

Relevance of Meaningful Use Requirements for Pathologists and Laboratories

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“Meaningful Use” and the Laboratory Outline

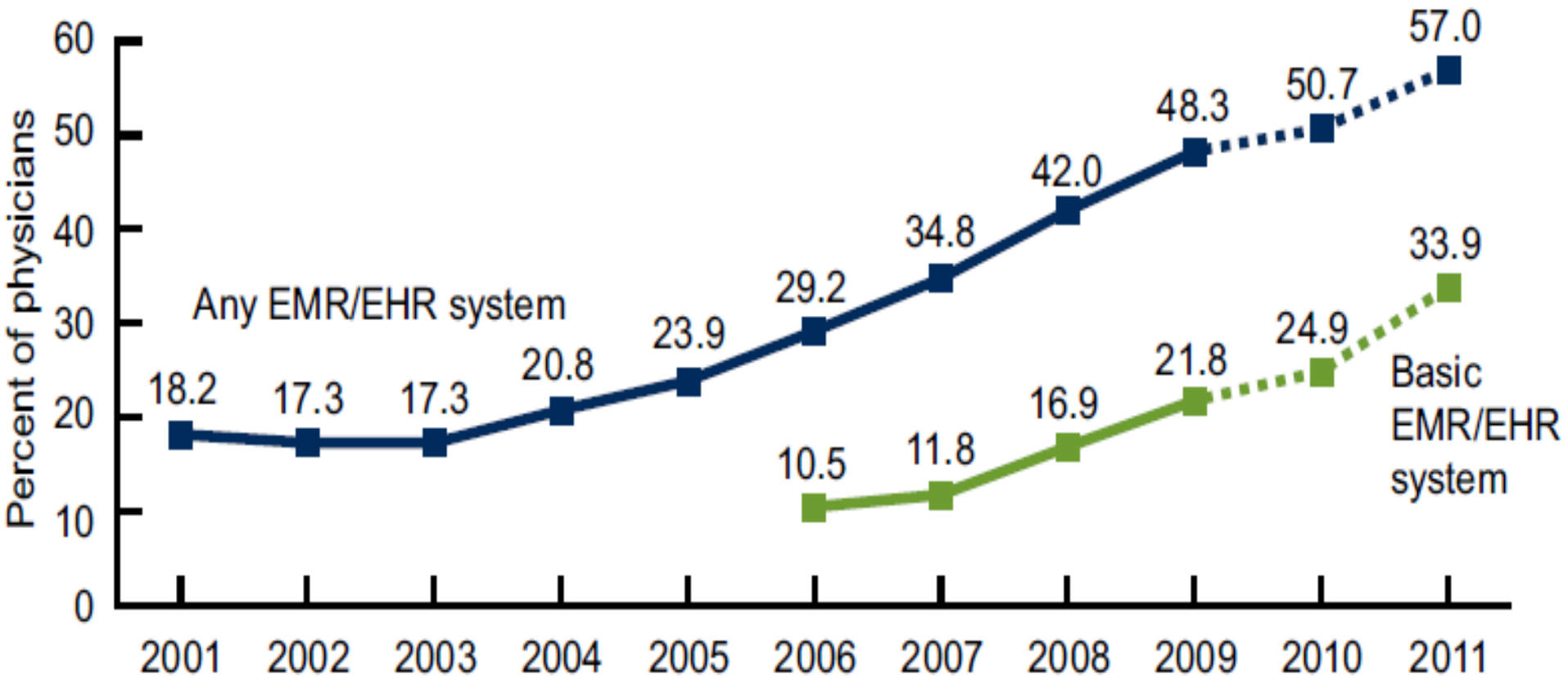
- EHRs – background and status
 - Recent federal regulations related to EHRs and their implications for laboratories and pathologists
 - Concerns and regulatory impact related to increased use of EHRs

EHR/EMR Definition

- Electronic record of health-related information on an individual
 - Patient demographic and clinical health information, such as medical history and problem lists
 - Clinical decision support
 - Computerized physician order entry (CPOE)
 - Capture and query of information relevant to health care quality
 - Capability to exchange and integrate electronic health information with other sources

per Section 3000 of Public Health Service Act (“HITECH” Act)

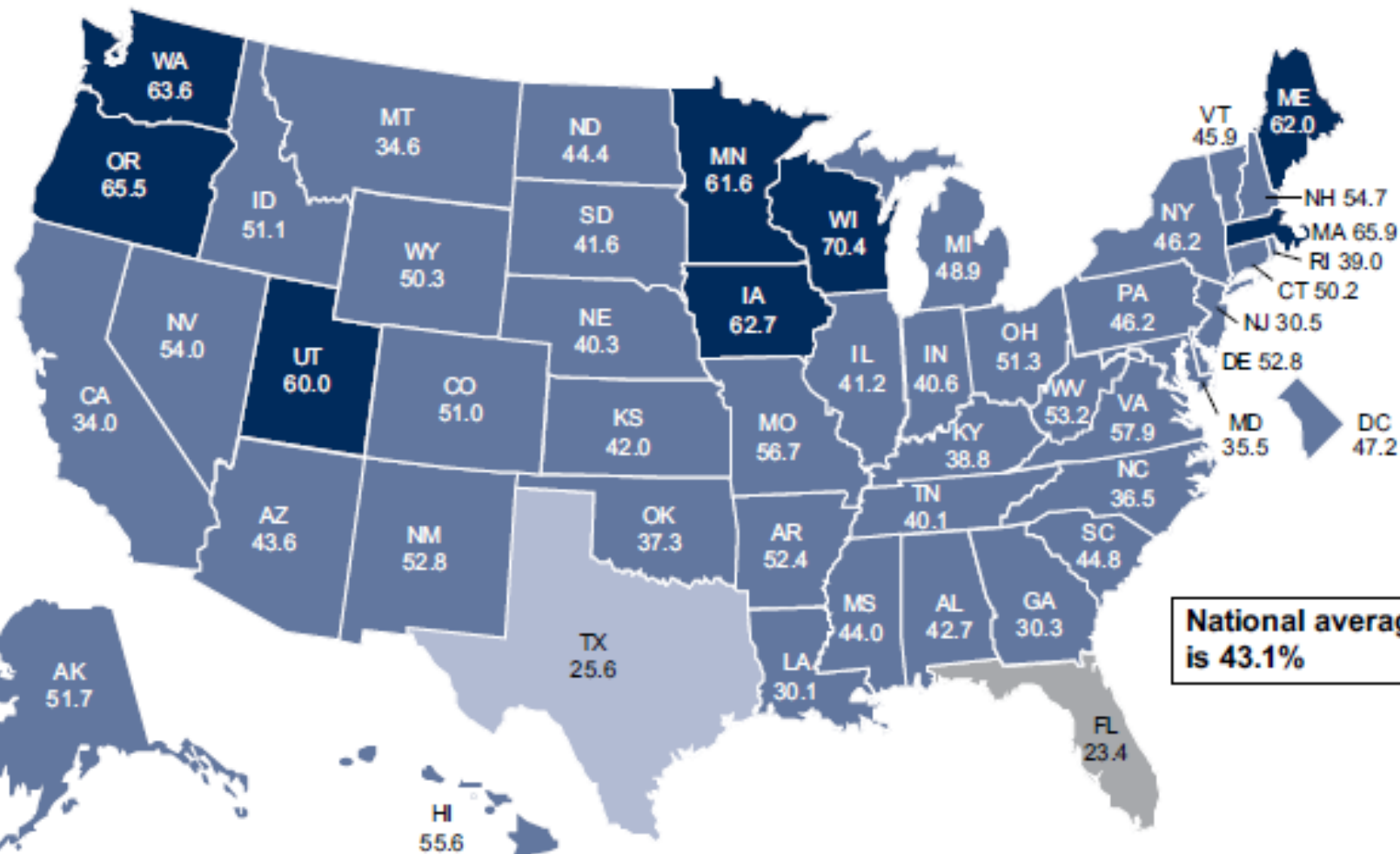
Status of EHR Use by Physician Practices



Source: CDC/NCHS National Ambulatory Medical Care Survey
www.cdc.gov/nchs/data/databriefs/db79.pdf

Percentage potentially able to meet meaningful use core criteria compared with national average:

- Significantly higher
- Not significantly different
- Significantly lower
- Percentage does not meet standards of reliability or precision



National average is 43.1%

NOTE: EHR is electronic health record.
 SOURCE: CDC/NCHS, National Ambulatory Medical Care Survey.

Status of Electronic Health Record (EHR) Implementation

Figure 18



Hospitals and institutions, n=326

22nd Annual HIMSS Leadership Survey, sponsored by Citrix

“Meaningful Use” and the Laboratory Outline

- EHRs – background and status
- Recent federal regulations related to EHRs and their implications for laboratories and pathologists
- Concerns and regulatory impact related to increased use of EHRs

What is Meaningful Use?

Meaningful Use is using certified EHR technology to:

- Improve quality, safety, efficiency, and reduce health disparities
- Engage patients and families in their health care
- Improve care coordination
- Improve population and public health
- All the while maintaining privacy and security

www.cms.gov/EHRIncentivePrograms/Downloads/MU_Stage1_ReqOverview.pdf

ARRA
(American Recovery and Reinvestment Act)

↓ includes

HITECH
(Health Information Technology for Economic and Clinical Health Act)

implemented in

CMS Rule

ONC Rule

↔ alignment

- Defines meaningful use criteria
- Establishes incentive payments for meeting meaningful use criteria (and penalties for not meeting)

- Establishes certification criteria that EHR technology will need to meet in order to support meaningful use

(ONC = Office of the National Coordinator for Health Information Technology in HHS)

CMS and ONC Final Rules in Federal Register July 28, 2010

**42 CFR Parts 412, 413, 422 et al.
Medicare and Medicaid Programs;
Electronic Health Record Incentive
Program; Final Rule**

**45 CFR Part 170
Health Information Technology: Initial Set
of Standards, Implementation
Specifications, and Certification Criteria
for Electronic Health Record Technology;
Final Rule**



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Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 495

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—**Stage 2**; Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, **2014 Edition**; Revisions to the Permanent Certification Program for Health Information Technology; Final Rules

EHR Meaningful Use vs. EHR Certification

- EHR certification criteria specify **WHAT** an EHR must be able to do.
- Meaningful use objectives specify **HOW** an EHR must be used to qualify for incentive and to avoid penalties.
- Meaningful use can be achieved only by using certified EHR technology (CEHRT).

CMS Definitions of EHR Users

- *Eligible Professional (EP):*
 - Physicians, optometrists, dentists, podiatrists, chiropractors (Medicare)
 - (+ CNPs, Nurse/midwives, PAs for Medicaid)
- *Hospital-based EP:*
 - EP who furnishes 90% or more of covered professional services in a hospital setting
- *Meaningful EHR user:*
 - EP (or) eligible hospital that demonstrates meaningful use of certified EHR technology
- *Qualifying EP (Medicare):*
 - EP who is a meaningful EHR user and not a hospital-based EP

CMS EHR Incentive Program

- Eligible Professionals (EPs) – Individuals
 - Up to \$44K over 5 yrs (Medicare)
 - \$63K over 6 yrs (Medicaid)
 - Hospital-based providers not eligible (as individuals)
- Hospitals
 - \$2M base payment
 - Further payments based on formula including discharges and inpatient bed-days

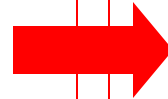
EHR Meaningful Use Stages

- Stage 1 – 2011 – Data capture and sharing
 - Stage 2 – 2014 – Advanced clinical processes
 - Stage 3 – Improved outcomes
-
- Proposed stage 2 requirements released in February 2012; Final Rule issued in early September 2012.
 - Requirement to meet stage 2 has been pushed back to 2014 for EPs that participated in stage 1

CMS EHR Incentive Program Requirements

Eligible Professionals (EPs)

- Stage 1
 - 15 core objectives
 - 5 of 10 menu set objectives
 - Report 6 CQMs



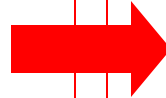
- Stage 2
 - 17 core objectives
 - 3 of 6 menu set objectives
 - CQM reporting now part of MU definition
 - CQM requirements will evolve

CQMs = Clinical
Quality Measures

CMS EHR Incentive Program Requirements

Hospitals

- Stage 1
 - 14 core objectives
 - 5 of 10 menu set objectives
 - Report 15 CQMs



- Stage 2
 - 16 core objectives
 - 3 of 6 menu set objectives
 - CQM reporting now part of MU definition
 - CQM requirements will evolve

Eligible Professionals (EPs): 17 MU Core Objectives (Stage 2)

- ***Computerized provider order entry (CPOE) incl. lab (30%), radiology (30%), medications (60%)***
- E-Prescribing (eRx)
- Record demographics
- Provide clinical summaries for patients for each office visit
- Record and chart changes in vital signs
- Record smoking status for patients 13 years or older
- Implement 5 clinical decision support rules and drug interaction checks
- ***Incorporate clinical lab test results as structured data (>55%)***
- Generate lists of patients by specific conditions

Eligible Professionals (EPs): 17 MU Core Objectives (Stage 2) (cont'd.)

- Send patient reminders for preventive care/follow up
- Provide patients the ability to view online, download, and transmit their health information (within 4 days)
- Use certified EHR technology to identify patient-specific education resources and provide to patient, if appropriate
- Use secure electronic messaging to communicate with patients
- Medication reconciliation
- Summary of care record for each transition of care
- Submit electronic data to immunization registries
- Conduct security analysis and include in risk management

Eligible Professionals (EPs): 6 MU Menu Objectives (choose 3; Stage 2)

- Imaging results and information are available in EHR (>10%)
- Record family health history as structured data
- Provide electronic syndromic surveillance data to public health agencies
- ***Identify and report cancer cases to State cancer registry***
- Identify and report specific cases to a specialized registry
- Enter electronic progress notes

Hospitals: 16 MU Core Objectives (Stage 2)

- ***Computerized provider order entry (CPOE) incl. lab (30%), radiology (30%), medications (60%)***
- Record demographics
- Record and chart changes in vital signs
- Record smoking status for patients 13 years or older
- Implement 5 clinical decision support rules and drug interaction checks
- ***Incorporate clinical lab results as structured data (>55%)***
- Generate lists of patients by specific conditions
- Track medications from order to administration through eMAR
- Medication reconciliation

Hospitals: 16 MU Core Objectives (Stage 2) (cont'd.)

- Provide patients the ability to view online, download, and transmit their health information
- Use certified EHR technology to identify patient-specific education resources and provide to patient, if appropriate
- Summary of care record for each transition of care
- Submit electronic data to immunization registries
- ***Provide electronic submission of reportable lab results to public health agencies***
- Provide electronic syndromic surveillance data to public health agencies
- Conduct security analysis and include in risk management

Hospitals: 6 MU Menu Objectives (choose 3; Stage 2)

- ***Provide structured clinical lab results to EPs (>20%)***
- Record advanced directives for patients 65 years or older
- Imaging results and information are available in EHR
- Record family health history as structured data
- Generate and transmit discharge prescriptions electronically (eRx)
- Enter electronic progress notes

Themes in MU Stage 2

- Patient engagement
 - >5% of patients must send secure messages to EP
 - >5% of patients must access their health information online
- Electronic communication
 - Summary of care document for transitions of care or referrals

EP CQMs Related to Laboratory Testing (Stage 1)

- Diabetes: hemoglobin A1c poor control
- Diabetes: low-density lipoprotein (LDL) management and control
- Colorectal cancer screening
- Appropriate testing for children with pharyngitis
- Oncology breast cancer: hormonal therapy for Stage IC–IIIC estrogen receptor/progesterone receptor (ER/PR) positive breast cancer
- Diabetes: urine screening
- Prenatal care: screening for human immunodeficiency virus
- Prenatal care: anti-D immune globulin
- Cervical cancer screening
- Chlamydia screening for women
- Ischemic vascular disease (IVD): complete lipid panel and LDL control
- Diabetes: hemoglobin A1c control (<8.0%)

Pay Now, or Pay Later

- In 2015, **penalties** kick in for those who are not “Meaningful Users”
- EPs: Reductions in Medicare physician fee schedule professional payments
 - 1% in 2015, 2% in 2016, 3% in 2017 and after
- Hospitals: Reductions (%) to the standard IPPS percentage increases
 - 25% in 2015, 50% in 2016, 75% in 2017 and after

IPPS = Inpatient Prospective Payment System

Are Pathologists Eligible Providers for MU?

- Hospital-based EPs are generally not eligible for MU incentives and not subject to future penalties...**BUT...**
- Current definition of “hospital-based” is >90% of submitted claims as “inpatient” (POS 21) or “emergency room, hospital” (POS 23)
- By definition, many pathologists could be considered EPs and subject to future penalties (if nothing changes), *despite fact that EHR use is not applicable to practice of pathology*

Short Term Relief for Pathologists in Stage 2 MU

- CMS to grant hardship exemptions for pathologists based on demonstrating criteria:
 - Lack of face-to-face or telemedicine interaction with patients
 - Lack of need to follow up regularly with patients

From the CMS Final Rule:

“We also encourage all anesthesiologists, radiologists, and pathologists to continue to build out their ability to participate in health information exchange, adopt CEHRT [Certified Electronic Health Records] and apply for the Medicare or Medicaid EHR incentives.”

Possible Legislative Solution

- H.R. 4066, “The Health Information Technology Reform Act” (Rep. Tom Price M.D., Georgia)
 - Removal of pathologists from eligibility for MU incentives or payment adjustments
 - Penalty relief permanent
 - Role of CAP Advocacy

My hospital wants to attest to MU on my behalf. Should I let them?


- Per CMS:

“Attestation is a *legal statement* that you have met the thresholds and all of the requirements of the Medicare EHR Incentive Program.”


- Per CAP MU FAQs:

“You should not attest or allow anyone else to do so for you, including your hospital unless you have met the program requirements, the majority of which are outside the scope of usual pathology practice. Therefore, attesting to MU can create some legal risk and it may be advisable to seek the advice of counsel.”

MU Objective Directly Relevant to Laboratory Data in EHRs


- Stage 1 (menu): More than 40% of clinical laboratory tests ordered whose results are in a positive/negative or numerical format are incorporated in EHR as structured data
- 
- Stage 2 (core): Requirement increases to more than 55% of such results
- *Realistically possible only with an interface from laboratory*

MU Objective Directly Relevant to Laboratory Data in EHRs

- Stage 1: No CPOE requirement for lab orders
- 
- Stage 2 (core): Use CPOE for more than 30% of laboratory orders
- Electronic transmission of orders not required but strongly encouraged

CPOE: (Computerized Provider Order Entry)

MU Objective Directly Relevant to Laboratory Data in EHRs

- Stage 1 (hospital menu): Capability to submit electronic submission of reportable lab results to public health agencies
- 
- Stage 2 (hospital core): Successful ongoing submission of such results
 - Per ONC certification criteria, this is to be accomplished using HL7 v2.5.1

New Stage 2 MU Menu Set Requirement for Hospitals

- Eligible hospitals send (directly or indirectly) structured electronic laboratory results to ambulatory ordering providers for more than 20% of electronic laboratory orders received
- Was not included in the Stage 2 Proposed Rule released earlier in 2012
- Included as a menu option, rather than a core requirement

New Stage 2 MU Menu Set Requirement for EPs

- Capability to identify and report cancer cases to a State cancer registry, with successful ongoing submission of cancer case information from Certified EHR Technology

**“Meaningful Use” of EHRs can be achieved
only through the use of *Certified* EHR
Technology (CEHRT)**

ONC Standards and Certification Criteria

- **2011 Edition**

- Published July 2010
- Supports Stage 1 MU



- **2014 Edition**

- Published Sept. 2012
- Supports Stage 2 MU
- Required to support MU beginning 2014
- No such thing as “Stage 2 certified”

EHR Certification – Complete vs. Module

- Complete EHR system – meets all certification criteria
- EHR Module – meets at least one certification criterion
- EHR Modules can be used in aggregate to meet MU objectives
- LISs may be certified as EHR Module



Certified Health IT Product List

The Office of the National Coordinator for Health Information Technology

HealthIT.HHS.Gov

- ONC maintains on-line list of certified EHR products.
- Certified products (as of October 6, 2012):
 - 2692 ambulatory EHR products
 - 887 inpatient EHR products
- <http://oncchpl.force.com/ehrcert/CHPLHome>

ONC Certification Criteria Related to Laboratories

- Incorporate lab results as structured data
- Include test report elements required in CLIA:
 - Patient identification
 - Name and address of performing laboratory
 - Report date
 - Test performed
 - Specimen source, when appropriate
 - Test result and, if applicable, the units of measurement or interpretation, or both.
 - Information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability

ONC Certification Criteria and Standards Issues Related to Lab – 2014 Edition

- Incorporate (ambulatory EHR) or transmit (inpatient EHR) lab results using HL7 version 2.5.1 and S&I* Framework Lab Results Interface Implementation Guide as proposed July 2012
- LOINC version 2.40 or higher (where used)
- Certification to March 2012 release (or later) of SNOMED-CT

*S&I: ONC Standards and Interoperability

ONC S&I* Framework Lab Results Interface (LRI) Initiative

- Aims to standardize various aspects of lab result reporting to ambulatory providers
- Defines results reporting from LIS to ambulatory EHRs
- Incorporates HL7 v2.5.1, LOINC, SNOMED-CT

*S&I: ONC Standards and Interoperability

ONC S&I* Framework Lab Results Interface (LRI) Initiative (cont'd.)

- Will publish LRI Implementation Guide
- Has established pilots underway with labs and vendors – feedback
- Laboratory Orders Interface (LOI) initiative recently started

*S&I: ONC Standards and Interoperability

ONC Interoperability Standards – Issues for Laboratories

- LIS interfaces may require conversion from HL7 v2.3.1 to v2.5.1.
- Laboratories may not have LOINC codes defined in or linked to LIS or in interfaces.
- LISs may not fully accommodate LOINC codes.

ONC Interoperability Standards – Issues for Laboratories (cont'd.)

- LOINC mapping can be complex and not easily implemented.
- LOINC codes must match across systems.
- Expertise and resources for assigning correct LOINC codes may be lacking.

ONC Health Information Exchange (HIE) Program

- HIE: State-level, federally funded organization and technology set up to enable sharing of health information across provider settings
- Providers and hospitals elect to participate and would have access to data from other participants
- Lab results are a focus of early HIE efforts
- Larger organizations may have to pay fees
- Sustainability of business model is in question

ONC Regional Extension Centers (RECs)

- ONC-funded organizations to assist providers and hospitals in their EHR adoption efforts (e.g. EHR selection and contracting)
- Community-based approach to facilitate health IT interoperability, standards, and information exchange
- Possible opportunity for laboratories to work with practices and EHR vendors

Summary of Transition to Stage 2 Meaningful Use

- Many menu objectives to become core requirements
- CPOE for laboratory test orders
- LOINC (version 2.40) (where used)
- HL7 v2.5.1
- More decision support
- More exchange of health data
- Reporting of hospital lab tests to outpatient providers (menu objective)
- Reporting of cancer (EP menu objective)

“Meaningful Use” and the Laboratory Outline

- EHRs – background and status
- Recent federal regulations related to EHRs and their implications for laboratories and pathologists
- Concerns and regulatory impact related to increased use of EHRs

Most Important Implication of “Meaningful Use” for Laboratories and Pathologists

- ***Dramatic increase in expectation for LIS-EHR electronic interfaces as physicians implement EHRs***
 - As a result of wider use of EHRs generally
 - To meet Meaningful Use 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*

Concerns for Laboratories Regarding EHR Interfaces

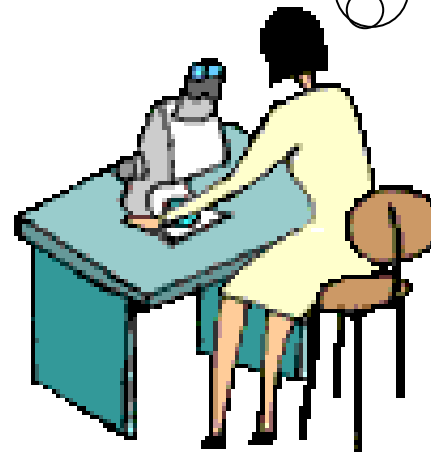
- Laboratory responsibility for transmission and validation of laboratory results to EHR
- Limitations of EHRs in laboratory test order and result handling
- Lack of control or involvement in the EHR management at physicians' sites

Concerns for Laboratories Regarding EHR Interfaces (cont'd.)

- Poor process design resulting in laboratory testing problems being blamed inappropriately on the lab
- Expenses of interface implementation and maintenance

I don't understand
this lab report in my
EHR. The lab
screwed it up. I need
to call the lab.

Our results are
reported in EHR, and
we have no control
over it; the doc's have
to talk to IT if they
have a problem



Lab Results Delivery and Notification in the EHR

- EHRs typically have a notification function that lets physicians know when new results are available (no arrival of printed report to prompt)

Key questions for laboratory tests in EHR test notification function:

- Are there any types of results that do not fall under the function?
- Can the function be configured differently in the inpatient vs. outpatient setting?
- Do notifications go to all physicians listed on a test order (as “copy to”) or just to the ordering physician?
- Do corrected reports and addenda trigger notifications?

“I Wish I Had Seen This Test Result Earlier!”

Dissatisfaction With Test Result Management Systems in Primary Care

Eric G. Poon, MD, MPH; Tejal K. Gandhi, MD, MPH; Thomas D. Sequist, MD; Harvey J. Murff, MD, MPH; Andrew S. Karson, MD, MPH; David W. Bates, MD, MSc

Ann Intern Med 2004;164:2223-8

Unintended errors with EHR-based result management: a case series

Thomas R Yackel,¹ Peter J Embi²

J Am Med Inform Assoc. 2010;17:104-7

- Two year experience with commercial EHR in setting of 54,000 lab test results per month
- New categories of result management errors:
 - Interface and results routing errors
 - Provider record issues – MD dictionary definitions
 - EHR system settings – user configuration, unsolicited orders
 - System maintenance-related errors
- Common thread – results not routed or available to provider who was expecting them
- Some involved settings in the LIS

Challenges with Computerized Provider Order Entry (CPOE)

- CPOE will meet goals for laboratory test ordering only if it:
 - can accommodate nuances of laboratory test ordering
 - is *configured* correctly for laboratory test ordering – menus, order sets, etc.
- CPOE systems must be configured to provide CLIA-mandated items in test order
- ***The computer screen is now the requisition***

CLIA-Required Information for Test Requests

- Identifying information of requesting person or lab
- Patient's name or unique patient identifier.
- Sex and age or date of birth of the patient.
- Test(s) to be performed.
- Source of the specimen, when appropriate.
- Date and, if appropriate, time of specimen collection.
- For Pap tests, the patient's last menstrual period, and indication of previous abnormal report, treatment, or biopsy.
- Any additional information relevant and necessary for accurate and timely testing and reporting of results, including interpretation, if applicable.

Implications of Improperly Designed or Implemented EHR CPOE for Laboratory

- Incorrect test orders
- Incomplete test orders
- Inappropriate test orders
- Inefficiencies in laboratories and providers owing to need for problem resolution
- Billing and compliance problems
- Pitfalls – future orders, duplicate handling, canceled orders

Computerized provider order entry in the clinical laboratory

Jason M. Baron, Anand S. Dighe

J Pathol Inform 2011;2:35.

When requests become orders—A formative investigation into the impact of a computerized physician order entry system on a pathology laboratory service

Int J Med Inform. 2007;76:583-91

Andrew Georgiou^{a,*}, Johanna Westbrook^a, Jeffrey Braithwaite^b, Rick Iedema^b, Sangeeta Ray^a, Rowena Forsyth^b, Anthony Dimos^c, Tony Germanos^c

- “[CPOE] was accompanied by some organizational dysfunctions including ...”
 - “Frustrated” orders without specimens
 - Add-on test problems
 - Discrepancies in recorded time of specimen collection.
- “Hospital and pathology staff adopted...efforts to increase clinical awareness to compensatory laboratory workarounds and enforced rule changes.”

“Meaningful Use” and the Laboratory Summary

- “Meaningful Use” and related federal programs aim to spur uptake of EHRs by physicians and hospitals.
- Expansion of EHR use and future stages of Meaningful Use will increase requirements for electronic exchange of laboratory information.
- With EHR use increasing, laboratories will be called upon to implement more LIS-EHR interfaces.

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