 + 2), fibrinolysis (D-dimer, DDE; plasminogen activator inhibitor 1; plasmin–antiplasmin complex), cell injury (plasma DNA, DNA; nucleosomes, Nuc), and inflammation (soluble P-selectin, sPS; myeloperoxidase, MPO). Patients are followed for cancer and thrombotic outcomes and results compared. **Results:** Demographics of patients with cancer are 60% male, and



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62% identify as non-Caucasian with an age range of 38 to 86 years. Noncancer controls are 52% male and 41% non-Caucasian with an age range of 23 to 64 years. Interim project data show increased thrombosis biomarker levels in patients with cancer, except for sPS and F1 + 2. Biomarker levels in patients with cancer (n = 9-52) were increased by approximately 300 ng/mL DNA, 100 ng/mL DDE, and 5 ng/mL MPO with a trending increase in FVIII (~30%) when compared to noncancer controls (n = 17-22). Freeze-thaw of plasma had no effect, while a 2-hour time to fractionation resulted in significantly increased MPO (~10 ng/mL), FVIII (~14%), and F1 + 2 (~310 pg/mL). Delay to testing for DNA and DDE showed no apparent effect on biomarker levels after 24 or 72 hours at 4°C. Current data show biomarker levels are impacted by presence of cancer rather than ethnicity of the patient. **Conclusions:** Donor recruitment is ongoing with recruitment goals of a diverse patient population. Rigorous use of hospital compatible SOPs contributes to identifying PAVs that matter for procedures that translate in the pathology setting for better diagnoses.

APC-I8-0002PC. Using Real-Time Laboratory INR Dashboard to Minimize Care Variation for Warfarin Anticoagulation in Hospitalized Patients

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Background: Warfarin contributes up to 20% of adverse drug events (ADEs) in hospital settings. High variability in warfarin dosing contributes to increased hospital costs. Pharmacy-led inpatient anticoagulation has improved patient outcomes but needs real-time laboratory information integrated with pharmacy data. **Objectives:** We describe the creation of a pathology-led enterprise-wide “warfarin international normalized ratio (INR) dashboard” that tracks and predicts INR overshoots and provides timely and actionable laboratory information to clinical pharmacists (CPs) to target patients at risk for warfarin ADEs. **Methods:** A gap analysis conducted by a pathologist (T.K.) by interviewing 4 CPs revealed that they had to manually screen patients for high INR results and then correlate with medication history in the EMR for each such patient. Clinical pharmacists spent between 1 and 3 hours daily manually reviewing INR results, sometimes with a lag of >24 hours after results verification.

There was no consistent way to identify patients with high INR who needed immediate warfarin dose adjustment. The pathologist (T.K.) in collaboration with CPs, anticoagulation specialists, and enterprise data warehouse team created an automated dashboard which stratifies INR values for all inpatients being administered warfarin. In addition, it tracks frequency of INR testing and delta INRs—important since lapses in INR measurement can lead to overanticoagulation and delta INR—difference between 2 consecutive INR values—has been shown to be a predictor of INR overshoots. **Results:** The dashboard is live for >6 months and presents real-time information on all hospitalized patients receiving warfarin—average 150 patients/d across 8 hospital facilities. It risk stratifies patients most likely to have warfarin ADEs or INR overshoots based on most recent INR (high to low) and delta INR results. It lists important data elements such as demographics, unit and bed location, admit date, and current length of stay. It allows drill down capabilities on an individual patient to monitor temporal trends in INR and correlate with warfarin dosing (initial and maintenance). Warfarin drug-drug interactions and parameters such as hemoglobin and platelet count are highlighted in real-time. **Conclusions:** Laboratory and pharmacy data when analyzed together provide significant opportunities for targeted intervention. This dashboard has increased time savings for CPs and provides a standardized approach for risk stratification for improving patient safety and reducing warfarin-associated ADEs. This is an example of how pathologists can leverage laboratory data to improve care coordination, efficiency, and system-based practice.

APC-I8-0003PC. Improving Time-in-Therapeutic Range for Warfarin Monitoring: Role of Pathologist in Anticoagulation Disease Management

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Background: Standardizing anticoagulation care for patients on warfarin presents a major clinical and operational challenge in outpatient settings. Laboratory international normalized ratio (INR) time-in-therapeutic range (TTR) data provide actionable information to improve disease monitoring for such patients. **Objectives:** We describe our experience and results from an interdisciplinary disease management (DM) program to improve warfarin outpatient anticoagulation. **Methods:** Pathology department was one of the earliest contributors to this DM effort, and a multidisciplinary clinical transformation team consisting of an anticoagulation expert

(A.C.), a pathologist (T.K.), and 2 nurse practitioners (C.P., M.V.) was assembled. In 2013, based on claims and laboratory data, we estimated that >5000 patients in our outpatient practices were on long-term warfarin. There was lack of standardized anticoagulation management protocol and measures to track optimal care processes and outcomes. Time-in-therapeutic range is the most valid measure for outpatient warfarin monitoring. We aggregated 2013 outpatient laboratory INR results from our Cerner Millennium Laboratory Information System to calculate the percentage of patients in therapeutic range. We targeted 25 high-volume internal medicine and cardiology outpatient practices for this standardization effort. Using aggregated PT/INR results, we calculated the mean TTR for each practice using the Roosendaal equation. The mean TTR for the 25 practices was about 58% (range: 45%-67%), the optimal being greater than 65%. Based on 2013 baseline data, a systematic education and quality improvement program was initiated by our team with a goal to improve mean TTR above 65% over the next 12 months. Interventions included the installation of clinical decision support software for using the Hamilton dosing nomogram, provider education, and standardization of testing equipment and operating procedures. We tracked the monthly mean TTR metric for each practice using aggregated laboratory INR results. **Results:** Since the initiation of this DM effort, the mean TTR for all 25 practices has improved to greater than 65% (range: 62%-70%). The results have been sustained over a 3-year period from 2014 to 2017. In addition to improvement in the TTR metric, we have created standardized protocols for point-of-care PT/INR testing in the laboratory patient service centers and outpatient practices. **Conclusion:** Laboratory TTR data are essential for monitoring variability in standards of care for patients on warfarin anticoagulation. Pathologists can play a crucial role in population health efforts by aggregating and analyzing laboratory INR data, creating actionable metrics, and being part of DM teams.

APC-I8-0004PC. Utilization of Whole Slide Imaging in a Multicenter Health Network: Contribution to Better Patient Care, Education, and Research

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Background: Digital whole slide imaging (WSI) provides rapid scanning of histopathology slides and high-resolution images that can be retrieved via the Internet, thereby enabling the implementation of WSI in routine pathology practice. Moreover, WSI also facilitates pathology education and research. Our medical center is a multisite academic institution with 10 hospitals and 8 clinical labs. All pathology technical work is centralized at 1 site. In this study, we aim to present 2

years of experience of deployment of WSI in our multicenter health network. **Design:** We evaluated the efficiency and accuracy of remote interpretation of after-hour frozen sections and routine diagnosis from satellite hospitals. In addition, we also assessed the application of WSI in multidisciplinary tumor boards and the organization of images for research projects. **Results:** (1) Whole slide imaging decreased after-hour frozen section turnaround time (eg, decreased the commuting time) with high accuracy. (2) Whole slide imaging decreased the turnaround time of routine diagnosis at satellite hospitals compared to physically transferring glass slides. (3) Whole slide imaging facilitated the preparation and running of the multidisciplinary tumor boards; compared to representative digital snapshots, WSI can provide a complete digital replica of the slide that can be viewed on a computer screen. Moreover, the preparation time was also decreased with high flexibility. (4) Whole slide imaging has been used in multiple research projects for image capture and storage. **Conclusion:** The ability to rapidly access high-resolution pathology images is important for pathology practice, education, and research. This study demonstrated that WSI improved the turnaround time in both after-hour frozen section and remote diagnosis. Moreover, WSI also facilitated the presentation in the multidisciplinary tumor boards and image organization of research projects. This study demonstrates a pivotal role of WSI in pathology practice, education, and research.

APC-I8-0005PC. The Use of Pathology Data to Improve High-Value Treatment of Cervical Neoplasia

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Objectives: Loop electrosurgical excision procedure for the removal of the transformation zone in preinvasive cervical disease has many advantages and has become the dominant treatment for preinvasive cervical neoplasia. However, there is a corresponding concern that this intervention is overutilized, subjecting some patients to unjustified costs and risks, particularly preterm labor in those patients of reproductive age. **Methods:** We investigated the influence of pathology data to improve patient outcomes in the treatment of high-

grade cervical neoplasia in a joint pathology and gynecology collaboration. Two of us reviewed all cytology, colposcopy, and surgical pathology results, patient history, and pregnancy outcomes from all patients with loop electrosurgical excision procedure specimens for a 33-month period (January 2011 to September 2013). We used this to determine compliance to 2006 consensus guidelines for the performance of loop electrosurgical excision procedure and shared this information in 2 interprofessional and interdisciplinary educational interventions with obstetrics/gynecology and pathology faculty at the end of September 2013. We simultaneously emphasized the new 2013 guidelines. During the postintervention period, we continued to provide follow-up using the parameters previously collected. Our postintervention data include 90 cases from a 27-month period (October 2013 to December 2015). **Results:** Our preintervention data include 331 cases in 33 months (average 10.0 per month) with 76% adherence to guidelines. Postintervention, there were 90 cases in 27 months (average 3.4 per month) and 96% adherence to the 2013 (more conservative) guidelines ($P < .0001$, χ^2 test). Preintervention, the rate of high-grade squamous intraepithelial lesion in loop electrosurgical excision procedures was 44%, whereas postintervention, there was a 60% high-grade squamous intraepithelial lesion rate on loop electrosurgical excision procedure ($P < .0087$ by 2-tailed Fisher exact test). The duration between diagnosis of low-grade squamous intraepithelial lesion and loop electrosurgical excision procedure also increased significantly from a median 25.5 months preintervention to 54 months postintervention ($P < .0073$; Wilcoxon Kruskal-Wallis test). Postintervention, there was a marked decrease in loop electrosurgical excision procedure cases as well as better patient outcomes. **Conclusions:** The use of pathology data to inform and educate clinical colleagues about health-care outcomes for their patients can improve quality and decrease costs. Thus, pathologists should be proactive in looking for opportunities to work with clinicians to improve value and outcomes.

APC-I8-0006PO. Development of a “Patient Harm Index” in Anatomic Pathology: A More Patient-Centric Adverse Event Measurement That Can Also Be Aggregated Into System-Wide Safety Metrics

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Objective: Errors/adverse events in anatomic pathology (AP) such as significant changes in diagnosis and frozen section (FS)/final discrepancies are often expressed as rates. Although such rates are useful to determine benchmarks and compare different labs, they are very dependent on the denominator (total volume) and often less so on the numerator (impacted patients). The goal of this study is to describe the development and use of a more patient-centric metric for measuring adverse

events in AP. **Methods:** As part of an institution-wide quality improvement project, service lines (SL) developed lists of preventable adverse events to aim for reduction. The sum of such adverse events in each SL represented their Patient Harm Index (PHI). Historic data were used to develop threshold, target, and reach goals for AP. **Results:** Cases with one of the following events resulting in patient harm or potential harm constituted the AP PHI: (1) major diagnostic error, (2) major FS discrepancy due to sampling, (3) major FS discrepancy due to interpretation, (4) significant/unexpected finding without documented communication in report, and (5) significant diagnostic delay, specimen loss, or results reported on wrong patient. Threshold, target, and reach goals were set as 48 (4% reduction), 45 (10% reduction), and 40 (20% reduction), respectively. Progress toward these goals was discussed at faculty, staff, and quality management meetings. By year-end, 38 patients had potential/adverse events. This 24% reduction in the potential/adverse event rate (0.061%-0.046%) appeared more meaningful when communicated as 12 less patients with potential/adverse events. **Conclusions:** By aggregating the total number of potential/adverse events in time and supplementing other, more traditional “rate-based” metrics, the PHI emphasizes the numerator and deemphasizes the denominator, keeping the focus on the patient rather than the total number of specimens. We believe that this, along with the ability to add up all events together into a single more comprehensible number, provides greater motivation for error reduction and the drive toward high reliability and also allows for easier incorporation into system-wide patient safety metrics.

APC-I8-0007PC. Rapid On-Site Evaluation (ROSE) by Cytopathologists of Image-Guided Biopsies in the Radiology Department Increases Specimen Adequacy

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Objective: Rapid cytologic analysis of image-guided biopsies can quickly evaluate cellular content and viability of CT and ultrasound (US)-guided fine needle aspirations (FNAs) and core biopsies, enabling the on-site cytopathologist to provide face-to-face communication and feedback to the interventional radiologist who has obtained the specimens. Pathology and radiology residents and fellows are involved in the process. Information regarding adequacy, the need for further specimen, and at times a preliminary diagnosis is provided. Further material can be obtained while the patient is still on the imaging table for molecular studies, cytogenetics, flow cytometry, and microbiology. We introduced this ROSE service, then compared the pre-ROSE versus post-ROSE adequacy rate for CT and US-guided FNAs and core biopsies. **Methods:** The cytopathology department was relocated to enable rapid cytology staff travel to radiology.

A room near the interventional radiology control room was obtained to store/use a double-headed microscope and other supplies. Pathology trainees examine radiology patient lists to identify procedures which may require ROSE and review patient medical history. When paged, the cytology team proceeds to radiology with DiffQuik stains, slides, and various fixatives. Fine-needle aspiration smears and core touch preps are made, stained, and interpreted. Preliminary findings and recommendations to obtain further passes for various tests are made to the radiologist. Specimen adequacy during a 3-month pre-ROSE period (off-site evaluation of slides, with many patients discharged from radiology prior to reporting) was compared to adequacy in the first 3 months post-ROSE period. **Results:** Twenty-nine procedures were performed during the pre-ROSE implementation period versus 103 in the post-ROSE period. The adequacy rate pre-ROSE was 66%, compared to 85% in the post-ROSE period. **Conclusions:** On-site cytopathology services in radiology improved our adequacy rate for FNA and core biopsies and more than tripled the number of procedures cytology was called to participate in likely due to increased radiologist satisfaction. Improved specimen adequacy along with collection of further passes for various tests based on preliminary findings may reduce repeat patient visits adding value and safety, may increase patient satisfaction, and ease radiology scheduling. Trainee involvement contributes to the institution's educational mission. Appropriate triage of collected materials and face-to-face pathologist radiologist communication including on-site clinical, pathologic, and imaging correlation with next best step determination yields high-quality care and the best, most complete final diagnosis possible.

APC-I8-0008PO. Cross-Validation of Pareto Principle in Pathology as an Evidence-Based Rationale for Management

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Objectives: Pareto principle (ie, "20/80 rule"), an extensively validated observation, states that, for many events, roughly 80% of occurrence can be attributed to 20% of possible causes. Based on this principle, we hypothesized that 20% of diagnostic entities in surgical pathology account for 80% of actual cases for each organ/site encountered. We previously tested and validated this hypothesis by a text-parsing method. The objectives of current project are (1) to further confirm it by cross-validation with 2 different methods and (2) to show representative results. The ultimate goal is to introduce Pareto principle as an evidence-based rationale for

strategic decision-making in management and educational endeavors. **Design/Method:** Routine surgical pathology reports in laboratory information systems of several separate institutions were exported out as text files and regrouped by organ/anatomic sites via text-parsing (nature language processing) method as we previously described (2). Alternatively, pathology reports were exported and regrouped by associated *ICD-10* code. The frequency of the diagnoses occurring in each organ/anatomic site was collated. At least 6000 reports were tested by both methods for result confirmation. The process with cross-validation is depicted in a flow-chart. **Result:** The results confirm our previous finding that Pareto principle also applies to diagnostic pathology. The diagnosis profile and its ranking list were affected by different practice settings (ie, expertise of clinical and pathology subspecialty). Both validation methods independently reach the same conclusion. Each of the methods has its pros and cons but they are mutually complimentary in analyzing a large number of pathology reports and can be easily adapted to different practice settings. **Conclusion and Discussion:** Scientific validation of Pareto principle establishes it as an evidence-based rationale to guide executive decisions in pathology and related educational and clinical fields. Identifying the "vital few" of specimens/diagnoses that account for main workload can guide resource allocation and strategic planning at management level. The diagnosis profile (ie, diagnoses by each organ/site) revealed by such studies is vital in designing educational curriculum in medical schools and training plan for resident physician to combat information overload.

APC-I8-0009PC. Securing Part A Funding Commensurate With Professional Effort in an Academic Pathology Department: Utility of APC Benchmark Data

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Objective: To ensure that sufficient funds are available to support pathologist effort in providing professional component services such as medical direction of laboratory sections. **Methods:** The pathology faculties are employed by the multispecialty practice group of an academic medical center. The practice group's compensation plan directs funds for approved faculty positions to departments based on the academic rank of the incumbent, applying blended benchmark data from MGMA (community and academic) and the Association of American Medical Colleges (AAMC). The pathology department updates its staffing plan at least annually to align pathologists' effort allocations with clinical, research, educational, and administrative needs. Work relative value unit-generating effort is derived

from comparison of budgeted workload to AAMC benchmarks, and medical student teaching effort is derived from 3-year rolling average data. Over a 3-year period, effort allocations for directorships in anatomic pathology were migrated to benchmark figures. Once Association of Pathology Chairs (APC) benchmark data became available for weeks on service and for part A allocations per pathologist full-time equivalent (FTE), these were incorporated into the planning process and used as comparators for departmental budgets submitted to the practice group for approval. **Results:** Directorships of laboratory sections are assigned FTE percentages based on APC benchmark data, and assigned service effort on anatomic pathology services has been adjusted based on APC benchmark data. Comparisons of proposed effort allocations and budgeted part A funding to APC benchmarks were provided with budget submissions for practice group and medical center review. Over a 3-year period, part A funding from the academic medical center to the pathology department increased by an average of 15% per year. **Conclusions:** When developing a sustainable compensation plan for an academic pathology department, incorporating APC benchmark data can support the interpretation of budgetary requests for increased part A funding as reasonable, making possible an effective case for increased funding.

APC-18-0010PO. Next-Generation Sequencing Evidence-Based Antimicrobial Stewardship Program for Reducing Daptomycin-Nonsusceptible *Enterococcus faecium*

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Objectives: The emergence of daptomycin resistance represents a serious clinical problem for treatment of severe vancomycin-resistant *Enterococcus faecium* (VREfm) infections. We recently identified a novel VREfm clone, ST736, and its association with daptomycin resistance. The objectives of this study were to assess the mechanisms of resistant and transmission of daptomycin-nonsusceptible *E faecium* (DNSE) using next-generation sequencing (NGS) and the effectiveness of NGS-based antimicrobial stewardship program in promoting appropriate use of daptomycin and reducing DNSE in a tertiary hospital setting. **Methods:** Selected daptomycin-susceptible and daptomycin-resistant VREfm clinical isolates were

analyzed by NGS using the Illumina systems. Multilocus sequencing type and single-nucleotide variants analysis were employed to explore the population genetics, resistance mechanisms, and transmission. The utilization of individual antibiotics and patients infected with DNSE were extracted from the hospital pharmacy and medical information systems. **Results:** A total of 250 *E faecium* isolates from 1994 to 1995 (n = 43), 2009 to 2012 (n = 115), and 2013 (n = 92) were analyzed by NGS. Comparative genomics and evolutionary analysis confirmed a shift in VREfm population over 20 years and the emergence of clone ST736 in the mid-2000s. Further analysis of ST736 isolates (n = 113) identified genetic alterations in *liaFSR* (100%) and *cls* (14.2%) genes that predisposed to daptomycin resistance. Genomic and epidemiological evidence suggests that the observed high prevalence of DNSE at our institution had resulted from the development of resistance during daptomycin therapy and/or from nosocomial transmission. Subsequent hospital antimicrobial stewardship program aimed to restrict the use of daptomycin and enhanced infection control measures led to a significant reduction in patients infected with DNSE. **Conclusions:** The implementation of NGS in molecular epidemiology at a pathology laboratory directs more precise institutional antimicrobial stewardship program and infection control practice, which promotes the appropriate use of antibiotics, improves patient outcomes, and decreases the development and spread of infections caused by multidrug-resistant organisms.

APC-18-0011PC. Leveraging Outpatient Inquiries Into Comprehensive Clinical Pathology Consultations

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Objectives: In hospitals, clinicians become aware of the important role of clinical pathologists through rounds, tumor boards, diagnostic management groups, and so on. In outpatient settings, laboratories and laboratorians are geographically removed, with limited opportunities for collaboration. Consultations are usually handled by core laboratories on a one-by-one, one-to-one basis. Here, we describe efforts to leverage this activity into a clinical consultation service (CCS) handling inquiries with a team-oriented approach, evaluating them in the context of all pertinent information, with input from all sections involved and with attention to teaching and quality improvement. **Methods:** The CCS meets in weekly rounds and consists of a clinician, pathologists, scientists, and residents. In 2017, it implemented these changes:

Phase	Previous System	New System	Action
(1) Receipt of the inquiry	Customer service	All medical consultations are directed to a CCS member as a single point of contact	An experienced professional assesses the inquiry and, if necessary, triages it to other CCS members
(2) Response preparation	Variable	Review of test results, literature, etc	Improved understanding prior to full response
(3) Response	One-to-one phone call	One or more calls involving one or more members	Centered on clinical context. If appropriate, provides action plan and follow-up
(4) Documentation	Minimal	Use of a customer relationship management system (CRM)	Activities and documents kept in the CRM, with 100% audit review of outcomes
(5) Reviews	Seldom	Weekly rounds	Select consultations discussed
(6) Quality management (QM)	Occasional	Active search for improvement opportunities	Often generates improvement initiatives
(7) Organizational optimization	Rarely	Continuous enhancement of consultation workflows	Based on aggregate data and weekly discussions

Results: A total of 175 cases were logged in 7 months after CRM⁵ implementation:

Clinical Category	Number	Percentage
Infectious diseases	89	50.9
Chemistry	19	10.9
Immunology	18	10.3
Endocrinology	15	8.6
Genetics	8	4.6
Coagulation	7	4.0
Hematology	6	3.4
Drugs of abuse	5	2.9
Therapeutic drug monitoring	4	2.3
Oncology	3	1.7
Toxicology	1	0.6
Total	175	100

About half (51%) of the inquiries pertained to infectious diseases. Sixty-one percent involved result interpretations, 21% test performance, and 18% test ordering issues. **Conclusions:** Triage ensured that the best suited expert(s) answered the inquiry regardless of their laboratory section, reflecting the cross-sectional nature of the inquiries themselves. Result interpretation inquiries prompted a project to redesign several test result reports. The higher levels of satisfaction in 2017 laboratory customer surveys might reflect increasing awareness among outpatient health-care providers of the important role of pathologists and other laboratory professionals.

APC-18-0012PC. Pathology Exposure in Gifted High School Students: A Unique Opportunity in a Unique Population

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Objectives: To build a pathology pipeline through providing early exposure to gifted high school students. **Methods:** The

Penn State Hershey Medical Center (PSHMC) is surrounded by local high schools filled with young talented individuals with strong interests in the basic sciences and the intention of pursuing health science careers. The PSHMC hosts students in the Pennsylvania Youth Apprenticeship Program and Healthcare Career Exploration Program programs: These programs allow high-achieving high school juniors and seniors to spend time exploring a variety of disciplines within the medical center over the course of a year. More recently over the past 4 years, pathology has been consistently chosen as one of the experiences. The pathology experience has included didactic presentations on general and subspecialty practice in pathology and hands-on active learning in anatomic pathology and laboratory medicine clinical areas. Recently, we have also established a pathology day at the Hershey High School for advanced science classes. We also participate in a summer high school science camp at a local college (Lebanon Valley College), which is also for gifted students who are pursuing careers within medicine. These experiences utilize Power-Point style presentations with visual and tactile exploration of bagged gross specimens and plasticized specimens from our extensive teaching collection. We can effectively accommodate groups of 25 to 30 students in each experience. Cumulatively over each year, approximately 10 to 12 hours of contact time was recorded for the different groups. **Results:** The outcome of these ongoing experiences has been positive with sessions getting excellent reviews. The students were engaged and asked intelligent questions. Additionally, many expressed further interest in pathology and many have sought out supplementary observerships in the department. At least 1 very competitive student is in the Pathology Match for AY 2018/19. **Conclusions:** Opportunities abound to get academic pathologists in front of talented high school students who are interested in pursuing medicine as a career. Meaningful, relevant, and interactive experiences are key to making a formative impression on this high potential audience. Matriculated medical students often have preconceived notions of pathology, and unfortunately, those notions are

often negative. As the trend continues of fewer and fewer medical graduates choosing pathology as a career, it is never too early to enlighten captive ears. A concerted effort to further develop pathology experiences for gifted high school students interested in medicine will hopefully aid in reversing the current trend and encourage the best and brightest to enter our field.

APC-18-0013PC. The Utility of Early Intervention in Helping Medical Students Consider Pathology

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Objectives: Bias among medical students toward popular specialties and against pathology may remain deeply rooted because our culture categorizes physicians by amoral factors including earning potential, perception of influence, and lifestyles of power. It is the objective of this study to quantify if simple intervention in the preclinical years by addressing these biases via introductory pathology informational session can help students consider pathology. **Methods:** We designed an informational session confronting bias against pathology as a medical specialty including the following 5 arguments and communications: (1) contrasting the differing roles of surgeons and pathologists, (2) highlighting the uniquely cerebral aspect of understanding and discovery not found in other specialties, (3) addressing flaws in the “need for patient interaction” defense, (4) introducing the role of social media in the field, (5) cultivating an institutional pathology student interest group. Data were collected from first- and second-year medical students who completed surveys before and after sessions. The following questions were examined: “How well do you understand pathology as a medical specialty?” and “How well do you understand the roles and responsibilities of the pathologist?” Responses were categorized and converted to “percentage understanding” values (not very well = 0%, somewhat well = 25%, fairly well = 50%, well = 75%, and very well = 100%). Data were subjected to χ^2 statistical analysis with 5% significance. Average percentage understanding was calculated between groups (before and after). **Results:** Our data demonstrate a significant difference in percentage understanding of pathology as a specialty among medical students before and after informational sessions addressing aspects of bias in specialty choice ($P = .004$). The average percentage understanding was 31.0% before the session, compared to 65.9% after. Similarly, there is a significant difference in student comprehension of the roles and responsibilities of pathologists (increasing 39.9%, $P = .0006$). **Conclusions:** Because societal bias continues to drive talented medical students toward popular specialties in medicine, efforts must be made to prevent individuals with a true interest in pathology from exiting the

preclinical years without the proper exposure to pathology to make an informed decision about it. This small, single-institution study suggests that even informal sessions can change medical student opinion. The pathologist should therefore be aggressive in his or her early outreach efforts by addressing the 5 aspects outlined by this study.

APC-18-0014PO. Integrated Training in Clinical Laboratory Management and Administration, Quality Improvement and Assurance: Methods and Outcomes

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Objectives: Graduating pathology residents often lack skills in laboratory management, the only discipline that touches every corner of both anatomic pathology and clinical pathology (CP). In 2013, we recognized that we could improve with better integration of residents in our laboratory administration and management problem-solving efforts. We aimed to establish structured expectations for productivity in quality assurance/quality improvement (QA/QI) projects and accreditation inspections. We describe the ongoing effort and outcomes to date. **Methods:** We have augmented our existing laboratory administration curriculum. During CP rotations, residents acquire both the discipline-related knowledge and skills in laboratory administration and management. This is achieved by working with faculty to solve laboratory management problems when encountered in a respective section. These experiences are then shared with all residents as problem-solving exercises via weekly CP service review. Each year, all residents undertake a formal mentored QA/QI project, structured with rigorous deadlines for a written report and presentation of findings. Rubric scoring by faculty ensures fairness and enables feedback to the residents. Based on rubric scores, the resident with the best QA/QI project earns special commendation at our annual graduation dinner. Residents are involved in the state and CAP inspection preparation process. During off-cycle years, residents are assigned to inspect areas where they have previously rotated; they produce and present deficiency reports to the group in a mock summation session. Seniors are well prepared to participate in off-site CAP inspections and routinely accompany our teams. When we are inspected, all residents attend summation conferences and they participate in root cause analysis and corrective action planning for deficiencies. **Results:** We have observed improvements in resident in-service performance, as well as ACGME survey performance in laboratory administration and management. For both 2015 to 2016 and 2016 to 2017 academic years, 25% of resident QA/QI projects have been accepted for presentation at national meetings. **Conclusions:** Our laboratory administration curriculum has moved to higher levels on Bloom’s taxonomy with continuous practical reinforcement of laboratory administration concepts and QA/QI methods. Via integration, we have mitigated

some key weaknesses of standalone block scheduling for laboratory management and administration rotations. The high quality of these experiences ensures that all of our residents are well prepared for the laboratory leadership roles expected of them in the future.

APC-18-0015PC. Training the Next Generation of Pathologists: A Novel Residency Program Curriculum

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Objectives: Pathology residency training is currently a time-intensive process, frequently extending up to 6 years in duration as overwhelming majorities of residents complete 1 or 2 fellowships. Montefiore has created a novel residency training program aimed at accelerating the acquisition of competency in pathology. **Methods:** To achieve an accelerated acquisition of baseline foundational knowledge and critical thinking skills, the new program is composed of 2 years of foundational anatomic and clinical pathology rotations, a third year of subspecialty rotations and graduated responsibility, hybrid rotations incorporating interaction with clinical teams, and a fourth year for residents to pursue areas of special interest in depth, with tracks offered as guidelines. Key aspects of the new pathology residency curriculum include an online onboarding process, a 1-month introductory “boot camp,” a unique surgical pathology teaching service for first-year residents, a standard introduction to the clinical laboratory, didactic, and small group learning, and an integrated pathology informatics essentials for residents approach throughout the residency. The following assessment tools are being used in this education program: daily surgical pathology assessments, entrustable professional activities, summative evaluations, boot camp tests, in-service examinations, and 360° evaluations. **Results:** We are in the second year of this new curriculum. The feedback from residents on the onboarding program has been universally positive. The resident survey at the completion of the onboarding program assessed the effectiveness from 1 (low) to 5 (high). The average score evaluating the onboarding curriculum was 4.24. Similarly, the residents have assessed the boot camp curriculum with positive reviews. Further, our data indicate that hands-on experiences were the most effective for knowledge retention. Regarding the new surgical pathology teaching service, faculty noted that it has allowed us to identify struggling residents much earlier and to more effectively intervene. **Conclusions:** To achieve accelerated competency, we have already learned from the data collected, and implemented or augmented our approach, such as enhancing and adding more hands-on learning activities. We will continue to measure our progress using the tools outlined above. It is our conviction

that this new curriculum provides the framework to allow Montefiore residents to find employment with just 1 fellowship, or even no additional fellowship training. We are hopeful that our curriculum will become a model for pathology residency education in the United States.

APC-18-0016PO. Advocacy and Leadership During Residency Training

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Introduction: Pathologists need to advocate for themselves so that the importance of pathology services in patient care and health-care systems can be correctly represented to hospitals, political leaders, and payers. Learning advocacy early-on in training can mold physician leaders to face the next generation of challenges. Because residents have already chosen pathology as their specialty, they are likely to care about issues that will affect their futures. We sought to understand how highly involved staff and trainees first became interested and what exposures were meaningful and inspired them toward political advocacy and leadership. **Methods:** Questionnaires, with a few follow-up interviews for clarification, were conducted with politically active senior staff (>40 years; 4), new-in-practice junior staff (within first 5 years; 4), and trainees (4), to see how they became involved and what early experiences they found most inspiring for future involvement. **Results:** The senior staff reported being involved in departmental and hospital-based advocacy meetings during their training and could name specific staff mentors who urged them into leadership. In some cases, this was the residency program directors. They were not involved with national resident advocacy groups or national leadership during training. New-in-practice staff and trainees were uniformly involved with national initiatives, such as national resident forums, and the CAP policy meeting. They were less involved with local advocacy, although a few did indicate that shadowing a staff member who was performing advocacy made a deep lasting impression and was inspired them to want to do more themselves. One factor that was significant to leadership across older and younger staff was being chief resident during training. **Conclusion:** Although opportunities for national participation have increased through the years, a constant between old and new is involvement during training. A senior pathologist stated that it was the residency leadership’s job to notice which trainees have a leadership spark. Pushing trainees into leadership tasks, to see which trainees rise to the occasion, is one way to test the spark. Particularly powerful is allowing trainees to shadow staff during advocacy events. This allows the trainee to see their staff mentors wearing more than 1 hat, that is, as an academic teacher and a professional advocate. Selecting a chief resident is a combination of seeing and encouraging a spark.

APC-18-0017PC. Quality Residents: Developing a Quality Improvement Curriculum That Doesn't Merely Check the Box

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Objectives: The Accreditation Council for Graduate Medical Education (ACGME) mandates that resident trainees in all specialties receive training and experience in quality improvement (QI). Michigan Medicine (MM) Department of Pathology's Divisions of Quality and Health Improvement and Education developed a QI curriculum (QIC) aimed at fulfilling this accreditation requirement and shaping future leaders in laboratory QI.

Methods: At MM, we developed and implemented a 5-month, lean-based QIC delivered every year to first- and second-year pathology residents in a "flipped classroom" format with 1-hour sessions integrated into a regular departmental education series and devoted to case studies and group work. We emphasized the "hands-on" involvement of residents in practical, focused QI projects that directly impact clinical operations and which are endorsed by laboratory leadership to ensure alignment with departmental priorities. Potential project lists were solicited from laboratory managers and directors, ensuring a focus on issues directly impacting clinical operations. A flipped classroom design allowed use of dedicated class time for teamwork and consultation. Pre- and posttests measured knowledge, a postcourse survey provided feedback for course leadership, and each team gave a final presentation that included a completed A3 form and initial project results.

Results: Our QIC occurred in 2016 and 2017. Scores increased significantly from pre- to posttest both years (mean pre = 12.6, post = 16, $P = .0001$ in 2016; pre = 14.2, post = 16.2, $P = .04$ in 2017; paired t test). Seven total projects resulted in countermeasures judged generally effective in mitigating the issue(s) addressed based on feedback from laboratory stakeholders. Results of the course at our institution have been positive and a number of resident-driven projects resulting in positive changes to laboratory workflow. **Conclusions:** Our experience at MM suggests that the Department of Pathology has one of the only residency programs in the institution that has developed a formal curriculum to address the ACGME requirements. Our QIC is an effective means of both fulfilling training requirements and systematically involving pathology residents in operational QI. Assessment methods, lessons learned, and strategies for integrating the projects and course output into the department's holistic QI activities will be discussed. The strategies described may also be applicable to other types of trainees as well as laboratory staff, resulting in a department-wide training program in QI and lean principles that may be useful in institutions with pathology residency programs.

APC-18-0018PO. Leveraging Rich Medical Student Curriculum Content to Enhance Introductory Pathology Resident Onboarding Instruction

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Objectives: While developing an onboarding month for incoming residents covering anatomic and clinical pathology knowledge content and basic grossing, dictating, frozen sectioning, microscopy, and histotechnology skill sets, it was apparent that there was a critical need for a defined, polished curriculum to serve as an instructional infrastructure.

Methods: Existing medical student teaching materials focused on basic and organ system-based topics were configured within the learning management system Blackboard for use during an onboarding month and elsewhere during resident training. This content was supplemented with existing histology and histotechnology teaching materials and vetted PDFs of key journal articles. **Results:** Well-developed content from 165 contact hours of medical student lecture and laboratory sessions was configured in Blackboard for use by junior residents during an onboarding month and for subsequent study as a total of 25 learning modules. The curriculum portal includes (1) teaching content including extensive outline-focused objectives and key words and topic summaries in Word syllabus and PowerPoint document for each module, (2) self-study content utilizing a PowerPoint-based question and answer format focused on key topics with relevant diagrams, tables, and summary slides providing comprehensive context to answers, (3) a broad array of test and quiz questions configured as (a) a pretest and posttest for the onboarding session and individual modules along with (b) quizzes during the navigation of specific topics, with grading done automatically by the learning management system, (4) faculty-vetted, key articles posted as PDFs, keyed to covered content, and separately assessable, and (5) links to electronic texts and other resources including whole slide imaging collections. During the onboarding month, this content is supplemented by exposure to gross organ sessions illustrating both normal anatomic features and critical pathologic topics. **Conclusions:** This repository of content, providing a comprehensive coverage of key pathology topics, has been well received by residents during its rollout. Both (1) pretest and posttest data and (2) surveys of incoming residents will be used to assess the value and gauge the effectiveness of this new curriculum portal and identify areas which need further development. It will provide an instructional infrastructure for an intensive month of onboarding instruction and experience and should serve as a rich teaching resource during residency.

APC-18-0019PO. Implementation of In-House Genomic Testing in a Medium-Sized Hospital: Contribution to Resident Education

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Background and Objectives: Molecular genomic testing has become an integral and crucial aspect of patient care, influencing clinical decision-making in dictating treatment regimens, patient response, individual prognosis, and overall survival. Moreover, the incorporation of molecular pathology in resident training has improved the overall educational experience and resident career opportunities. Here, we aim to demonstrate the pivotal and positive role that the molecular laboratory has had on the education of pathology residents as part of a Graduate Medical Education training program. **Methods:** A retrospective review was performed for the residents at our institution between 2007 and 2017, which trains 12 residents over a 4-year AP/CP training program. Residents were assessed for the number of accepted journal publications and United States and Canadian Academy of Pathologists (USCAP) Annual Meeting presentations. **Results:** (1) Thirty seven posters/abstracts were presented at USCAP in the past 3 years (2016-2018) including 2 platform presentations. This correlated with >1 poster per resident every year for all residents. (2) Almost all residents have journal publications before graduation. At least 2 resident's publications with an accumulated impact factor >10. Several residents published in prestigious pathology journals, such as *American Journal of Surgical Pathology*. **Conclusions:** This study demonstrates the increased role of molecular genomic testing in pathology as a pivotal tool for fostering research and scholarship productivity during resident training. The increased exposure has produced resident involvement on a national and international level through various collaborations and publication.

APC-18-0020PC. Pathology Mortality and Morbidity Conference as a Model for Trainee Patient Safety Education

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Background: In 2015, The National Academy of Medicine issued a call to action to the pathology community, identifying diagnostic error as a major, unaddressed patient safety concern. The Accreditation Council for Graduate Medical Education has also recently augmented requirements for trainee patient safety education; however, few pathology-specific patient safety

curricular resources exist. Without structured, practical instruction, pathology trainees will not acquire critical skills in adverse event analysis and management. **Design:** To encourage trainees' participation in adverse event management, we transformed our monthly Pathology Morbidity and Mortality Conference (MMC) from laboratory manager- and director-led to trainee-led presentations for adverse event review. An MMC guide was developed as a checklist, allowing trainees to take a structured systems approach to investigating incidents by engaging stakeholders, developing a time line of events, classifying errors, and identifying systems vulnerabilities. The MMC guide also provided guidance for conducting a root cause analysis (RCA) using tools such as cause maps and fishbone diagrams. Patient safety resources such as articles and web site links were embedded in the guide. An MMC PowerPoint presentation template was created to assist trainees in translating their findings into a logically organized presentation. For additional reference, previous MMC presentations were made available. **Results:** Five residents and 1 fellow have utilized the MMC guide to analyze adverse events and develop MMC presentations in the 4 months since its rollout. Adverse events covered included both preanalytical (eg, missed test order) and analytical incidents (eg, misdiagnosis). Early feedback from participating trainees was obtained by using an anonymous survey with a Likert scale. Regarding the MMC guide, 100% of trainees strongly agreed or agreed that the resources were helpful and that their ability to investigate adverse events had improved. All trainees agreed they had learned RCA skills useful for their future practices. Eighty percent strongly agreed or agreed that the experience had helped them to become better practicing pathologists, while 20% felt neutral. **Conclusion:** Trainee-led MMCs can be used as a model for pathology trainee patient safety education. Trainees found the process helpful in learning RCA and as a preparation for their future careers. Our novel MMC guide and practical MMC templates facilitated trainee learning experiences. Current data reflect trainee experiences only. Next steps include developing a validated assessment tool to determine overall quality and utility of MMC.

APC-18-0021PO. Preparing Our Residents, Medical Students, and Fellows for a Digital World

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Background: With the FDA approval of digital pathology for routine use, many departments are rushing to purchase scanners and digital pathology infrastructure. These are huge investments and can be more than half a million dollars, besides the personnel and service contracts. However, once a diagnosis will be made, they have no means to make use of the digital slides in a meaningful way. The prime responsibilities of

pathology departments besides providing pathology services include training, education, and research. As pathology transitions to digital, trainees need to feel comfortable at viewing slides on a computer and confident about making diagnoses. All this can only come with practice. PathPresenter.net (PP) provides easy and free access to thousands of digital slides from any device and the tools to use the slides in a meaningful way. The platform has been built by pathologists who understand the requirements of pathologists and pathology departments. **Methods:** Digital slides can be uploaded into MySlideBox. Slides from MySlideBox and PP open library (over 10 000 slides) can be searched and grouped into folders for teaching specific topics. Integration of PowerPoint presentations allows the development of spectacular medical presentations for intradepartmental and interdepartmental conferences. Radiology images and videos can easily be integrated into these presentations. Slides can be annotated prior or during the presentation to highlight areas of interest. Screen and voice recordings allow development of teaching videos that can be uploaded to social media platforms or departmental sites for teaching. **Results:** The high-yield section contains handpicked cases for each subspecialty and essentially converts the computer into a multiheaded scope where the specialists point out histologic features in the digital slide. These cases are integrated with clinical, radiological, and IHI images for a complete teaching experience. A medical school section covers entities that medical students should be familiar with and gives them an introduction to digital pathology. For departmental use, there is a quiz building modality that allows faculty to build quizzes and assign to residents. Assigned administrator(s) of the department can also create graphs and overviews of trainee progress, which can be used to provide feedback to the ACGME. **Conclusion:** The platform facilitates sharing of slides, cases, or entire presentations. These features can be used to get or give second opinions. Other features include capturing pictures for publications, adding slides to social media feeds, blogs, and discussion forums. I will walk the audience through the features of PP in my presentation.

APC-I8-0022PO. Implementation of a Global Health Elective at New York Medical College at Westchester Medical Center: A Model for the Global Health Elective in Pathology Residency Programs

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Objectives: To establish an elective rotation to participate in global health as a unique training opportunity for current pathology residents, to develop a formal rotation curriculum, and to develop a framework for future program expansion.

Methods: Starting with 1 pathology resident, a 4-week elective rotation was created to allow for participation in an internationally located pathology laboratory. The creation of the elective included an outline of educational goals and objectives and a list of requirements for reporting postreturn. An active pathology laboratory at the Mbarara University of Science and Technology training hospital was identified in Mbarara, Uganda that is home to a small residency program with access to limited resources. The resident was expected to take notes on interesting cases, journal about time spent, and reflect on the unique obstacles and offer theoretical solutions. After completion, the resident was expected to give a 1-hour presentation summarizing the experience. **Results:** Completion of this elective was deemed an extremely successful venture and plans to expand to include more residents are currently being discussed. As per the final resident presentation, there was abundant knowledge gained of how laboratories function in low-resource settings, enormous exposure to the pathology of advanced and rare diseases related to the developing world, and ample opportunities for team work and problem-solving in an unfamiliar setting. The resident found the training time to be extremely worthwhile. **Conclusions:** Participation in global health is something most clinical residency programs have access to but is rare in pathology training programs. Giving residents the opportunity to improve their diagnostic and clinical skills in a low-resource setting is a highly valuable training tool. An elective in Global Health provides a unique training opportunity to foster communication skills, work in teams, and expand comfort zones. Creation of a Global Health curriculum and international rotation is a worthwhile endeavor and can help to enrich the pathology resident's training.

APC-I8-0023PO. Orientation of Incoming Pathology Residents—Implementation and Testing of a New Approach

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Objectives: This study aimed to assess the effect of modification to the pathology resident orientation procedures at Westchester Medical Center in order to increase the ability of residents to independently problem-solve and acclimate to the residency program with increased efficiency. **Methods:** An orientation committee was formed of 2 second-year AP/CP residents to analyze the current protocols and resources provided to the incoming residents. The information was then organized into 1 main network folder to centralize the information. Any information that was traditionally only provided through verbal instructions was written out and included in this folder. The entirety of this material was reviewed with the incoming first-year residents at the end of their standard orientation period. The residents in the 4 years prior to the incoming

first-year residents were surveyed with a 12-question survey assessing their ability to independently problem-solve given no additional orientation materials. The same survey was given to the incoming first-year residents at the completion of their orientation. The survey was composed of 12 questions in total, with 9 containing information that was present in the newly created orientation folder and 3 questions with answers that were given during the orientation period but were not included in the centralized folder materials. **Results:** Nine residents between PGY-2 and PGY-4 and 4 PGY-1 residents responded to the survey. Out of the 12 questions, the PGY-1 residents scored significantly higher than the PGY2-4 residents ($68.75\% \pm 20.90\%$ vs $39.17\% \pm 10.78\%$, $P = .00013$). Out of the 9 questions that assessed self-sufficient ability to answer each question, the PGY-1 residents scored better than the more senior residents in 8 of 9 questions ($P = .005$). One of 9 questions showed an equal ability to answer independently ($72.78\% \pm 22.24\%$ vs $36.67\% \pm 11.11\%$, $P = .0002$). Of the 3 remaining questions that assessed knowledge based on orientation only, the first-year residents scored similarly to the senior residents ($56.67\% \pm 11.55\%$ vs $46.67\% \pm 5.77\%$, $P = .13$). **Conclusions:** The results of this survey indicate that the introduction of a centralized and easily accessible folder of orientation materials has provided a repository for the incoming residents to access information to acclimate to the program with increased independence compared to their seniors. When the residents are answering questions without this additional resource, the outcomes of independent problem-solving ability are similar, as was exposed by the 3 survey questions that tested for this. The pathology program at Westchester Medical Center continues to strive to attain excellence in the training provided to the resident pathologists.

APC-I8-0024PO. A Strategy for Wellness in a Pathology Residency Program

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Purpose: Physician burnout is a national crisis and is among occupations with higher suicide risk, at 1.8 times the national average. Few pathology departments address this issue, and even fewer pathology residency programs offer formal resilience training. Learning from the business world, we implemented a high-stress environment resiliency strategy to our pathology residency program, and its purpose was to analyze and apply initiatives utilized in the high-stress business world and measure their effectiveness. **Methods:** A survey of pathology residents indicated need for resilience training. Utilizing methods from companies like Goldman Sachs, we adopted initiatives in our residency program:

- Approach burnout as a dilemma that needs a tridimensional strategy: wellness initiatives for the individual,

group strategies for the program, and an institutional plan that considers wellness.

- Formalize curriculum with wellness talks focusing on stress prevention, management, and treatment.
- Offer free sessions with trained resilience coaches, psychological help, employee assistance program, and chaplain services.
- Implement mentorship program.
- Pair first-year residents with senior residents.
- Implement mindfulness during wellness talks.
- Provide easy access to volunteer activities and networking.
- Offer fitness center discounts.

A pulse survey to identify one positive, one frustration, and one thing needing change was conducted at the beginning of this study. At 6 months, we evaluated the efficacy of the initiatives with another survey. We will continue assessing our program at 1 year. **Results:** An anonymous survey of 15 residents was conducted during a staff meeting. After implementing the strategies mentioned above, a 6-month survey was conducted. Data indicated that residents were more educated about tools to improve wellness after 6 months. **Conclusions:** A recent study showed that resident burnout among residents ranged from 59% to 75%. While pathology is not considered a high burnout discipline, in 2016, a Maslach Burnout Inventory put our department at the same burnout rate as that of our clinical colleagues. Our goals are to increase wellness among pathology residents to prepare them for a high-stress environment before entering the work force and to increase their ability to bring tools to their new work places. The 6-month survey shows positive movement toward our goals. We are providing our residents with tools to maintain the joy, humanity, and satisfaction of practicing pathology throughout their careers.

APC-I8-0025PO. Evaluation of Transfusion Medicine Instruction During Medical School

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Objectives/Background: Traditionally, transfusion medicine education has been an underemphasized discipline of course instruction in medical school education. In the current environment, striving for excellence in quality care and quality assurance, hospital systems have sought the expertise of the transfusion medicine subspecialty to evaluate blood utilization and laboratory utilization within their systems. The aim of our study is to determine how effective current educational practices are and how pivotal introducing transfusion medicine and its practices early on and throughout the 4 years of medical education could potentially impact blood ordering confidence and practices among graduates. **Methods/Design:** An

interview of the fourth-year medical student class of 2018 (160 students) at Loyola Stritch Medical School in Maywood, Illinois, with the use of a Google Forms survey was conducted. The survey included questions about general transfusion medicine practices, length of transfusion medicine instruction, information about obtaining consents, and recommendations on length and format of transfusion medicine instruction. **Results:** (1) We received 54 (33.75%) responses. (2) Of the 54 responses, 38 (70.4%) stated that they do not feel comfortable adequately ordering blood products in their future residency career, while only 16.7% (9/54) did not feel comfortable obtaining consent for transfusing blood products. (3) At Loyola Stritch Medical School, the pathology department assists in providing medical school instruction during their first and second years of medical school. (4) With that in mind, only 38.9% (21/54) felt that they received adequate instruction during their first 2 years in medical school. (5) The class provided opportunities for improvement in transfusion medicine instruction, which ranged from lecture format in the first 2 years to cheat sheets to use while on rotations and their residency years. **Conclusion:** Overall, we believe, and our brief study demonstrates, that providing continued assistance and education in transfusion medicine practices throughout medical school and residency training is not only preferred but also could impact transfusion ordering practices providing better quality care to the patients we serve.

APC-18-0026PC. Introducing Laboratory Medicine to Medical Students Before They Enter Clinical Clerkship: Oakland University William Beaumont School of Medicine's Experience

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Objectives: The transition between second and third year of medical school is a huge change. Although students are taught by both pathologists and clinicians in courses on anatomic/biomedical foundations and organs/systems, they have very little understanding about laboratory operations and test utilization when they start their third year of medical school. Therefore, we organized a short course to introduce laboratory medicine before they enter clinical clerkships at Oakland University William Beaumont School of Medicine (OUWSOM). **Methods:** As the first part of a longitudinal diagnostic medicine clerkship, this has been a single-day course offered to the entire class of medical students together at the end of their second year. A variety of classroom activities are organized on topics including STATS, critical values, turnaround time, chemistry panels, preanalytical variables, analytical variability, reference intervals, laboratory formulary, send-out tests,

search lab test directory, anatomic pathology service, and how to use microbiology laboratory. All students are brought to tour representative sections of anatomic and clinical pathology laboratories. Attendance is mandatory for all medical students. Students are not graded but feedback from students is collected. **Results:** Five classes of OUWSOM students have completed this course. Significant improvements have been made over the last 5 years. Hour-long didactic lectures have been replaced with half-hour-long lectures. Lecturing to the entire class together has been replaced with small-group interactive sessions and case studies. Continuous long laboratory tours have been reconfigured into small fragments and mixed with short classroom interactive didactic lectures or case discussions. In the most recent class, students considered it as one of the best organized days they have ever experienced. Not 1 minute was wasted. The entire experience was interactive and engaging. This course did a great job of connecting the basic science foundations to the clinical aspects of applying this knowledge. They all considered it a great course in introducing them to the operations of the pathology laboratory and how is used in the context of treating patients. This course greatly piqued their interest in pathology. **Conclusion:** Combining small-group classroom activities and laboratory tours at the end of the second year approves to be a very effective approach to introduce laboratory medicine to an entire class in a single day. It can be successfully done with careful planning and coordination and commitment by a large group of faculty, laboratory staff, and residents.

APC-18-0027PC. Teaching Medical Students Choosing Wisely in Diagnostic Medicine Clerkship: Oakland University William Beaumont School of Medicine's Experience

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Objectives: Based on published literature, 10% to 40% of laboratory tests have been considered unnecessary. The Choosing Wisely campaign launched by ABIM Foundation 5 years ago has increased the awareness among health-care providers and patients. To prepare our medical students to become wiser laboratory users, we have devoted a significant portion of our laboratory medicine curriculum to teach them how to choose laboratory tests wisely in the diagnostic medicine (DM) clerkship at Oakland University William Beaumont School of Medicine (OUWSOM). **Methods:** As the second part of a longitudinal DM clerkship, all medical students must rotate in the pathology department in their fourth year at OUWSOM. For example, half of a day is allocated for the anemia session. Prior to this session, students were asked to perform a pretest. Within this session, students were provided with 8 representative cases selected from common or critical setting for

diagnostic workup where inappropriate test utilization is frequently observed in clinical practice. Students were asked to first formulate a list of differential diagnosis, then to order appropriate laboratory tests to confirm the most likely diagnosis or to rule out a specific disease among their differential diagnosis. The diagnostic utility and cost of the tests are discussed. **Results:** The pretest has helped to identify a significant knowledge gap in test utilization for anemia workup after the third year of clerkship (mean % score: 50; SD: 13). This knowledge gap was essentially the same among students who rotated the DM clerkship at different times in their fourth year, indicating additional clinical rotations did not fill this learning gap. This gap was consistent with the inappropriate utilization pattern frequently seen among the practicing physicians within our hospital system and community. For an example, flow cytometry and molecular studies were overused to rule out homological malignancy in the blood. Reticulocyte was underused in anemia workup. Students lacked clear understating of diagnostic utility of blood smear review. Generation of appropriate differential diagnosis based on CBC and differential count was hard for many of them. They essentially had no clue of the cost of the commonly used hematology tests. **Conclusions:** Pathologists are in a unique position in teaching medical students to choose laboratory tests wisely because of their domain expertise of the diagnostic utility and cost of tests and observation of ordering mistakes clinicians frequently make. A curriculum in medical education focused on choosing wisely, such as in our DM clerkship, may help improve test utilization.

APC-I8-0028PU. Pathology for Generation Y in New Integrated Curriculum

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Objectives: Almost 80% of US medical school use integrated curricula in their preclerkship years. At Eastern Virginia Medical School, the new integrated curriculum was launched in August 2016. From this moment the year-long pathology course previously offered to second-year medical students was no longer needed. To ensure pathology was retained in the curriculum pathology, faculty took an active role in designing the new integrated curriculum. Pathology content was securely divided among 9 modules spanning the first and second years. Besides organ modules, a general mechanism of disease module was designed to introduce first-year students to basic concepts of diseases. **Methods:** In each module, the discipline of pathology is introduced by live lectures intermixed with online recordings of concise material. Application of this knowledge is later acquired during small groups and whole class sessions based on clinical scenarios and integrated with other disciplines such as histology, physiology, microbiology, immunology, pharmacology, and clinical skills, and so on. Clinical cases range from less complex for early learners to more complex

cases for organ-based modules and almost exclusively are built by pathologists and then reviewed by other experts. They are formatted as question and answer sessions reported by online tools and then verbally in a class. **Results:** Based on the responses of a cohort of 142 second-year students from the longest, 11-week module, 78% strongly agreed/agreed that those sessions facilitated their learning. Based on the NBME exam results, those students scored 5% to 6% higher than the predictive mean on pathology portion of the integrated exams. This was comparable to their peers' scores taking our year-long pathology course in the discipline-based curriculum from previous years. **Conclusions:** Creating clinical cases with the integrated approach is time-consuming venture and it seems to erase delineations between pathology and other disciplines. Providing a particular format (small groups vs whole class, questions and answers vs discussion with experts in the room) has its own challenges also. We do not know how well those students will apply the basic disease concepts during their future clinical rotations and we do not have any methods to measure those outcomes yet besides their satisfaction and their performance on licensing exams. Present trainees belong to generation Y, grew up with technology, are team-oriented, and prefer hands-on, nontraditional knowledge acquisition. Our approach seems to appeal to their characteristics and invoke active participation and engagement during sessions. We contribute this to providing context to the content and avoiding situations where pure memorization is rewarded.

APC-I8-0029PU. Maintaining Pathology in the Era of Integrated Curricula

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Objectives: As most US medical schools transitioned to an integrated preclerkship curricula, traditional pathology-disciplined courses disappeared. Eastern Virginia Medical School (EVMS) launched its new integrated curriculum in August 2016. Pathology faculty insured involvement in its creation and implementation. Pathology was securely divided among our various modules spanning first and second years. Besides system modules, a general mechanism of disease module was designed to introduce first-year students to general pathology concepts and reinforce disease mechanisms. We hypothesize that this approach is necessary to prepare our learners adequately for the organ-based modules and standardized board exams as well as future practice. **Methods:** Eastern Virginia Medical School General Mechanisms of Disease module consists of 6 weeks of instruction based on content from *Robbins Basic Pathology* but also includes pediatric disorders, fundamentals of microbiology, and pharmacokinetics. Red and white blood cell disorders were also introduced to illustrate application of general mechanisms to an

organ system. Material is taught by live and online lectures, by problem-based learning sessions, called minicases, and through virtual patients. Students participate in tumor board, opioid, and HIV panel discussions and are introduced to the process of autopsy and filling out death certificates to reinforce disease mechanisms. **Results:** Data from NBME exams in general pathology category during the general mechanisms module (integrated curriculum) and general mechanisms block in our discipline-based curriculum show no difference in our students' performance: 83% predictive and 81% achieved versus 80% predictive and 78% achieved in 2016, and 81% predictive, 79% achieved in 2015, respectively. Although there is no difference in grades, we argue that this organization provides our students with the foundation to understand organ system disorders throughout subsequent modules under the guidance of pathology and nonpathology faculty. Our first cohort of students in the new integrated curriculum is preparing to take step 1 within the next few months. At that time, we will be able to compare their board scores with the scores of previous cohorts of students taught in the traditional discipline-based curriculum. **Conclusions:** Inclusion of a dedicated general mechanism of disease module in the new integrated curriculum at EVMS was possible due to engagement of the pathology faculty. This approach prepares our learners to the organ-based module while providing students opportunities on how to generate a differential diagnosis based on disease mechanisms as well as stand-alone course in old traditional curriculum. It also increases and maintains visibility of the discipline of pathology which could otherwise be lost in an integrated system.

APC-18-0030PU: Diagnostic Medicine as a Required Clinical Rotation

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Objectives: Advancements in education theory and practice have lead medical schools to a wave of curriculum revision. Often these are prompted by changes in advice or requirements in medical school accreditation. The once-conventional "2 plus 2" year format for classroom and clinical experience is largely being replaced by integrated and shortened foundation courses followed by clinical rotations that often begin earlier in the medical students' education. Pathology, as a discipline, frequently loses a separate place in the curriculum under these modifications, and there is a danger that students will fail to learn the essential messages of diagnosis and management that pathology and laboratory medicine embody. Furthermore, a pipeline of medical students choosing pathology as a career may suffer if the visibility of pathology in the curriculum continues to erode. We

aim to mitigate these challenges with a new clinical rotation for our medical students. **Methods:** We are collaborating with radiology to create a new clinical rotation called diagnostic medicine that will be required for all medical students at our institution. It combines radiology and imaging with pathology and laboratory medicine over a 3-week rotation. Importantly, this rotation is positioned early in the medical students' clinical schedule exposing students to these career options well before their commitment to residency training. **Results:** We are only at the pilot stage. **Conclusions:** We discuss the goals, mechanics, and advantages of this new clinical experience.

APC-18-0031PO. Early Exposure and Recruitment to Pathology Through a 2-Week Summer Experience

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Objective: Traditional lecture formats, often including pathologists, are being replaced by active learning approaches that focus on more exposure to clinical practices earlier in medical school training. There is a risk that pathologists may experience a reduction in visibility as a career choice among medical students during their formative first 2 years prior to making residency decisions. Our department has set forth to expose medical students to pathology early in their medical education in order to increase early interest and personal commitment to the specializations within pathology. **Method:** To combat the misperceptions students may have of pathology early in their medical education, our department has devised a paid 2-week summer program. This intensive program took place between the students' first and second years, when the students had fewer clinical commitments. Each day students would rotate through a pathology subspecialty and interact with both pathologists and clinicians, in order to observe the importance of the clinical-pathological correlation needed for good patient care. **Results:** This program allowed a small group of first-year medical students to rotate through and observe the vast pathology services within anatomical and clinical pathology. Topics focused on the relationship between pathologists and their clinical counterparts, which is rarely noticed by students during the third- and fourth-year clinical rotations. Whenever possible, experiences began with patient interviews and interactions and ended with a pathological diagnosis. For example, students observed ultrasound-guided fine needle aspirations. The students then followed the specimen through the pathology department, which culminated in the medical student sitting with the pathologist to develop the final diagnosis. Students also attended tumor boards and other interdepartmental conferences and experienced the critical role the pathologists play in patient care. **Conclusion:** Many medical

students view pathology as a subject that one merely memorizes in preparation for an exam or a hurdle to their experiences on the clinical floors. This trend is unfortunate and concerning, as within pathology lays the basis of all diagnosis and subsequent therapies. All too often, medical students do not realize the far reaching role pathology plays in the day-to-day within medical practice. This 2-week paid summer program has evolved over the last several years and has resulted in early exposure to the many career options within pathology prior to a personal commitment to other medical fields and a better appreciation of the daily role a pathologist plays in patient care.

APC-I8-0032PC: Forensic Autopsy Experience and Core Entrustable Professional Activities: A Structured Introduction to Autopsy Pathology for Preclinical Students

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Objectives: The forensic practice provided an autopsy experience for our school's MS1&2 students, reinforcing forensic autopsy pathology as the practice of medicine and highlighting core entrustable professional activities (Core EPA) in an autopsy. **Methods:** Students self-selected for an autopsy observership. Prior to the experience, we reviewed the expectations with students and assured that all HIPAA and safety training was completed. Groups of up to 4 students were on call for a weekend autopsy. They observed and participated, ideally from scene review through autopsy performance, slide review, and toxicology/laboratory results. The group had a structured presentation format for summarizing the autopsy experience, forming a differential and final diagnosis, completing the death certificate, discussing quality management, and learning issues in the case. At the end of the semester, all students participating in the experience met and each group had 10 minutes to provide the structured review of "their" case. **Results:** A high number of students completed the voluntary observership (32/79) with 10 cases reviewed. The structured, 10-minute review forced student groups to collaborate and select critical issues for Core EPA: documenting (EPA5) and preparing an oral (EPA6) presentation of clinical encounter, EPA 1 gathering history and physical examination, and EPA 2 prioritizing a differential diagnosis. A discussion of autopsy consent and forensic/public health ordering of an autopsy along with cultural sensitivity and respect provided an excellent example of EPA 11, obtaining informed consent from patients. Many cases required integration of past medical or mental health encounters, social work, EMS, police, and other personnel; students needed to address the team work needed in these cases (EPA 9). Finally, a required element of the presentation was documenting unexpected findings at autopsy. Although many were diagnostically minor, some rose to reportable discrepancies and students had

to address how autopsy contributes to EPA 13: system failures and culture of safety. **Conclusions:** The program received high ratings by students; 50 are participating this year. At least 6 core EPAs were addressed in every autopsy review; some had more when advanced clinical questions or safety issues were identified. Additionally, 1 student presented his case at a national meeting and publication is pending. The experience (1) provided a positive introduction to autopsy pathology, (2) reinforced the role of pathology in medicine, and (3) provided concrete examples of core EPA within pathology for students in preclinical years.

APC-I8-0033PO. Incorporating Hematology Quiz Application in Hematology Education

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Abstract

Medical students and other trainees are continuously in search of assessment tools to improve their collective educational experience. Digital online quiz banks in particular are popular assessment tools but are mostly provided by nonexperts or those in private industry, which can render them less accurate. Additionally, many students prefer that these assessment tools be on mobile platforms, which poses additional challenges. To address these issues, we have developed a mobile hematology quiz bank application edited by experts in hematology. This new application allows medical students and residents to assess their medical knowledge in a user-friendly digital environment throughout medical school and beyond. **Objectives:** At the University of California at Davis School of Medicine, we have developed a quiz bank application containing hundreds of questions on various topics in non-neoplastic hematology, neoplastic hematology, molecular hematology, and transfusion medicine. This quiz bank is now available to resident and fellow trainees as well as medical students. As an adjunct to our regular teaching sessions on hematology, the quiz bank provides the opportunity for self-assessment while also allowing the learner to compete or compare scores with a peer at the end of the session through its game center feature. **Methods:** This native application is built with Objective-C and X-code. Hence, it is only available on the iOS platform (iPhone and iPad). **Results:** This quiz bank provides hundreds of hematology and hematopathology multiple-choice questions with full answer explanations. The questions are separated into 17 hematology categories, including normal hematopoiesis, anemias, hemoglobin disorders, coagulation, clotting and bleeding disorders, acute myeloid leukemias, B- and T-ALLs, myeloproliferative neoplasms, myelodysplastic syndrome, B-cell and T-cell non-Hodgkin lymphomas, plasma cell neoplasms, Hodgkin lymphomas, molecular hematology, and transfusion medicine. The questions in each

category are written and edited by content experts from various institutions of higher learning. Colorful microscopic pictures and illustrations are incorporated into many questions. Additionally, randomization ensures that each question and the respective answer choices will be presented in a different order with each new session. This will minimize memorization recall by the user and will reinforce learning based on true knowledge retention. After each question is answered, full answer explanations are provided for both correct and incorrect answer choices. This application also incorporates game center capability to allow students to compete against their peers and compare scores, resulting in a more enjoyable user experience. **Conclusion:** Question banks that utilize technological advances give medical students the flexibility of self-assessment at their convenience and help with learning and knowledge retention throughout all 4 years of medical school and beyond. We anticipate that the use of this quiz bank will continue to grow, thereby facilitating learning for our medical students and other trainees, and we plan to expand testing to include other pathology subjects with the same platform.

APC-I8-0034PU. Microscopic Examination of Lesions Discovered in Anatomy Lab: Fostering Medical Students' Interest in Pathology

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Objectives: In recent years, there has been a downward trend in interest among medical students in pursuing careers in pathology. In 2015, a program was developed at the University of Alabama at Birmingham (UAB), which aimed to expose first-year medical students to the medical specialty of pathology by giving them the opportunity to “biopsy” and subsequently microscopically examine lesions they discovered during cadaver dissections. Groups of students were encouraged to integrate cadaver’s clinical histories, gross findings, and microscopic findings and presented correlations with the rest of the class in oral presentations in a formal classroom setting. The purposes of this presentation are to share our experience integrating this project into a traditional dissection curriculum, consider students’ evaluations of the activity, and consider the potential positive impact educators can have on early pathology education. **Methods:** Samples were obtained during the thoracic and abdominal cavity dissection laboratory sessions of the fundamentals course. A pathologist and course instructor were available for consultation for medical students regarding which tissues may be useful and educational to sample and view microscopically. Standard tissue processing was performed, and tissues were placed on slides and scanned for virtual microscopic viewing. Groups orally presented their findings to the rest of the class. Students were surveyed after the activity. **Results:** Tissue was

obtained from a total of 19 cadavers. Ninety-two percent of students indicated that microscopic examination of lesions helped emphasize the basic mechanisms involved in the development of those lesions. Eighty-two percent of students indicated that microscopic examination of lesions helped them better understand the pathologists’ role in patient management. Eighty percent of students recommended making microscopic evaluation of lesions a routine part of the dissection course. Twelve percent of students indicated they might consider pursuing a pathology residency as a result of some of their experiences in the course. **Conclusions:** Integration of biopsies into medical students’ dissection curriculum can be a useful way to expose medical students, at an early time in their training, to pathology and how the pathologist is integrated into the health-care system. Nonetheless, there are some practical challenges that must be considered anytime a new activity is introduced into a curriculum. Starting in 2017, this project was fully integrated into the first-year fundamentals curriculum as a participation component, and all groups were required to take biopsies and do 15-minute oral presentations. This project was funded by the UAB Faculty Development Grant Program.

APC-I8-0035PC. Case-Based Asynchronous Interactive Modules in Undergraduate Medical Education

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Objectives: Undergraduate medical education is evolving toward non-lecture-based integrated curriculums. Although this provides students with repeated exposure to pathology in a clinical context, it requires collaborative curriculum design with a focus on new educational technology. At Thomas Jefferson University, the Pathology and Obstetrics/Gynecology (ObGyn) departments are collaborating to pilot a series of case-based asynchronous interactive modules (AIMs) to teach gynecologic pathology in a clinical context, interweaving other educational components, such as evidence-based medicine, clinical skills, and basic sciences. Case-based modules highlight principles of pathology and the role of pathologists. In this study, we used a case-based AIM to teach pathology to third-year medical (MS3) students during their ObGyn clerkship. **Methods:** An AIM was code-signed by the ObGyn and pathology clerkship directors to simulate 4 colposcopy clinic patients. The AIM was presented to MS3 students midway through their ObGyn clerkship. Students interpreted histologic and clinical images while being evaluated on clinical management skills, gynecologic diagnoses, general principles of population health,

and pathology throughout the AIM. The students also completed a 7-question pre-and posttest which had no bearing on the students' course grade. Commentative learner feedback was also solicited. **Results:** One hundred thirty-nine students from 5 blocks did the pretest, of which 68 students from 3 blocks completed a posttest with the following scores: Block 1—6.30 (pre, 90%) to 6.67 (post, 95.29%); block 3—6.13 (pre, 87.57%) to 6.40 (post, 91.43%), and block 4—5.44 (pre, 77.71%) to 5.99 (post, 85.87%). The average score increased by 5.7%. Learner feedback was positive, with suggestions to apply this method to other medical specialties, particularly radiology. **Conclusions:** Asynchronous interactive modules are an efficacious and popular method of pathology education. All participants showed improvement in interpreting history and physicals, lab data, and gynecologic pathology findings in routine clinical scenarios as well as improved case-based decision-making. Future directions include collaborating with other departments to create modules that help teach and contextualize the role of both pathologists and principles of pathology in clinical decision-making.

APC-18-0036PU. Teaching Pathology From Human Gifts Registry Donations: An Innovative Approach

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Objectives: To evaluate the feasibility and perceived value of integrating pathology into gross anatomy. **Methods:** Study cohort was 18 dissection teams each with 8 to 9 pre-clinical medical students. Selected pathologic abnormalities (n = 8) were reviewed, discussed tableside, and sampled for routine histology processing. H&E tissue sections were digitized. The images, relevant normal histology, and differential diagnostic entities were presented and discussed with the team. The pathology correlations were posted to the schools' learning management system with tracking of student views (hits). An end of course evaluation (Likert scale 5) with narrative comments was obtained. **Results:** (1) Embalmed cadaveric tissue was suitable for processing and evaluation. (2) Student satisfaction was highly favorable—average score of 4.42 (± 1.00); overall course average score 3.81 (± 1.01). (3) There were 47 student hits to review the posted material. (4) Student comments include “For the purposes of teaching future doctors to understand disease pathology much better, it is a great idea; I did not get much time with Dr X in the lab, but I did review his pathology correlations posted on UBlearns and I think more like this would definitely be helpful; to me, this seems like the best way to learn both subjects. Synthesis of the two of them, at the same time (even if it requires a longer course) would not only improve performance in both disciplines but would result in a more complete understanding

of both going forward as well.” **Conclusions:** Review of cadaver pathology begins to integrate pathology with clinical medicine. Minimal knowledge of pathology did not limit the educational value nor reduce student satisfaction. Inclusion of all dissection groups with photographic documentation of the abnormalities and presentation of the findings as a “case of the week” would enhance the educational value. A student-prepared final anatomic diagnosis could be required to confirm or refute the cause of death as recorded on the death certificate.

APC-18-0037PO. Use of Online Tools in Improving Medical Student and Resident Education in Anatomic Pathology

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Background: Medical students, residents, and fellows are exposed to a wide expanse of medical knowledge every day, which can be challenging for them to synthesize and apply. One means of encouraging knowledge retention in trainees is through the provision of question banks. Given the preferences of our current generation of trainees, technological tools in the form of applications or “apps” on smart phones and tablets are highly convenient and portable, and as such are often used. At the University of California at Davis School of Medicine, we have developed an application that contains questions on various subspecialties in anatomic pathology. This application allows medical students, residents, and fellows to evaluate their own knowledge base, identify areas for improvement, and compare personal performance with that of their peers. **Objectives:** We have developed a new anatomic pathology question bank application for medical students and residents at the University of California at Davis School of Medicine. This application serves as a self-assessment tool for the trainees and helps them identify and correct knowledge gaps through use of the provided answer explanations. **Methods:** This native application is built with Objective-C and X-code. Hence, it is only available on the iOS platform (iPhone and iPad). **Results:** Experts in different areas of anatomic pathology (eg, gastrointestinal and liver pathology, renal pathology, bone and soft tissue pathology, etc) have crafted numerous multiple-choice questions on each topic. Gross and microscopic images are incorporated into some questions. An explanation for correct and incorrect answers is provided at the end, accompanied by a score. Peer review of the questions, answers, and answer explanations is performed to ensure content accuracy. Application users can elect to answer questions by topic or by randomization and can compare scores with their peers. **Conclusion:** Technological tools can be incorporated in medical student and resident education to improve and enhance their learning experience and self-assessment.

APC-I8-0038PU. Summer Training Experiences in Pathology for Medical Students (STEPS): A Pathology-Oriented Clinical Enrichment Program for Early-Stage Medical Students Engaged in Summer Research in Pathology

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Background: In 2015, the University of Pittsburgh Medical Center, Department of Pathology began offering medical students performing pathology research during the summer between first and second year of medical school the opportunity to participate in pathology-specific clinical enrichment activities. We named the new initiative Summer Training Experiences in Pathology for Medical Students (STEPS) and developed it with the intention of augmenting students' limited exposure to the discipline of pathology afforded during medical school training at the University of Pittsburgh. **Methods:** Pathology education at our institution consists of a 2-week introductory course during the first-year basic science core, while organ-specific pathology is taught during the organ systems courses which extend from the end of the first year through the second year. Summer Training Experiences in Pathology for Medical Students are composed of 8 unique pathology-centric clinical offerings held weekly over the course of the 8-week summer research fellowship. Each STEPS activity lasts up to 3 hours and typically occurs on Monday morning. The offerings include participating in an autopsy, practicing fine needle aspirations, exploring molecular testing, rounding with the blood bank attending, performing a point-of-care testing exercise, attending an unknown slide conference, observing slide preparation in the histology lab, and learning about intraoperative consultation. **Results:** From 2015 to 2017, 13 students participated in the STEPS program. We reviewed anonymized student responses to a University of Pittsburgh IRB-approved survey of the STEPS program and found that all students responding to the survey (9/9) agreed that participating in the STEPS program was enjoyable and benefitted their medical education. All respondents (9/9) agreed that participating in the STEPS program did not interfere with their ability to conduct research during the summer fellowship. The majority of respondents (8/9) agreed that participating in the STEPS program made them feel better equipped to contact a pathologist to discuss a patient or specimen issue in the future. Students described the best features of the STEPS activities to be "the hands-on chance to actually see what a pathologist does," "getting an up close and personal view of pathology with residents and attendings," "participating in the personalized medicine session," and "the opportunity to assist in an autopsy," among others. Areas of improvement to be

considered include altering the day and time of STEPS activities (as Monday morning happened to coincide with some research lab meetings) and providing parking for those students who travel to the hospital from distant research labs to participate. **Conclusion:** The STEPS program offers early career medical students performing summer research in pathology a variety of opportunities to interface with pathologists and actively engage in activities related to clinical pathology practice. One benefit of participating in this program, among several, may be to increase the comfort level of the medical student to interact with pathologists and pathology laboratories in the care and management of their future patients.

APC-I8-0039PU. Pathology Education in an Integrated Medical School Curriculum: The UCSF Bridges Experience

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Objectives: In 2017, UCSF implemented Bridges, a 4-year MD curriculum with 3 phases: foundations 1 (F1, pre-clerkship), foundations 2 (F2, clerkship), and career launch (advanced studies). We describe our strategies for integrating pathology content in this curriculum; the emphasis is on clinicopathologic correlation in F1, guidance on utilization of diagnostic pathology services in F2, deep exploration of diagnostic pathology in career launch, and career advising throughout. **Methods:** As UCSF pathology co-stewards, the two of us communicate closely about all aspects of UME teaching and are members of the leadership team for each block, a necessary step for success in overhauling pathology curricula. The F1 pathology curriculum has been significantly restructured, with faculty- and fellow-facilitated small-group discussion sessions used as the main teaching modality in all blocks. Additional F1 teaching methods include classroom lectures, online learning resources (such as prerecorded lectures and annotated self-study modules), and gross specimen review labs. For F2, we developed 2 new elements—the pathology portion of the longitudinal course "Appropriate Use of Diagnostic Tests" and a 2-week introductory pathology elective; in Career Launch, we offer the 2- and 4-week advanced pathology electives. The two of us write all pathology assessments for Bridges, including required weekly checkpoints; we also grade all pathology questions on block exams, which in this curriculum consist exclusively of open-ended questions that require knowledge application. **Results:** To evaluate the success of the redesigned pathology curriculum, we plan to use several independent quantitative measures including (1) student evaluations of small-group facilitators, (2) facilitator evaluations of the teaching experience and materials, (3) enrollment in the career launch electives (also available in the prior curriculum, enabling direct comparison), (4) performance on USMLE step 1, which is scheduled post-F2 for Bridges students, and (5)

performance on the annual graduation questionnaire. As Bridges was implemented only 1.5 years ago, data collection has just begun; however, our experience already underscores the value of close teaching oversight by pathology education leaders. **Conclusions:** Curricular reform can result in positive changes for pathology teaching in the modern training environment. Pathologists are key stakeholders in the design and implementation of new programs, and leveraging the clinical and diagnostic aspects of pathology in teaching facilitates a positive outcome in student and physician perception of our field.

APC-I8-0040PU. Core EPAs in Basic Science Courses: An Important Role for Pathology

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Background: Many medical schools have begun to utilize some of the core EPAs for entering residency, developed by the AAMC, as a framework for their medical school competencies or outcomes. The EPAs were developed for a clinical context and most are being evaluated in the clinical years of medical school. However, the medical knowledge essential for many of the core EPAs is learned in the basic science courses. **Methods:** We have developed an online system for providing formative feedback to medical students during the second-year pathology teaching for two of the core EPAs: EPA 2 (develop a prioritized differential diagnosis and select a working diagnosis) and EPA 3 (recommend and interpret common diagnostic and screening tests). Our online system charts levels of achievement and also allows students to do self-evaluations to compare to the faculty evaluation. **Results:** In an initial pilot, students have been excited to understand how the case-based pathology teaching sessions allow them to become better prepared for their clinical rotations and to realize the value of informed selection of laboratory tests. **Conclusion:** We will present our preliminary data in our presentation and emphasize how pathologists can directly demonstrate the value in preparing students for clinical encounters.

APC-I8-0041PU. Using Virtual Images From BEST Network to Integrate Pathology and Immunology in Teaching M1 Foundation Science Module

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Objectives: At Eastern Virginia Medical School, innovative digital tools and virtual images are being used to teach immunology with histopathological context to engage the first-year medical students. The purpose of this study is to demonstrate the effectiveness of these technology tools in their learning. **Methods:** The basic concepts of immunology—the innate and adaptive immunity—are taught in the foundation science (FS) module II module of the M1 curriculum. An interactive learning session with the integration of immunology concepts with pathological examples (pneumonia and lymph node hyperplasia) was developed by using an adaptive e-learning platform (smartsparrow.com) and high-resolution virtual images from Slice digital database of Biomedical Education Skills and Training (BEST) Network. The students were engaged in a live demonstration by a tutor, problem-solving exercises, and discussion in small groups. A survey questionnaire to assess the students' perception was deployed at the end of the FS-II module. **Results:** Forty students out of 117 students enrolled in the course (34% participation rate) and completed a survey questionnaire. Ninety percent of the respondents either agreed or strongly agreed that designed interactive session was interesting and engaging. Eighty-eight percent of the respondents felt that it was valuable to their understanding of concepts. Eighty-five percent wanted more lessons in a similar format. Sixty-four percent felt that it was easy to navigate the lesson in the adaptive learning platform. The exam data for the FS-II module during 2016 and 2017 were compared, which showed no statistically significant change in grades. The comments from students indicated that it was a helpful activity, appropriate for first-year medical students, consolidated their knowledge, and enhanced their understanding of complex concepts. **Conclusions:** With a number of institutions moving toward integrated curriculum, educators often struggle to provide clinical relevance and pathological correlations while teaching basic sciences. The BEST network has a database of over 20 000 macroscopic and microscopic images in partnership with leading institutions across Australia and the United States. Our results showed that the virtual images with annotations from BEST network are an effective tool to engage medical students and promote active learning.

APC-I8-0042PU. Multidisciplinary Electives for Medical Students: The View of Pathology Departments in Large Metropolitan Areas

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Objectives: One approach for exposing medical students to the field of pathology and to the meaning of being a pathologist is

to provide a combined elective in which the pathology department formally pairs up with a clinical service. The student thus might “follow the specimen” in a structured manner, for example, witnessing the processing and analysis of a lesion surgically removed from a patient who the student had followed at the bedside or in the radiology suite during preceding days. Although some senior pathologists attest that such multidisciplinary electives were usefully offered in decades past, it is unclear how commonly they are offered in the present training landscape and it is unknown how enthusiastically such joint ventures might be embraced by more recently hired pathologists in the teaching arena. **Methods:** In order to examine these questions in 1 selected setting—the academic training program in the major metropolitan area—we distributed surveys seeking

the views of directorship-level pathologist teachers working in the 25 largest metropolitan areas in the United States (cities that together hold over 40% of the nation’s population). Pathologist educators from multiple cities in each of the 5 major national regions responded to the survey. **Results:** The survey results reveal a striking incongruity, namely that although more than 70 percent of respondents ranked such electives highly (“excellent” or “good” both for teaching about pathology department activities and for raising awareness of pathology as a career option), less than 25% of respondents reported that their department presently offers such an elective. **Conclusions:** If multidisciplinary electives are as promising for student enlightenment as our survey estimates suggest, then there is clearly ground for expanding such offerings nationwide.

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The Association of Pathology Chairs (APC) is seeking Educational Case submissions to *Academic Pathology*, the association's official journal. Once published, Educational Cases are indexed on Pub Med, openly accessible worldwide, and citable for scholarly credit, similar to other peer-reviewed articles. Educational Cases are tools for implementing the Pathology Competencies for Medical Education (see doi: [10.1177/2374289517715040](https://doi.org/10.1177/2374289517715040)), which is a national standard to provide all medical students with a broad foundation of knowledge, skills, and attitudes essential to understand the normal and pathological processes of each organ system, the ability to apply disease mechanisms to describe the pathobiology, and the ability to continually improve diagnostic acumen and optimal treatment decisions through lifelong learning.

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