Validation of Laboratory Results Exchanged Among Multiple Hospital Enterprise Systems

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Digital Slide-based Second Opinion Consult Service

• Subspecialty expert consultation sites is one of most important clinical applications envisioned for digital pathology/WSI

• Addressing workflow elements that differ in WSI-based consultation service vs. conventional consultation practice is required

• This session examines operational and administrative considerations unique to WSI-based subspecialty consultation
Validation of Laboratory Result Exchange

- Laboratories must share laboratory results electronically with multiple systems, most notably EHRs
- How best to validate appropriate exchange and display of laboratory data across systems is a great challenge
Validation of Laboratory Result Exchange
Session Overview

• Brief framing comments
• Guided, interactive, open discussion among participants
• Aim of sharing experiences and garnering best practices related to LIS-foreign system validation
Validation of Laboratory Result Exchange – What’s the Achievable Balance?

- Feasibility
- Limits of Responsibility/Control
- Resources
- Time

- Patient care and best practice
- Stewardship of laboratory data
- Regulatory and accreditation requirements
CLIA Requirement for Results Transmission

- 42 CFR 493.1291(a) The laboratory must have adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:...(2) Results and patient-specific data electronically reported to network or interfaced systems
CMS Revised Guidance for Electronic Exchange of Laboratory Information

• Revised Guidance for CLIA laboratory surveyors:
  – Electronic exchange of laboratory information
  – Transmission of laboratory results to authorized individuals and others designated by the authorized person to receive the information
• Data retention requirements
• Management of corrected reports in EHRs
• FAQs – including clarification on HIEs and designating “agents” for receipt of laboratory tests.

• GEN.48500 There is a procedure to verify that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (whether paper or electronic).
• Reference ranges, comments, and report formats to be evaluated.
• First downstream (or interfaced) system in which the ordering clinician/client may be expected to routinely access patient data.
• Applies to individual interfaces
CAP Laboratory Accreditation Program
Requirement - Guidance

- New interface or change: at least 2 reports of below
- Every 2 years: at least 2 reports from at least 4 of below
  - Surgical pathology reports
  - Cytopathology reports
  - Clinical laboratory textual reports
  - Quantitative results
  - Qualitative or categorical results
  - Microbiology reports
  - Blood bank reports
- Corrected results
- Packages/batteries, abnormal flags, footnotes
CAP Laboratory Accreditation Program Requirement

• GEN.41067  An individual meeting CAP laboratory director qualifications reviews and approves the content and format of paper and electronic patient reports at least every two years.

• “…Further details on review of electronic reports are given in GEN.48500.”
Validating Laboratory Result Exchange Discussion Questions

• How do you approach this issue in your laboratory?
• How do you approach this in your outreach program?
• What have been the obstacles?
• Are the requirements too stringent? Not stringent enough?