PIER Essentials Resource Toolkit

Release 5
2025

Access PIER releases at the Association of Pathology Chairs website.
https://www.apcprods.org/pier

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PIER RESOURCE LIBRARY

The resources listed below can be used to teach informatics topics. Some of these resources may require advance purchase or login access. We recommend that you identify and obtain the resources you plan to use prior to implementing PIER.

College of American Pathologists (CAP)

The CAP has developed online informatics activities about fundamental informatics concepts. 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.

LIS Fundamentals

Interfaces and Middleware: LIS Connectivity Options That Can Improve and Streamline Laboratory Operation

Clinical Informatics Educational Resources

American Society for Clinical Pathology (ASCP)

Lab Management University Fundamentals

Association for Pathology Informatics (API)

PIER and API

Pathology Informatics Training Resources

Parwani, AV. Surgical Pathology Clinics, Volume 8, Issue 2, xi – xii

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Topic 1: Informatics in Pathology Practice	
Learning Objectives	**Subtopics**
1.1 Describe the differences between information technology and informatics.	• Distinction between informatics and information technology (IT) • Scope of pathology IT: systems and tasks • Pathology IT, informatics, lab administration relationship
1.2 Explain the relevance of informatics to the practice of pathology and lab medicine.	• Scope of informatics knowledge and expertise necessary for daily practice of pathology • Data literacy for pathology practice (eg, how to extract, how to use, how to manage)
1.3 Describe the appropriate relationship between pathology informatics and clinical informatics within a health system.	• Practices of and interactions between clinical and pathology informatics • Difference between pathology data (eg, specimen centric) from other sub-disciplines of health informatics (eg, patient centric) • Roles that pathologists can play in EMR-based laboratory IT environment
1.4 Use correct terminology to describe the major types and components of computer hardware and software.	• Key components of computer hardware diagram and software • Networks: communications, architecture, protocols • Major types of software: system vs. application software • Architecture of software

Recommended Resources

Harrison, J. Session 0: Pathology Informatics and Data. Association for Pathology Informatics. Updated May 15, 2025. Accessed May 20, 2025. **https://www.pathologyinformatics.org/teaching-slide-sets**

Harrison, J. Session 1: Computer Hardware, Software, and Networking. Association for Pathology Informatics. Updated May 15, 2025. Accessed May 20, 2025. **https://www.pathologyinformatics.org/teaching-slide-sets**

Pantanowitz L, Tuthill JM, Balis UGJ, eds. Chapter 1: Pathology Informatics: An Introduction. In: Pantanowitz L, Tuthill JM, Balis UGJ, eds. *Pathology Informatics: Theory and Practice*. ASCP Press; 2012: 1-8.

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

Harrison, JH. Management of pathology information systems. In: *Laboratory Administration for Pathologists*, 2nd Ed. Wagar EA, Cohen MB, Karcher DS, Siegel GP, Eds. CAP Press; 2019: 93-94.

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Practical Exercises

1. **Identifying Informatics in the Laboratory**
   During rotations, have the resident keep a log of informatics-related activities and questions that occur during a defined rotation. Provide regular opportunities for residents to meet with a mentor to share these observations and experiences and allow them to ask questions about unfamiliar vocabulary, activities, or observations.

2. **Laboratory Dashboards or Practice Reports**
   Explore how your department uses informatics to monitor lab operations (eg, dashboards or reports of lab turn-around times, specimen processing and/or histology operations and discuss with faculty. Questions to consider:
    1. What is the data source of this report? How often is it updated?
    2. How is the dashboard or report used in laboratory operations?
        a. What would happen if it were broken?
        b. What is the “downtime solution”?

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Topic 2: Data Science	
Learning Objectives	**Subtopics**
2.1 Define the core aspects related to data.	• Data representation: unstructured vs. structured data • Data quality (i.e. accuracy, completeness, validity, consistency, uniqueness, timeliness and fitness for purpose) • Data flow in an organization from creation to use • Overview of data science applied to pathology
2.2 Understand fundamentals of statistical approaches to data analysis.	• Descriptive Statistics (mean, median, standard deviation) • Inferential Statistics (hypothesis testing, confidence intervals) • Common Statistical Tests Used in Pathology Research
2.3 Describe the major features of big data.	• Key Features of Big Data (5Vs of Big Data: volume, velocity, variety, veracity, value) • Sources of Big Data in Pathology (genomics, imaging, EHRs) • Integration of big data analytics in pathology practice
2.4 Define artificial intelligence and machine learning.	• Algorithm categories, supervised vs. unsupervised learning, CNN • Generative AI: definition, applications in pathology (image analysis, diagnostics) • Best practices of performance verifications • Common performance problems: bias, drift, brittleness • Framework for AI implementation in pathology • Ethical and Regulatory Considerations of AI in Healthcare

Recommended Resources

Harrison, J. Session 6: Machine Learning. Association for Pathology Informatics. Updated May 15, 2025. Accessed May 20, 2025. **https://www.pathologyinformatics.org/teaching-slide-sets**

Introduction to Data Science (Machine Learning/Artificial Intelligence)

Vos S, Hebeda K, Milota M, et al. Making Pathologists Ready for the New Artificial Intelligence Era: Changes in Required Competencies. *Mod Pathol*. 2025;38(2):100657. doi:10.1016/j.modpat.2024.100657

Introduction to Statistics and Data Structure

Milner DA, Meserve EK, Soong TR, Mata DA. *Statistics for Pathologists*. 1st ed. Demos Medical; 2016.

Generative and Non-Generative AI/ML

Rashidi HH, Pantanowitz J, Hanna MG, et al. Introduction to Artificial Intelligence and Machine Learning in Pathology and Medicine: Generative and Nongenerative Artificial Intelligence Basics. *Mod Pathol*. 2025;38(4):100688. doi:10.1016/j.modpat.2024.100688

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Applications and Implementation of AI/ML

Baxi V, Edwards R, Montalto M, Saha S. Digital pathology and artificial intelligence in translational medicine and clinical practice. *Mod Pathol*. 2022;35(1):23-32. doi:10.1038/s41379-021-00919-2

Gomes B, Ashley EA. Artificial Intelligence in Molecular Medicine. *N Engl J Med*. 2023;388(26):2456-2465. doi:10.1056/NEJMra2204787

Ethics, Bias, and Safety of AI/ML

Chauhan C, Gullapalli RR. Ethics of AI in Pathology: Current Paradigms and Emerging Issues. *Am J Pathol*. 2021;191(10):1673-1683. doi:10.1016/j.ajpath.2021.06.011

Caruana R, Lou Y, Gehrke J, Koch P, Sturm M, Elhadad N. Intelligible Models for Healthcare: Predicting Pneumonia Risk and Hospital 30-Day Readmission. Proceedings of the 21th ACM SIGKDD International Conference on Knowledge Discovery and Data Mining. August 2015:1721-1730. Supplementary Material. Accessed May 20, 2025. **https://dl.acm.org/doi/10.1145/2783258.2788613#abstract**

Plass M, Kargl M, Kiehl TR, et al. Explainability and causability in digital pathology. *J Pathol Clin Res*. 2023;9(4):251-260. doi:10.1002/cjp2.322

Regulatory Guidance of AI/ML

Pantanowitz L, Hanna M, Pantanowitz J, et al. Regulatory Aspects of Artificial Intelligence and Machine Learning. *Mod Pathol*. 2024;37(12):100609. doi:10.1016/j.modpat.2024.100609

Practical Exercises

1. **Medicare Pay for Performance, Test Requirements**
   Describe a Medicare pay for performance standard in terms of the laboratory test information it requires. Then determine:
   a. What LOINC, UCOM and/or SNOMED CT codes are used for the test?
   b. Trace the information systems through which the information flows from the laboratory to its final destination to CMS.
   c. List the main messaging standards for transmission (eg, HL7/FHIR) between each pair of systems.

2. **State Public Health Agency Test Reporting**
   What laboratory tests are required to be reported to your state public health agency? Then determine for one of the tests:
   a. What LOINC, UCOM and/or SNOMED CT codes are used for reporting the test results?
   b. Trace the information systems through which the information flows to its final destination to the public health agency.
   c. List the main messaging standards (eg, HL7/FHIR) for each transmission between systems.

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Topic 3: Data Availability and Security	
Learning Objectives	**Subtopics**
3.1 Describe the competing demands of data availability and data security within and between health systems.	• Data security concepts • Cyberattacks and malware: goals and types • Data and system security assurance: goals and tactics • Vulnerability scans and testing
3.2 List the regulatory requirements for PHI as it pertains to laboratory and patient data.	• HIPAA: privacy, security and breach notification rules • State regulation related to specific data types: substance abuse, HIV • Business associate and data use agreement • CAP checklist system security
3.3 Define high reliability as it pertains to health information systems and access to patient data.	• Best practices for health care data warehouse • Data and system backup: hardware, frequency, rotating vs. hot backups • Data recovery
3.4 Describe how your department manages protected health information (PHI) (de-identification and re-identification risk) for educational and research use.	• HIPAA safe harbor rule • Existent institutional safeguards • Definitions of public data, de-identified data and coded data

Recommended Resources

Harrison, J. Session 8: Cybersecurity. Association for Pathology Informatics. Updated May 15, 2025. Accessed May 20, 2025. **https://www.pathologyinformatics.org/teaching-slide-sets**

Health Information and Management Systems Society (HIMSS). Cybersecurity in Healthcare. Accessed May 20, 2025. **https://www.himss.org/resources/cybersecurity-healthcare**

U.S. Department of Health and Human Services. Health Information Privacy: HIPAA for Professionals. Accessed May 20, 2025. **https://www.hhs.gov/hipaa/for-professionals/index.html**

UC Davis PSNet Editorial Team. High Reliability. Agency for Healthcare Research and Quality (AHRQ): PSNet. Updated September 14, 2024. Accessed May 20, 2025. **https://psnet.ahrq.gov/primer/high-reliability**

Assistant Secretary for Technology Policy (ASTP). Guide to Privacy & Security of Electronic Health Information. Accessed May 20, 2025. **https://www.healthit.gov/topic/health-it-resources/guide-privacy-security-electronic-health-information**.

Supplemental Resources

U.S. Department of Health and Human Services. HPH Cybersecurity Performance Goals. Accessed May 20, 2025. **https://hhscyber.hhs.gov/performance-goals.html**.

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Administration for Strategic Preparedness and Response (ASPR). HHS 405(d) Aligning Health Care Industry Security Approaches. Hospital Resiliency Landscape Analysis. Accessed May 20, 2025. https://405d.hhs.gov/landscape-analysis

Practical Exercises

1. **Cybersecurity Threats and Violations**

   The resident reviews the recommended resources listed above and develops a list of potential cybersecurity threats and violations of the HIPAA Final Security Rule from the following case scenario:

   > The laboratory has requested to purchase and install a single new middleware server directly in the laboratory to help manage autoverification and quality checking of results coming in from high-throughput chemistry analyzers. The new middleware will be connected to multiple instruments as well as to the LIS, and it will house PHI associated with laboratory orders and results. Laboratory staff state that they have limited space and will need to install the server behind several chemistry analyzers near the instrument heat vents. The server's cables will need to run next to a commonly used walkway in order to reach the nearest available network jack. Laboratory staff want to be able to access the server without a password due to the high volume of work, and the vendor has requested to be able to access the server remotely for support and troubleshooting when needed.

2. **Hospital IT Downtime**

   The resident reviews the recommended resources and creates a list of steps they would need to consider in an IT downtime from the following case scenario:

   > The laboratory technologists come to you as medical director of the lab and are reporting that the phones are ringing non-stop, and the Lab Information System isn't working as it should. Shortly after, IT sends a system-wide alert of IT network outages due to network disruptions caused by local construction teams. There is no network availability within your hospital or laboratory, so orders, results and any necessary registration information do not cross between any hospital systems. Clinical staff still need lab results to be able to care for the patients in your Level I Trauma center. IT has engaged support staff but estimates at least a 12-hour downtime of the network.

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Topic 4: LIS Components and Functions	
Learning Objectives	**Subtopics**
4.1 Define the core function, role, and LIS elements - dictionaries, interfaces, audit trails, billing, and dictation systems.	• Definition and major features of the LIS • Outreach systems
4.2 Describe the role of the LIS in facilitating appropriate ordering of tests by clinicians.	• Role of the LIS in laboratory operation • AP and CP LIS similarities and differences • Specialized LIS (i.e., reasons, distinctions and uses)
4.3 List and define commonly used automated operational rules in the laboratory.	• Automated Calculations: Built-in computations (eg, eGFR, LDL cholesterol) • Autoverification: Automatic validation and release of test results • Reflex Testing Rules: Triggering additional tests based on results • Quality Control Checks: Delta checks and critical value alerts
4.4 Describe importance of barcode technology applications and tracking as the key aspects of a positive patient identification process/protocol.	• Asset tracking systems: barcodes & RFID, software, hardware, dashboards • Benefits of tracking • Routing vs. tracking • Current barcode standards
4.5 Explain the role of the LIS in monitoring the quality of lab performance and error tracking/reduction.	• Positive patient identification • Test utilization in the laboratory • Error tracking and reduction

Recommended Resources

Harrison, J. Session 2: Databases. Association for Pathology Informatics. Updated May 15, 2025. Accessed May 20, 2025. **https://www.pathologyinformatics.org/teaching-slide-sets**

Harrison, J. Session 3: LIS and Health Information Systems. Association for Pathology Informatics. Updated May 15, 2025. Accessed May 20, 2025. **https://www.pathologyinformatics.org/teaching-slide-sets**

Pantanowitz L, Tuthill JM, Balis UGJ, editors. *Pathology Informatics: Theory And Practice*. Chicago, IL: American Society for Clinical Pathology; 2012

College of American Pathologists. *Clinical Informatics Resource Guide.* Section 5: Integration and Management of Information Systems; 2018. Accessed May 20, 2025. **https://documents.cap.org/documents/2018-clinical-informatics-rg-toc-v1.2.1.0.pdf**

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Henricks WH, Sinard JH, O'Leary MF. College of American Pathologists. *Laboratory Information Systems (LIS) Fundamentals*. Accessed May 20, 2025. **https://education.cap.org/content/laboratory-information-systems-lis-fundamentals#group-tabs-node-course-default1**

Lippi G, Chiozza L, Mattiuzzi C, Plebani M. Patient and Sample Identification. Out of the Maze?. *J Med Biochem*. 2017;36(2):107-112. Published 2017 Apr 22. doi:10.1515/jomb-2017-0003

Practical Exercises

1. **LIS Specimen Processing, Tracking and Routing**
   On at least one AP and/or CP rotation, the resident should follow a specimen from receipt through to final report generation. In addition to noting each instance where a person or device (eg, lab instrument) interacts with the LIS, the resident will: record how barcodes/RFID tags are used to label and track the specimen at various steps, identify and document the digital trail (tracking log) generated by the LIS, including location data and timestamps and note any automated routing decisions taken by the LIS (eg, routing to specific test panels or triggering reflex testing) based on the barcode/RFID data and test order.

2. **Patient Identification**
   Study how your lab and institution positively identifies patients prior to obtaining a specimen, compares to other existing methods of positive patient identification, and discuss with a faculty member.

3. **Automated Operational Rules – Autoverification**
   On one of your clinical laboratory rotations, identify one test that undergoes autoverification within your LIS. Under supervision, the resident will:
   - Investigate and document the specific rule criteria for autoverification (eg, the conditions that must be met for a test result to be automatically validated and released).
   - Interview or consult with lab staff to understand how the autoverification rule was developed, implemented, and monitored.
   - Observe or simulate the autoverification process (if possible), noting any variations in the workflow when the rule is triggered.

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Topic 5: Messaging Standards, Interoperability, and Interfaces	
Learning Objectives	**Subtopics**
5.1 Understand the basics of the standards development process.	• Role of pathologist in development and adoption • Standard development organizations (SDOs) (eg, HL7, ISO, IHE, ONC)
5.2 List the key features of the communication standard, HL7.	• Features of HL7, versions, benefits and limitations
5.3 Describe the characteristics and appropriate applications of standard terminologies used to represent pathology data in the LIS and EHR.	• Definition and types of interoperability: syntactic vs. semantic • Clinical interoperability: CPT, ICD, SNOMED CT, DICOM, UCOM, and LOINC • AP interoperability: CAP cancer protocols
5.4 Describe middleware, how it relates to the LIS, and roles for middleware in laboratory operations.	• Definition and types of laboratory interface • Middleware definitions, types, and roles in the laboratory
5.5 Describe the importance of ancillary data (eg, from middleware, financial systems, business intelligence) to optimize the clinical, operational, and financial performance of the laboratory.	• Data-driven decision making (DDDM): steps, benefits, best practices and challenges

Recommended Resources

Harrison, J. Session 4: Interoperability and Interfaces. Association for Pathology Informatics. Updated May 15, 2025. Accessed May 20, 2025. **https://www.pathologyinformatics.org/teaching-slide-sets**

Centers for Disease Control and Prevention. National Center for Health Statistics ICD-10-CM. Accessed May 20, 2025. **https://icd10cmtool.cdc.gov/?fy=FY2021**

Digital Imaging and Communications in Medicine. DICOM Whole Slide Imaging (WSI). Accessed May 20, 2025. **https://dicom.nema.org/Dicom/DICOMWSI/**

Stram M, Gigliotti T, Hartman D, et al. Logical Observation Identifiers Names and Codes for Laboratorians. *Arch Pathol Lab Med*. 2020;144(2):229-239. doi:10.5858/arpa.2018-0477-RA.

Pantanowitz L, Tuthill JM, Balis UJ, eds. *Pathology Informatics: Theory & Practice*. 1st American Society Clinical Pathologists; 2012.

Bietenbeck A, Streichert T. Preparing Laboratories for Interconnected Health Care. *Diagnostics (Basel)*. 2021;11(8):1487. Published 2021 Aug 17. doi:10.3390/diagnostics11081487

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Practical Exercises

1. **Working with HL7 Messaging**

   Review the National Library of Medicine (NLM) Guidance for "**Sending Electronic Newborn Screening Results with HL7 Messaging**". After reading about HL7 messaging standards in the NLM Guidance, review the NBS_HL7_Message.txt and answer the questions below. In addition, the resident can create or test HL7 message or troubleshoot a bad message based on NBS_HL7_Message.txt along with the **Guide for Corrections**.

   NBS_HL7_Message.txt

   MSH|^~\&|NBSLab|12345|StateDOH|NBSProgram|202405301200||ORU^R01|MSGID1234|P|2.5.1
   PID|1||123456789^^^Hospital^MR||DOE^BABY^J||20240501|M|||123 Main St^^Anytown^TN^55555||555-123-4567
   NK1|1|DOE^JANE|MTH|456 Maple St^^Anytown^TN^55555|555-987-6543
   PV1|1|I|NICU^Room12^Bed3^^Hospital||||123456^Smith^John^A|||NICU|||||9876543210
   ORC|RE|ORD448811|||
   OBR|1|ORD448811||NBS^Newborn Screening^L|||20240502|||||||123456^Smith^John^A|||||||||
   OBX|1|TX|NBS001^Birth Hospital^LN||211 Small Street, Anytown, TN 55555
   OBX|2|NM|TSH^Thyroid Stimulating Hormone^L||1.5|uIU/mL|0.5-5.0|N|||F
   OBX|3|NM|GALC^Galactocerebrosidase^L||0.9|U/dL|>=0.4|N|||F

   - What is the field called where the infant's mother's name appears? (Answer: NK1 – Next of Kin 1)
   - What is the address of the birth hospital, and which segment of the message does this information appear in? (Answer: 211 Small Street, Anytown, Tennessee 55555; OBX|1|TX)

   Broken HL7_Message.txt

   MSH|^~\&|NBSLab|12345|StateDOH|NBSProgram|202405301200||ORU^R01||P|2.5.1
   PID|1||123456789^^^Hospital^MR||DOE^BABY^J||20240501|M|||
   NK1|1|DOE^JANE|MTH||555-987-6543
   PV1|1|I|NICU^Room12^Bed3^^Hospital
   ORC|RE||||
   OBR|1|||NBS^Newborn Screening^L|||20240502
   OBX|1|TX||211 Small Street, Anytown, TN 55555
   OBX|2|NM|TSH^Thyroid Stimulating Hormone^L||1.5|uIU/mL|||

2. **Browsing, Lookup and Automatic Coding**

   This exercise covers browsing, lookup, and automatic coding using standard terminologies. Have the resident:

   - Code a set of AP and/or CP pathology reports that contain a range of procedures and clinical concepts of varying complexity.
   - Compare ICD code options to match the text of the diagnosis.
   - Compare text diagnoses with the respective code descriptions.

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- Websites to use for this exercise:
    - HL7: **http://www.hl7.org/**
    - LOINC: **http://loinc.org/**
    - SNOMED CT: **http://www.ihtsdo.org/**
    - DICOM: **http://dicom.nema.org**
    - IHE Pathology: **http://wiki.ihe.net/index.php?title=Anatomic_Pathology**
    - IHE Laboratory: **http://wiki.ihe.net/index.php?title=Laboratory**

3. **Working with LOINC Codes**

   After reading about LOINC codes, have the resident identify all of the LOINC codes in their area of interest. For example, for cystic Fibrosis screening, these are the associated LOINC codes. **Raw HL7 NBS example** about cystic fibrosis. (Answer: 54078-1 **Cystic fibrosis newborn screening panel**, 46769-6 **Cystic fibrosis newborn screen interpretation**, 57707-2 **Cystic fibrosis newborn screening comment-discussion**).

   Identify which of the LOINC codes in the raw HL7 message should be used for the interpretation. (Answer: 46769-6)

   For the code identified the above question, what would the correct answer ID be for a “borderline” result? (Answer: LA4259-3)

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Topic 6: Clinical Decision Support	
Learning Objectives	**Subtopics**
6.1 Describe the role, architecture, and general guideline for an effective CDS.	• Systems of decision-making (type I vs. type II) • General guideline: the five rights and 10 commandments
6.2 List categories and common applications of CDS.	• Resource utilization vs. result value (examples) • Categories: ordering, education, diagnostics
6.3 Explain common limitations and challenges in CDS deployment.	• Alert fatigue, automation bias • Governance and implementation
6.4 Describe the methods of evaluating CDS effectiveness.	• CDS tool and utilization metrics: acceptance rate • Outcome vs. process measure, longitudinal vs. randomized study • Examples of CDS success in your organization

Recommended Resources

Harrison, J. Session 7: Clinical Decision Support. Association for Pathology Informatics. Updated May 15, 2025. Accessed May 20, 2025**.** **https://www.pathologyinformatics.org/teaching-slide-sets**

Bates DW, Kuperman GJ, Wang S, et al. Ten commandments for effective clinical decision support: making the practice of evidence-based medicine a reality. *J Am Med Inform Assoc*. 2003;10(6):523-530. doi:10.1197/jamia.M1370

Sutton RT, Pincock D, Baumgart DC, Sadowski DC, Fedorak RN, Kroeker KI. An overview of clinical decision support systems: benefits, risks, and strategies for success. *NPJ Digit Med*. 2020;3:17. Published 2020 Feb 6. doi:10.1038/s41746-020-0221-y

Hughes AEO, Jackups R. Clinical Decision Support for Laboratory Testing. *Clin Chem*. 2022;68(3):402-412. doi:10.1093/clinchem/hvab201

Waibel E, Garcia E, Kelly M, Soles R, Hilborne L. Systematic Review of Non-ASCP Choosing Wisely Recommendations Relevant to Pathology and Laboratory Medicine. *Am J Clin Pathol*. 2018;149(3):267-274. doi:10.1093/ajcp/aqx159

Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health IT. Safety Assurance Factors for EHR Resilience (SAFER) Self-Assessment: Computerized Provider Order Entry with Decision Support. Accessed May 20, 2025. **https://www.healthit.gov/sites/default/files/topiclanding/2025-01/3.%20CPOE%20Final.pdf**

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Practical Exercises

1. **CDS application in patient care.**
   Have the resident identify one clinical decision support (CDS) intervention in the current workflow. They should describe the objective of CDS and its various features, including category and application. Additionally, assess the design to determine if it encompasses all five rights of effective CDS.

2. **Evaluation of the effectiveness of CDS.**
   Have the resident analyze a real-world scenario where CDS tool could improve patient management.

3. **Integrating Clinical Decision Support (CDS) into clinical workflows.**
   Guide the resident to map their clinical workflows and identify areas where CDS tools can be integrated for improved efficiency and accuracy.

Topic 7: Digital Pathology Systems

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Learning Objectives	Subtopics
7.1 Articulate the uses of digital pathology systems in the practice of pathology.	• Basic principles of imaging management (eg, capture, storage, retrieval, viewing) • Types of digital images (eg, static, dynamic, WSI) • Types of digital pathology applications (eg, telepathology video streaming, Whole slide imaging)
7.2 Describe the impact of the format and resolution of images application in pathology.	• Image Formats in Digital Pathology: Understanding different file types and their appropriate uses (JPEG, TIFF, DICOM) • Image resolution vs. file size and storage: compression techniques (lossy vs. lossless) • Display and Viewing Requirements: Monitor specifications and calibration, Influence on image perception
7.3 Explain the potential role of image analysis for patient care and pathologist productivity.	• Primary methods: image processing, pattern recognition • Computer aided diagnosis vs. prognosis • Applications: cell counting, mitosis detection, morphometry, etc.
7.4 Explain validation and regulatory requirements of digital pathology systems.	• CAP guideline for validating anatomic pathology specimens: Recommendations and good practice statements

Recommended Resources

Harrison, J. Session 5: Digital Imaging. Association for Pathology Informatics. Updated May 15, 2025. Accessed May 20, 2025. **https://www.pathologyinformatics.org/teaching-slide-sets**

Harrison, J. Session 6: Machine Learning. Association for Pathology Informatics. Updated May 15, 2025. Accessed May 20, 2025. **https://www.pathologyinformatics.org/teaching-slide-sets**

University of Michigan. Library Research Guides. Accessed May 20, 2025. **https://guides.lib.umich.edu/c.php?g=282942&p=1885346**

Zia S, Yildiz-Aktas IZ, Zia F, Parwani AV. An update on applications of digital pathology: primary diagnosis; telepathology, education and research. *Diagn Pathol*. 2025;20(1):17. Published 2025 Feb 12. doi:10.1186/s13000-025-01610-9

Hanna MG, Ardon O, Reuter VE, et al. Integrating digital pathology into clinical practice [published correction appears in Mod Pathol. 2022 Feb;35(2):287. doi: 10.1038/s41379-021-00948-x.] [published correction appears in Mod Pathol. 2022 Feb;35(2):286. doi: 10.1038/s41379-021-00968-7.]. *Mod Pathol*. 2022;35(2):152-164. doi:10.1038/s41379-021-00929-0

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Ardon O, Klein E, Manzo A, et al. Digital pathology operations at a tertiary cancer center: Infrastructure requirements and operational cost. *J Pathol Inform*. 2023;14:100318. Published 2023 May 16. doi:10.1016/j.jpi.2023.100318
Niazi MKK, Parwani AV, Gurcan MN. Digital pathology and artificial intelligence. *Lancet Oncol*. 2019;20(5):e253-e261. doi:10.1016/S1470-2045(19)30154-8

Baxi V, Edwards R, Montalto M, Saha S. Digital pathology and artificial intelligence in translational medicine and clinical practice. *Mod Pathol*. 2022;35(1):23-32. doi:10.1038/s41379-021-00919-2

Evans AJ, Brown RW, Bui MM, et al. Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology. *Arch Pathol Lab Med*. 2022;146(4):440-450. doi:10.5858/arpa.2020-0723-CP

Practical Exercises

1. **Navigate a WSI**
   Navigate a WSI (eg, pan, zoom) and if possible, compare a WSI to glass slide in a microscope.

2. **Image editing**
   Didactic demonstration session (or a “hands-on” workshop session) using basic image editing software (eg, Preview, Photoshop Elements) to edit a digital image (eg, crop, resample, adjust colors). Take a digital gross or microscopic image and save copies of it with different levels of lossless and lossy compression, then compare the sizes of the files and perceived resolution loss.

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Topic 8: Pathologist Role in LIS and EHR Projects	
Learning Objectives	**Subtopics**
8.1 Explain the role and responsibilities of pathologists in managing test ordering and lab result display in the EHR.	• Pathologist involvement in LIS and EHR projects, including decision support and troubleshooting order and result display issues • Common data challenges in the laboratory: orders, results, etc.
8.2 Understand the process and requirements for test definitions.	• Process of building a test: request, vet information, build, test, copy, monitor • Characteristics of high-reliability system environment for test changes • Best practices for testing the build
8.3 List the key steps in the evaluation, selection, and implementation of a new LIS or module.	• LIS life cycle: requirements, selection, installation and testing, operation and maintenance, termination • System selection: RFI vs. RFP • LIS system configuration (eg, test creation and maintenance, dictionaries maintenance) • LIS testing and training
8.4 Understand the accreditation and regulatory aspects of information maintenance in the LIS.	• Laboratory IT procedure manual : General operation, LIS, other systems, interfaces, reports, quality assurance, security, disaster recovery • Change control document • CAP checklist

Recommended Resources

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Lorenzi NM, Riley RT. Managing change: an overview. *J Am Med Inform Assoc*. 2000;7(2):116-124. doi:10.1136/jamia.2000.0070116

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Neeley, W, Davis G, Davis RR. CLSI AUTO10 Autoverification of Clinical Laboratory Test Results. Clinical and Laboratory Standards Institute (CLSI). 2006;26(32). Accessed May 20, 2025. **https://clsi.org/shop/standards/auto10/#:~:text=CLSI%20AUTO10,-Autoverification%20of%20Clinical&text=This%20guideline%20provides%20a%20comprehensive,efficiency%2C%20accuracy%2C%20and%20consistency.**

Mountain PJ, Knafel AJ, Butch SH, Markin RS, O'Bryan D. CLSI AUTO13 Laboratory Instruments Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition. *Clinical and Laboratory Standards Institute (CLSI)*. 2003 23(4). Accessed May 20, 2025. **https://clsi.org/shop/standards/auto13/**

Perrotta, Peter L, Karcher, DS. Validating Laboratory Results in Electronic Health Records: A College of American Pathologists Q-Probes study. *Arch Path Lab Med*. (2016)140(9): 926-931. https://doi.org/10.5858/arpa.2015-0320-CP

Practical Exercises

1. **IHC Panels**
   Provide the resident with a list of all IHC Panels that are available in the Anatomic Pathology LIS Ordering panel. Review the panels, perhaps together with an attending pathologist. The resident should identify at least one panel for each of the following categories:
   - IHC Panel is obsolete. Recommend that this panel be removed to avoid confusion.
   - IHC Panel is not described clearly in the LIS order interface. Recommend change to the panel name or display of components
   - IHC Panel should be changed. New panel should be added, or specific component should be added or removed?

2. **New Test Build**
   The resident should review the request-and-build-process of a new test that was recently implemented in your clinical laboratory. Answer the following questions:
   - What is the new test's name, clinical relevance Are the names clear? Was it initiated by the Pathology Department or by Clinical Providers?
   - What are the result fields? What were the areas of choice where the laboratory needed to decide on result fields? (Ie. should there be a separate field for numerical value vs interpretation? Should multiple data points be concatenated or reported separately? Should a specific data point remain internal or reported to the providers? Should the categories be divided into 3 or four levels (Mild, Moderate, High, Severe)

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- Review the documentation forms necessary for implementation of this test. For each component, why was this piece of information necessary? Who provides the information, pathologist or technical team? If the pathologist, where would you get this information from?
- Review FDA documentation and package insert. Describe at least one piece of information that is needed from your laboratory from each document.
- What equipment or supplies needed to be procured for implementation?
- What validation was needed for implementation? Is this test FDA approved, and what components of the validation are affected by the FDA status?

3. **Choosing a New LIS System**

   The resident will provide detailed recommendations on 5 LIS features that are "needed" in your institution, 5 that are "desirable but not needed", and 5 that are “not relevant” and would not add value. Justify each recommendation based on your institution's internal workflow.

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