

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.

<http://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter10-12.pdf>

CAP Laboratory Accreditation Program Requirement

- **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?