PIER Essential 4 Resource Toolkit

E - 1
PIER Essentials 1

- Informatics in Pathology Practice
- Information Technology Fundamentals
- Introduction to Data Science
- Data Availability and Security

E - 2
PIER Essentials 2

- LIS Components & Functions
- Specialized LISs and Middleware
- Interoperability, Messaging Standards, and Regulations
- Digital Imaging
- Basics of the Health Care Information Ecosystem

E - 3
PIER Essentials 3

- Pathologist Role in LIS and EHR Projects
- LIS Lifecycle
- Information Systems and Laboratory Performance
- Introduction to Data Warehousing and Analytics/Visualization Tools

E - 4
PIER Essentials 4

- LIS Management & Oversight
- Laboratory Data Analytics for Quality Improvement, Education, and Research
- Laboratory Data for Quality Improvement and Research
- Advanced Digital Imaging

2021
Release 4

College of American Pathologists

APC — Association of Pathology Chairs

api — PATHOLOGY INFORMATICS

PIER RESOURCE LIBRARY

This section provides information about resources that can be used to teach informatics topics.

College of American Pathologists (CAP) Online Activities

The CAP has developed several online informatics activities about fundamental informatics concepts. See list below. These activities are free. A login is required to access the activities and can be created by clicking on the **LOG IN** button on the CAP website. There is no charge for creating an account.

- Tackling Today's Technology: A Pathologist's Guide to Health IT Basics
- Working With Electronic Health Records: Practical Insights for Pathologists
- Medical Coding Basics
- LIS Fundamentals
- Telepathology and Whole Slide Imaging
- Interfaces and Middleware: LIS Connectivity Options That Can Improve and Streamline Laboratory Operations

Essentials 4 Recommended Resources Requiring Advanced Purchase/Login Access

1. Hanna MG, Parwani A, Sirintrapun SJ. Whole Slide Imaging: Technology and Applications. *Adv Anat Pathol*. 2020 Jul;27(4):251-259.

2. Pantanowitz L, Tuthill JM, Balis UGJ, eds. *Pathology Informatics: Theory and Practice.* 1st ed. Chicago, IL: ASCP Press; 2012.

3. Park S, Pantanowitz L, Parwani AV. Digital imaging in pathology. *Clin Lab Med*. 2012 Dec;32(4):557-84.

4. Wager KA, Lee FW, Glaser JP, eds. A Practical Approach for Healthcare Management. 4th ed. San Francisco, CA: Jossey-Bass; 2017.

5. de Baca ME, Spinosa JC, Aller R, Badizadegan K, Blouin AG, Castellani W, Chen P, Gilbertson J, Harrison J, Henricks W, Kennedy M, Knapik C, Pantanowitz L, Reichard RR, Robb J, Stram M. CAP Pathology Resource Guide: Clinical Informatics. Version1.2.0.0. Northfield, IL: College of American Pathologists; 2018.
   a. To Access: https://www.cap.org/member-resources/pathology-resource-guides.
   b. Click on the "Online Versions" link under the "Member-only Benefits" header.

6. The Association for Pathology Informatics website is a good source for material that can be used to teach PIER concepts.
   a. From the main menu, select "Education and Resources" then "PIER Education".
   b. Access to PIER-specific content may require an API membership. API has options for teaching institutional memberships that will give access to all your faculty and residents.

Quick Access Menu

- Topic 1: LIS Management and Oversight

- Topic 2: Laboratory Data Analytics for Quality Improvement, Education, and Research

- Topic 3: Laboratory Data for Quality Improvement and Research

- Topic 4: Advanced Digital Imaging

- Appendix A: Practical Exercises

- Appendix B: Additional Learning Resources

Essentials 4 – PIER Resource Options

Topic 1:	LIS Management and Oversight
Rationale	Pathologists share in the responsibility of data and functionality management within the LIS.
PIER Outcome Statements (OS) ➜ Indicates high priority OS	**OS1** Maintain LIS policy and procedure manuals. ➜ **OS2** Explain the role and responsibility of pathologists with regard to the selection, oversight, and use of all systems used by the laboratory. ➜ **OS3** Identify opportunities to modify the LIS to improve operations. ➜ **OS4** Participate in a meeting, committee, etc. involving an aspect of LIS governance (eg, adding new lab test).
Subtopics (Content covered within topic)	1. Laboratory procedures and hospital policies 2. LIS support model (eg, departmental versus institutional) 3. Vendor relationships 4. Change management (eg, everything from break fixes to upgrades) 5. End user support and communication practices

Recommended Resources

OS	Resource
OS1, OS2, OS3, OS4	Wager KA, Lee FW, Glaser JP, eds. *Health Care Information Systems: A Practical Approach for Healthcare Management*. 4th ed. San Francisco, CA: Jossey-Bass; 2017. • Chapter 5: System Acquisition; 141-178. • Chapter 6: System Implementation and Support; 179-214. • Chapter 7: Assessing and Achieving Value in Healthcare Information Systems; 215-250. • Chapter 8: Organization of Healthcare Information Systems; 251-284.
OS1, OS2, OS3, OS4	Pantanowitz L, Tuthill JM, Balis UGJ, eds. *Pathology Informatics: Theory and Practice*. 1st ed. Chicago, IL: ASCP Press; 2012. • Chapter 7: Laboratory Information Systems Operations
OS1, OS2, OS3, OS4	de Baca ME, Spinosa JC, eds. *Clinical Informatics Resource Guide*. Northfield, IL: College of American Pathologists; 2018. • Selection and purchasing process • Sinard J. Information system (LIS) selection process • Carter AB. What needs to be in the purchasing contract for a new laboratory information system or middleware? • Insights from adopters at 2 institutions that implemented new LIS • Accreditation and regulatory aspects 6.1 CLIA and LAP accreditation requirements • CAP LAP: accreditation

➜ Additional Learning Resources

Practical Exercises

OS	Exercise
OS1, OS3	LIS Backup/Down Time
OS2	LIS Vendor and Contracts
OS2, OS3, OS4	Mock CAP LIS Inspections

Essentials 4 – PIER Resource Options, Topic 2

Topic 2:	**Laboratory Data Analytics for Quality Improvement, Education, and Research**
Rationale	The analysis of pathology data is critical to the safe, effective, and efficient operation of the lab, as well as medical education and research.
PIER Outcome Statements (OS) ➔ Indicates high priority OS	➔ **OS1** Describe the importance of ancillary data (eg, from middleware, financial systems, business intelligence) to optimize the clinical, operational, and financial performance of the laboratory. ➔ **OS2** Present how your department manages protected health information (PHI) (de-identification and re-identification risk) for educational and research use. ➔ **OS3** Analyze test utilization data to identify a single lab test that might benefit from the creation of a clinical decision support (CDS) tool and propose how the CDS tool might work. ➔ **OS4** Utilize the analysis of pathology data in either a research study or an educational presentation.
Subtopics (Content covered within topic)	1. CDS tool and test utilization metrics 2. Business intelligence tools 3. Research data infrastructures 4. Regulations regarding secondary use of clinical data

Recommended Resources *(Note: Some resources may not have web access.)*

OS	Resource
OS1	Crawford JM, Shotorbani K, Sharma G, et al. Improving American Healthcare Through "Clinical Lab 2.0": A Project Santa Fe Report. *Acad Pathol*. 2017;4:2374289517701067.
OS2	Department of Health & Human Services. Guidance regarding methods for de-identification of protected health information in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. 2012 Nov 26.
OS3, OS4	Krasowski MD, Chudzik D, Dolezal A, et al. Promoting improved utilization of laboratory testing through changes in an electronic medical record: experience at an academic medical center. BMC Med Inform *Decis Mak*. 2015;15:11.

➡ Advanced Learning Resources

Practical Exercises

OS	Exercise
OS1	Metrics and Quality Assurance (QA)
OS1, OS2, OS3	QA Data and Metric Requirements
OS1, OS2, OS4	Quality Improvement Project

Topic 3:	Laboratory Data for Quality Improvement and Research
Rationale	Laboratory data is utilized for analytics at the enterprise level and requires pathologist input for maximal effectiveness.
PIER Outcome Statements (OS) ➔ Indicates high priority OS	**OS1** Explain how data from disparate sources are brought together in support of interoperability both within a healthcare organization and between health systems.
	➔ **OS2** Report on what pathology/laboratory data is and is not being stored in your hospital's data warehouse.
	➔ **OS3** Contribute to the analysis and interpretation of integrated pathology and enterprise data sets for improving care effectiveness or quality.
	OS4 Explore data analysis horizons, including machine learning and data blocking legislation.
Subtopics (Content covered within topic)	1. Data integration, including extract, transformation, and load principles 2. Data warehousing, including health information exchange considerations 3. Contributions to population health and Accountable Care Organizations (ACO) 4. Machine learning techniques (eg, "artificial intelligence") 5. Data blocking legislation

Recommended Resources

OS	Resource
OS1, OS3	Crawford JM, Shotorbani K, Sharma G, et al. Improving American Healthcare Through "Clinical Lab 2.0": A Project Santa Fe Report. *Acad Pathol*. 2017;4:2374289517701067.
OS2	Krasowski MD, Schriever A, Mathur G, Blau JL, Stauffer SL, Ford BA. Use of a data warehouse at an academic medical center for clinical pathology quality improvement, education, and research. *J Pathol Inform*. 2015;6:45.
OS4	Madabhushi A, Lee G. Image analysis and machine learning in digital pathology: Challenges and opportunities. *Med Image Anal*. 2016;33:170-175.
OS4	Office of the National Coordinator for Health Information Technology. Information blocking. HealthIT.gov website.

➔ Advanced Learning Resources

Practical Exercises

OS	Exercise
OS1, OS2	Using a Data Warehouse For Test Monitoring
OS3	Use System-level Data to Respond to a Clinical Case
OS4	Identify New Development or Threat to Informatics

Essentials 4 – PIER Resource Options, Topic 4

Topic 4:	Advanced Digital Imaging
Rationale	The acquisition, storage, viewing and analysis of pathology and other clinical images is rapidly becoming a component of pathology practice.
PIER Outcome Statements (OS) ➜ Indicates high priority OS	**OS1** Understand the history of FDA regulation of whole slide imaging systems.
	➜ **OS2** Investigate the development of image analysis and machine learning applied to pathology and other clinical images with a focus on the need for large, high-quality data sets.
	➜ **OS3** Use a whole-slide image viewer to annotate a whole slide image (WSI).
	OS4 Explain the importance of and key aspects of an enterprise imaging strategy, including a vendor neutral archive.
Subtopics (Content covered within topic)	1. WSI consensus guidelines 2. FDA Regulation of WSI and WSI data 3. Vendor neutral archive and enterprise imaging strategies 4. Machine learning principles applied to image analysis 5. Annotation and analysis of WSI

Recommended Resources

OS	Resource Citation
OS1	Evans AJ, Salama ME, Henricks WH, Pantanowitz L. Implementation of Whole Slide Imaging for Clinical Purposes: Issues to Consider From the Perspective of Early Adopters. *Arch Pathol Lab Med*. 2017 Jul;141(7):944-959.
OS2	Volynskaya Z, Chow H, Evans A, Wolff A, Lagmay-Traya C, Asa SL. Integrated Pathology Informatics Enables High-Quality Personalized and Precision Medicine: Digital Pathology and Beyond. *Arch Pathol Lab Med*. 2018 Mar;142(3):369-382.
OS3	Hanna MG, Parwani A, Sirintrapun SJ. Whole slide imaging: technology and applications. *Adv Anat Pathol*. 2020 Jul;27(4):251-259.
OS4	Park S, Pantanowitz L, Parwani AV. Digital imaging in pathology. *Clin Lab Med*. 2012 Dec;32(4):557-584.

➜ Advanced Learning Resources

Practical Exercises

OS	Exercise
OS1	Assessment of WSI Devices
OS2	Analysis of Microscopic Images
OS3	Using a WSI Viewer for Annotation

Appendix A: Practical Exercises

Appendix A provides a practical exercise worksheet for the topics with specific exercises. Note: Not all topics may have an exercise and topics may combine exercises with two or more topics. Many of the exercises are case based to provide the resident with real life situations where informatics tools are needed to solve a problem or confirm a diagnosis. Outcome measurements are intended to demonstrate the resident has sufficient knowledge related to the topic content. They are usually a demonstration format (eg, presentation, demonstration of skill, short written report).

Essentials 4 Topic 1 Practical Exercises (**Return to E4T1**)

Practical Exercise 1: LIS Backup/Down Time	Exercise Type: Research
PIER Outcome Statements	OS1, OS3
Setup	Have the resident review the department's policy for data backup to identify when it is performed and how often is it performed. Resident then would perform the following actions: • Review the laboratory's downtime policy/SOP • Identify their role and job requirements during a downtime • Check the policy for the review cycle • Confirm the policy is up-to-date Resident should be able to identify and contact the individual who is designated for notification of unexpected LIS downtime. Resident should be able to describe how the laboratory director learns of LIS system problems and under what circumstances (ie, what is the escalation process).
Informatic Tools	None
Resources	Department's policy for LIS data backup
Activity Time	4-5 days
Completion Proof	Written document in which the resident: • Lists as many potential problems and/or regulatory violations with the proposed installation above according to what he/she read in the recommended resources. • Describes the possible worst case scenario for each problem/violation if it were allowed to be installed in this way, specifically those that could adversely impact the healthcare organization, the laboratory and/or the patient. • Lists potential mitigations for each of the problems identified.

Practical Exercise 2: LIS Vendor and Contracts	Exercise Type: Research
PIER Outcome Statements	OS2
Setup	Resident reviews the LIS request for proposal (RFP) and vendor response to identify important information to provide the vendor and portions most important for pathologists input. Then have resident review an LIS vendor contract if available to identify elements such as: licensing module (eg, per seat), pricing, vendor support agreement). Next, have the resident name the vendor(s) of the following systems in use: LIS(s), EHR, laboratory web portal, and any major middleware information handling systems, including point of care testing data management. For LIS(s), have residents determine the version name/numbers that the laboratory is using. Resident should also review documentation for a recent LIS laboratory upgrade.
Informatic Tools	None

Resources	RFP and vendor responses, LIS vendor contract, vendor support agreement (eg, 24/7, phone, email); documentation for recent LIS upgrade (eg, testing, training documentation).
Activity Time	4-5 days
Completion Proof	Written document in which the resident: • Lists name the vendor(s)/versions of systems in use, such as: LIS(s), EHR, laboratory web portal, and any major middleware information handling systems, including point of care testing data management. • Lists problem/violation in contracts, specifically those that could adversely impact the healthcare organization, the laboratory and/or the patient

Practical Exercise 3: Mock CAP LIS Inspections	**Exercise Type: Hands-on (Group)**
PIER Outcome Statements	OS2, OS3, OS4
Setup	Have the resident review the IT related policies, check against LAP Checklist items, verify compliance and/or list problem areas. Have the resident prepare for a mock CAP inspection with attention to aspects of the Laboratory General Checklist related to laboratory information management. Then, have resident perform with a selected group of residents perform an "inspection" of the LIS based on the CAP checklist questions related to the LIS.
Informatic Tools	None
Resources	CAP Laboratory General Checklist related to laboratory information management; CAP Laboratory
Activity Time	5-7 days
Completion Proof	Written document in which the resident: • Lists as many potential problems and/or regulatory violations according to what he/she read in the recommended resources. • Describes the possible worst case scenario for each problem/violation if it were allowed to continue, specifically those that could adversely impact the healthcare organization, the laboratory and/or the patient. • Lists potential mitigations for each of the problems identified.

Essentials 4 Topic 2 Practical Exercises ([Return to E4T2](#))

Practical Exercise 1: Metrics and Quality Assurance (QA)	**Exercise Type: Research**
PIER Outcome Statement	OS1
Setup	The resident should know which metrics the laboratory is expected to report for institution-level QA activities.
Informatic Tools	
Resources	Institution's Policy and Procedures for laboratory metrics for QA activities.
Activity Time	1-2 hours
Completion Proof	Resident is required to report on findings/discussion during one or more rotations to the program director for the assigned rotation.

Practical Exercise 2: QA Data and Metric Requirements	**Exercise Type: Research**
PIER Outcome Statement	OS1, OS2
Setup	Attend QM (or analogous) team meetings and recognize data requirements and sources for the metrics discussed/followed in the laboratories QA plan.
Informatic Tools	None
Resources	Institution's quality assurance plan, any policies and procedures that maybe associated with the metrics and/or data requirements.
Activity Time	1-2 hours
Completion Proof	Resident is required to report on findings/discussion during one or more rotations to the program director for the assigned rotation.

Practical Exercise 3: Quality Improvement Project	**Exercise Type: Hands-on**
PIER Outcome Statements	OS1, OS2
Setup	Have the resident use data mining techniques/business intelligence tools in the performance of a laboratory quality improvement project.
Informatic Tools	Data mining and business intelligence tools.
Resources	None
Activity Time	1-2 days
Completion Proof	Resident will present analysis of lab data and recommend actions to improve a lab or clinical workflow in response.

Essentials 4 Topic 3 Practical Exercises ([Return to E4T3](#))

Practical Exercise 1: Using a Data Warehouse For Test Monitoring	**Exercise Type: Hands-on**
PIER Outcome Statements	OS1, OS2
Setup	Pull test data from data warehouse or similar source containing instances of a single test order over time, with results and associated metadata (eg, ordering provider).
Informatic Tools	If your institution does not have a lab data warehouse or comprehensive research data warehouse, see if your EHR vendor has a built-in data search module available.
Resources	
Activity Time	2-5 days (may be longer depending on the duration indicated for single test monitoring).
Completion Proof	Resident is required to provide a file containing instances of a single test order over the agreed upon activity time, with results and associated metadata.

Practical Exercise 2: Use System-level Data to Respond to a Clinical Case	**Exercise Type: Hands-on**
PIER Outcome Statement	OS3
Setup	Use system-level patient data to respond to a clinical case providing a summary of analysis of laboratory test data in relationship to a clinical problem, quality improvement request, or an error reported on a patient.
Informatic Tools	None

Resources	If your institution has an incident ticket reporting system or QI committee, these could be used to identify potential projects that a resident could participate in.
Activity Time	2 - 5 days depending on the problems and the investigation time required.
Completion Proof	Resident is required to provide a summary of analysis of lab test data regarding the problem investigated.

Practical Exercise 3: Identify New Development or Threat to Informatics	**Exercise Type: Research**
PIER Outcome Statements	OS4 (This is recommended as an optional exercise.)
Setup	Report on a new development or threat in pathology informatics.
Informatic Tools	LIS, Informatics equipment
Resources	Institution's policy and procedure manual related to pathology informatics equipment Research literature regarding new developments (eg, artificial intelligence) Research literature regarding potential threats (eg, patient safety, patient data, specimen tracking) CAP accreditation checklists
Activity Time	2 - 5 days
Completion Proof	Resident will present findings during one or more rotations to the program director.

Essentials 4 Topic 4 Worksheets (Return to E4T4)

Practical Exercise 1: Assessment of WSI Devices	**Exercise Type: Research**
PIER Outcome Statements	OS1
Setup	Have resident review the *Technical Performance and Assessment of Digital Pathology Whole Slide Imaging Devices* from the FDA.
Informatic Tools	None
Resources	1. FDA paper – *Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices*. 2. Institutions policies and procedures on whole slide imaging equipment. 3. CAP Laboratory General Checklist (GEN.52920)
Activity Time	1-2 hours
Completion Proof	The resident compares the guidelines to the institution's whole slide imaging equipment and policies and procedures to identify any discrepancies and/or suggest recommendations for institutional updates.

Practical Exercise 2: Analysis of Microscopic Images	**Exercise Type: Hands-on**
PIER Outcome Statements	OS2
Setup	Use a department provided or free online software (eg, ImageJ) to perform a simple analysis on a microscopic image (eg, perform a manual count and then have image analysis perform an automated count and compare).
Informatic Tools	ImageJ or similar software either internal to institution or external.
Resources	5-10 IHC slides of Ki67

Activity Time	2-5 hours
Completion Proof	The trainee is provided with 5-10 IHC slides of Ki67 and has to download Image J or similar program and use these images to quantitate Ki67 and provide screen shots of the analysis.

Practical Exercise 3: Using a WSI Viewer for Annotation	Exercise Type: Hands-on
PIER Outcome Statements	OS3
Setup	Demonstrates the use of a whole-slide image viewer using the department provided equipment or a free online viewer to annotate a whole slide image.
Informatic Tools	A number of freely available viewers can be used (eg, QuPath, Free Viewers)
Resources	Digital Pathology Association has a WSI repository.
	Webinar: Quantitative Pathology & BioImage Analysis
Activity Time	2-5 hours
Completion Proof	The trainee provides a summary of the key features of the WSI viewer in a written report.

Appendix B: Additional Learning Resources

Appendix B contains resources for those residents who are looking for additional content on a particular topic or want to expand their knowledge related to informatics.

Topic 1: LIS Management and Oversight

Brassel JH. Interfaces and middleware: laboratory information system (LIS) connectivity options that can improve and streamline laboratory operations. College of American Pathologists; Online course. Updated 2018.

Darcy TP. Demystifying regulatory requirements for the management of laboratory information and information systems. College of American Pathologists; Recorded webinar. Released 2017.

Henricks WH, Wilkerson ML, Castellani WJ, Whitsitt MS, Sinard JH. Pathologists as stewards of laboratory information. *Arch Pathol Lab Med.* 2015 Mar;139(3):332-337.

Judith Sligo, Vaughan Roberts, Robin Gauld, Luis Villa, Sarah Thirlwall, A checklist for healthcare organisations undergoing transformational change associated with large-scale health information systems implementation, *Health Policy and Technology*, Volume 8, Issue 3, 2019, Pages 237-247, ISSN 2211-8837

Shirley, D. *Project management for Healthcare*; 2nd edition; CRC Press, Boca Raton, FL; 2020

Sinard JH, Castellani WJ, Wilkerson ML, Henricks WH. Stand-alone laboratory information systems versus laboratory modules incorporated in the electronic health record. *Arch Pathol Lab Med*. 2015 Mar;139(3):311-318.

Splitz AR, Balis UJ, Friedman BA, Tuthill JM. Using the LIS toolkit: a methodology for assessing functionality and enabling comparisons among competing systems (white paper). Association for Pathology Informatics website. 2013.

Tan BT, Fralick J, Flores W, Schrandt C, Davis V, Bruynell T, Wilson L, Christopher J, Weber S, Shah N Implementation of Epic Beaker Clinical Pathology at Stanford University Medical Center. *Am J Clin Pathol*. 2017 Mar 1;147(3):261-272.

Unertl KM, Novak LL, Van Houten C, Brooks J, Smith AO, Webb Harris J, Avery T, Simpson C, Lorenzi NM. Organizational diagnostics: a systematic approach to identifying technology and workflow issues in clinical settings. *JAMIA* Open. 2020 Apr 20;3(2):269-280.

VanSandt M, Turner K, Dash R, Gui D, Tuluc M, Hart S, Raess PW. Pathologist Opinions about EPIC Beaker AP: a Multi-Institutional Survey of Early Adopters. *J Med Syst*. 2020 May 6;44(6):111.

Weemaes M, Martens S, Cuypers L, et al. Laboratory information system requirements to manage the COVID-19 pandemic: A report from the Belgian national reference testing center. *J Am Med Inform Assoc*. 2020;27(8):1293-1299.

Topic 2: Laboratory Data Analytics for Quality Improvement, Education, and Research

None at this time.

Topic 3: Laboratory Data for Quality Improvement and Research

None at this time.

Topic 4: Advanced Digital Imaging

Evans AJ, Bauer TW, Bui MM, Cornish TC, Duncan H, Glassy EF, Hipp J, McGee RS, Murphy D, Myers C, O'Neill DG, Parwani AV, Rampy BA, Salama ME, Pantanowitz L. [US Food and Drug Administration Approval of Whole Slide Imaging for Primary Diagnosis: A Key Milestone Is Reached and New Questions Are Raised](#). *Arch Pathol Lab Med*. 2018 Nov;142(11):1383-1387.

Ghaznavi F, Evans A, Madabhushi A, Feldman M. Digital imaging in pathology: whole-slide imaging and beyond. *Annu Rev Pathol*. 2013 Jan 24;8:331-359.

Li AC, Zhao J, Zhao C, Ma Z, Hartage R, Zhang Y, Li X, Parwani AV. Quantitative digital imaging analysis of HER2 immunohistochemistry predicts the response to anti-HER2 neoadjuvant chemotherapy in HER2-positive breast carcinoma. *Breast Cancer Res Treat*. 2020 Apr;180(2):321-329.