Relevance of Meaningful Use Requirements for Pathologists and Laboratories

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"Meaningful Use" and the Laboratory Outline

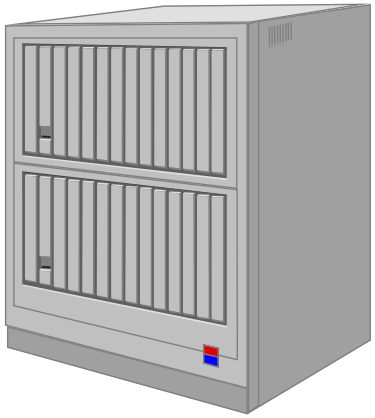
- EHRs – background and status
- Recent federal regulations related to EHRs and their implications for laboratories and pathologists
- Concerns and regulatory impact related to increased use of EHRs

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)

EHR is the Physician's Connection to the Laboratory



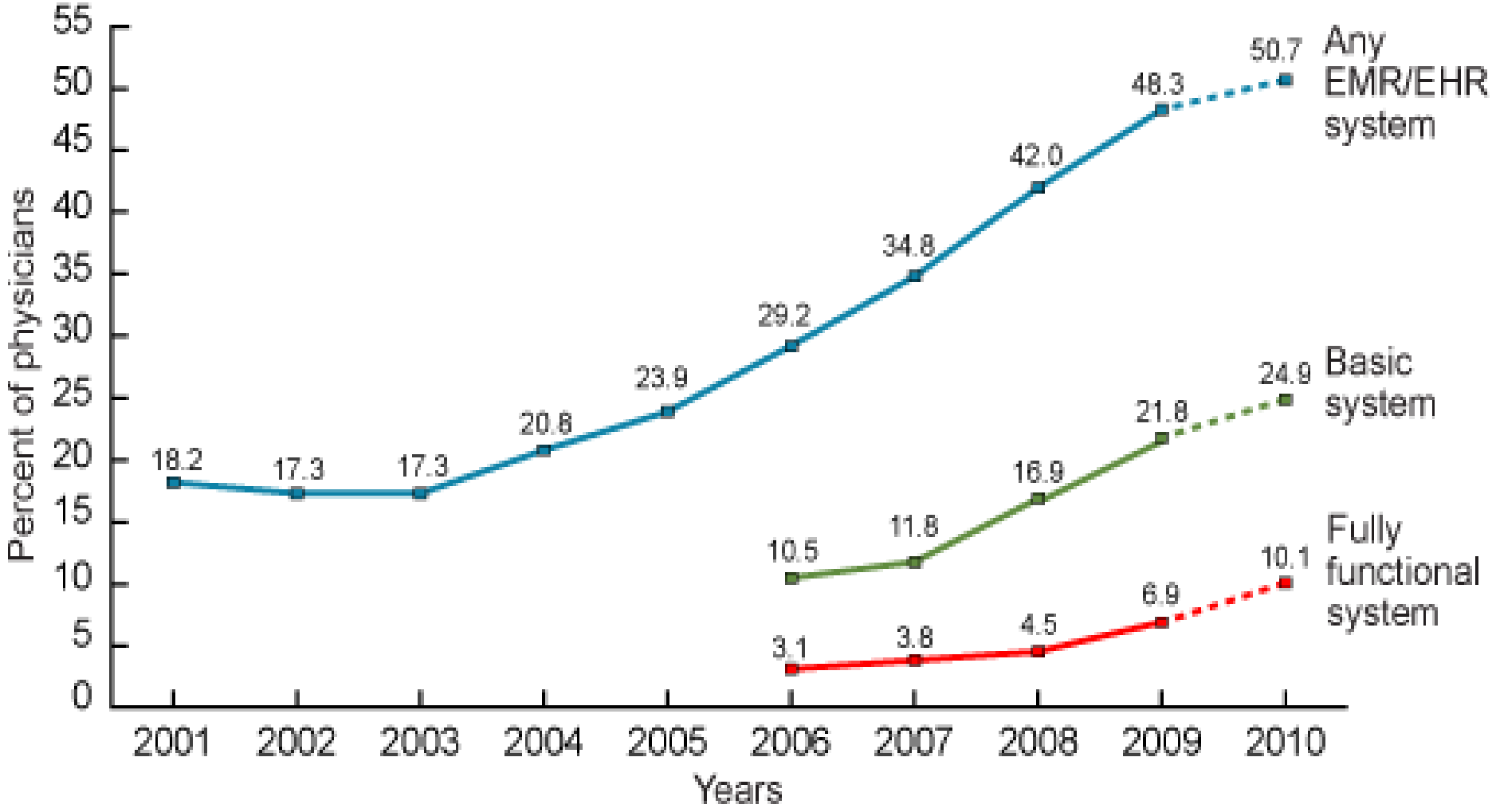
Other departmental systems

Laboratory information system (LIS)

Radiology information system

Pharmacy information system

Status of EMR Use by Physician Practices



Source: CDC/NCHS National Ambulatory Medical Care Survey
www.cdc.gov/nchs/data/hestat/emr_ehr_09/emr_ehr_09.htm

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

Recent Governmental Actions Aim to Spur Use of Electronic Health Records (EHRs)

- Goals related to healthcare information technology:
  - Improve health care quality, safety, and efficiency through the promotion of health information technology (HIT) and the electronic exchange of health information
  - Promote the adoption and meaningful use of interoperable health information technology and qualified EHRs.

What is Meaningful Use?

Meaningful Use is using certified EHR technology to:

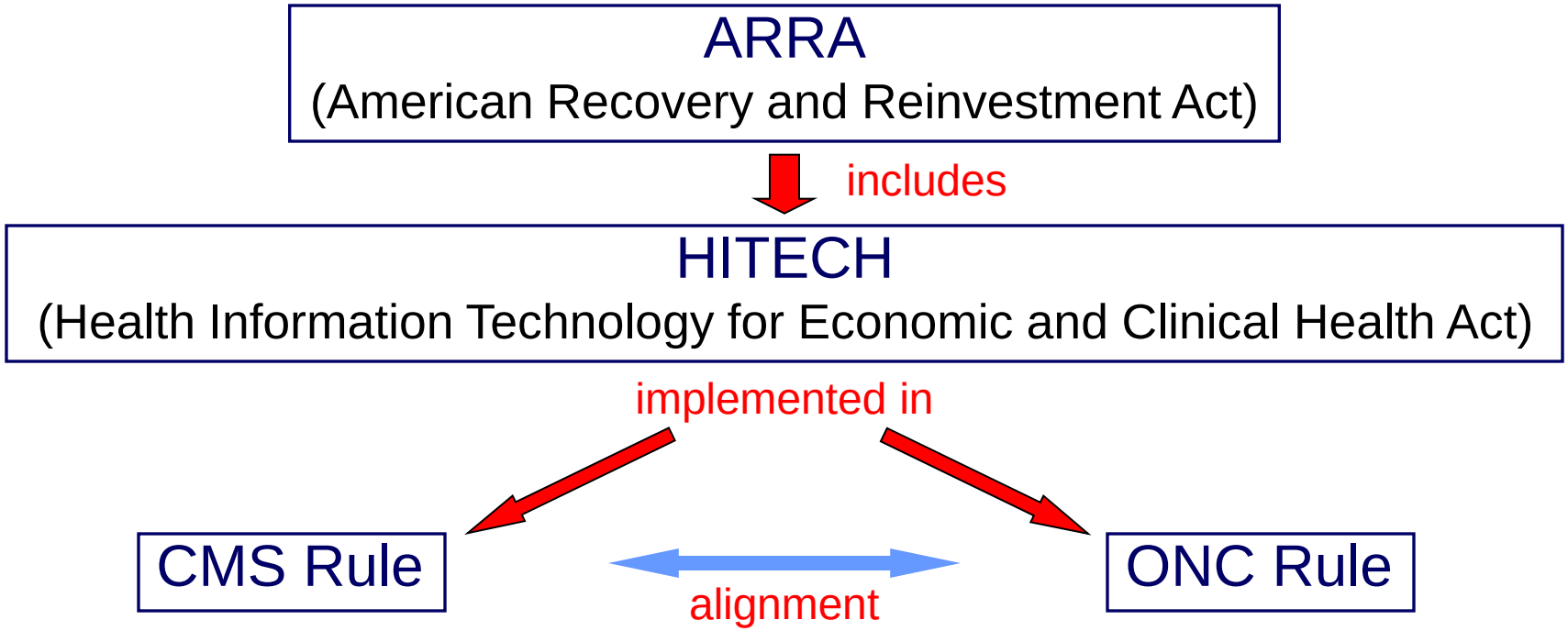
- Improve quality, safety, efficiency, and reduce health disparities
- Engage patients and families in their health care
- Improve care coordination
- Improve population and public health
- All the while maintaining privacy and security

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

Agencies Relevant to EHR Meaningful Use

- Department of Health and Human Services – rule making
  - Centers for Medicare and Medicaid Services (CMS)
  - Office of the National Coordinator for Health Information Technology (ONC)
- State Medicaid agencies
- NQF – source of clinical quality measures (CQMs)
- NIST – EHR testing and certification process
- ANSI – accreditation of EHR certification bodies
- CDC – interoperability of reportable results

NIST = National Institute of Standards and Technology; ANSI = American National Standards Institute; NQF = National Quality Forum



- 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

EHR Meaningful Use vs. EHR Certification

- EHR certification criteria specify WHAT an EHR must be able to do.
- Meaningful use criteria specify HOW an EHR must be used to qualify for incentive and to avoid penalties.
- Meeting criteria for meaningful use must be accomplished using certified EHR technology in order to qualify.

CMS Definitions of EHR Users

- *Eligible Professional (EP):*
  - Physicians, optometrists, dentists, podiatrists, chiropractors (Medicare)
  - (+ CNPs, Nurse/midwifes, 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

CMS EHR Incentive Program Requirements

- Eligible Professionals (EPs)
  - 80% of patient records in EHR
  - 15 core objectives
  - 5 objectives of menu set of 10
  - Reporting requirements for 6 Clinical Quality Measures (CQMs)
- Hospitals
  - 14 core objectives
  - 5 objectives of menu set of 10
  - Reporting requirements for 15 CQMs

Eligible Professionals – 15 Core Objectives for MU

- Computerized provider order entry (CPOE)
- E-Prescribing (eRx)
- Report ambulatory clinical quality measures to CMS/States
- Implement one clinical decision support rule
- Provide patients with an electronic copy of their health information, upon request
- Provide clinical summaries for patients for each office visit
- Drug-drug and drug-allergy interaction checks
- Record demographics

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

Eligible Professionals –15 Core Objectives for MU (cont'd)

- Maintain an up-to-date problem list of current and active diagnoses
- Maintain active medication list
- Maintain active medication allergy list
- Record and chart changes in vital signs
- Record smoking status for patients 13 years or older
- Capability to exchange key clinical information among providers of care and patient-authorized entities electronically
- Protect electronic health information

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

Hospitals – 14 Core Objectives for MU

- Computerized provider order entry (CPOE)
- Drug-drug and drug-allergy interaction checks
- Record demographics
- Implement one clinical decision support rule
- Maintain up-to-date problem list of current and active diagnoses
- Maintain active medication list
- Maintain active medication allergy list
- Record and chart changes in vital signs

Hospitals – 14 Core Objectives for MU (cont'd)

- Record smoking status for patients 13 years or older
- Report hospital clinical quality measures to CMS or States
- Provide patients with an electronic copy of their health information, upon request
- Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request
- Capability to exchange key clinical information among providers of care and patient-authorized entities electronically
- Protect electronic health information

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

Eligible Professionals – 10 Menu Objectives (choose 5)

- Drug-formulary checks
- Incorporate clinical lab test results as structured data
- Generate lists of patients by specific conditions
- Send reminders to patients per patient preference for preventive/follow up care
- Provide patients with timely electronic access to their health information

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

Eligible Professionals – 10 Menu Objectives (choose 5) (cont'd.)

- Use certified EHR technology to identify patient-specific education resources and provide to patient, if appropriate
- Medication reconciliation
- Summary of care record for each transition of care/referrals
- Capability to submit electronic data to immunization registries/systems*
- Capability to provide electronic syndromic surveillance data to public health agencies*

* At least 1 public health objective must be selected.

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

Hospitals – 10 Menu Objectives for MU (choose 5)

- Drug-formulary checks
- Record advanced directives for patients 65 years or older
- Incorporate clinical lab test results as structured data
- Generate lists of patients by specific conditions
- Use certified EHR technology to identify patient-specific education resources and provide to patient, if appropriate

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

Hospitals – 10 Menu Objectives for MU (choose 5) (cont'd.)

- Medication reconciliation
- Summary of care record for each transition of care/referrals
- Capability to submit electronic data to immunization registries/systems*
- Capability to provide electronic submission of reportable lab results to public health agencies*
- Capability to provide electronic syndromic surveillance data to public health agencies*

* At least 1 public health objective must be selected.

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EHR Meaningful Use Timeline

- Stage 1 – 2011 – Data capture and sharing
- Stage 2 – 2013 – Advanced clinical processes
- Stage 3 – 2015 – Improved outcomes

- Requirements for stage 2 to be posted for comment late 2011/early 2012
- Requirement to meet stage 2 has been pushed back to 2014 for EPs that participated in stage 1

Incentives Now, Penalties Later

- In 2015, providers who are not meaningful users of certified EHR technology will receive less than 100 percent of the fee schedule for their professional services (= penalty!)
  - 2015: 1% reduction in Medicare physician fee schedule payments
  - 2016: 2% reduction
  - 2017 and thereafter: 3% reduction

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 entirely not applicable to practice of pathology*

Implications of "Meaningful Use" for Laboratories and Pathologists

- MU requirements directly applicable to laboratory data in EHR
- ONC certification requirements applicable to handling of laboratory data in EHR systems
- Role in helping hospitals meet MU requirements
- Opportunities to facilitate clients' ability to meet MU requirements

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
  - To meet specific Meaningful Use requirements

Meaningful Use Stage 1 Criteria Relevant to Laboratory Data in EHRs

- At least 40% of clinical laboratory tests ordered whose results are in a positive/negative or numerical format are incorporated in EHR as structured data

  – *Realistically possible only with an interface from laboratory*

  – Not applicable to AP results (stage 1); uncertain for stage 2

Meaningful Use Stage 1 Criteria Relevant to Laboratory Data in EHRs

- Dropped from stage 1: CPOE (Computerized Provider Order Entry) requirements for laboratory test orders

- CPOE for laboratory orders will be a stage 2 MU requirement

Meaningful Use Stage 1 Requirements Relevant to Physician Practices

- Providers must report on Clinical Quality Measures (CQMs), some of which include laboratory tests

- Example: % patients aged 18-75 with Hemoglobin A1c > 9.0%

EP CQMs Related to Laboratory Testing

- 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 (HIV)
- 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%)

Meaningful Use Stage 1 Criteria Relevant to Laboratory Data in EHRs

- For hospitals: Capability to provide electronic submission of reportable lab results to public health agencies

- Per the ONC certification criteria, this is to be accomplished using HL7 v2.5.1

"Meaningful Use" of EHRs can be accomplished only through the use of *Certified EHR Technology*

How Do EHRs Get "Certified"?

- ONC Certification Program
- NIST develops test methods correlating to ONC requirements
- 6 ONC-Authorized Testing and Certification Bodies (ATCBs)
- Transition to "permanent" certification program in January 2012
- ATCBs will need to be accredited as ACBs (Authorized Certification Bodies)
- ANSI selected as ONC-approved accrediting body for ACB's

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 1, 2011):
  - 809 ambulatory EHR products
  - 426 inpatient EHR products
- http://onc-chpl.force.com/ehrcert

ONC Interoperability Standards Most Relevant to Laboratories

- HL7 (Health Level Seven)
  - structure and syntax for electronic data exchange ("interfaces") in healthcare
  - A "transmission" standard
- LOINC (Logical Observation Identifier Names and Codes)
  - coding system to identify laboratory tests in electronic systems and in HL7 messages
  - A "vocabulary" standard

ONC Rule Interoperability Standards – Issues for Laboratories

- Submit reportable lab results to public health agencies using HL7 version 2.5.1(for inpatient EHRs).
- Re-use a LOINC code when received from the laboratory and such code is accessible in the EHR.
- Broader requirements for LOINC and HL7 expected in future stages.
- *Many existing laboratory interfaces are on older HL7 version 2.3.1 and will require conversion to v2.5.1.*
- *Many laboratories do not have LOINC codes defined in or linked to LIS or in interfaces.*

ONC-Sponsored Programs to Foster EHR Adoption

- Regional Extension Centers (RECs)
  - To assist providers and hospitals in their EHR adoption efforts (e.g. assistance in EHR selection and contracting)
  - Possible opportunity for laboratories to work with practices and EHR vendors
- HIEs (Health Information Exchanges)
  - Groups of organizations aimed at improving healthcare delivery in a region, typically a state
  - Focus on technology, interoperability, standards
  - May be relevant to laboratories that wish to/need to participate

Anticipated Requirements in Future Stages of Meaningful Use

- All menu objectives to become core requirements
- Broader range of laboratory tests covered, including AP
- CPOE for laboratory test orders
- LOINC
- HL7 v2.5.1
- Reporting of hospital lab tests to outpatient providers
- Reporting of cancer conditions
- More decision support related to laboratory tests
- Exchange of healthcare data with unaffiliated entities
- Greater expectations for electronic data exchange

"Meaningful Use" and the Laboratory Outline

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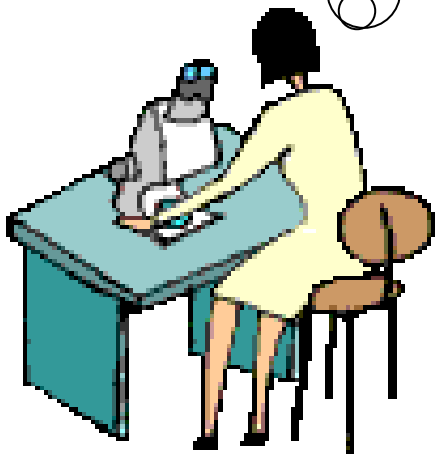
I don’t understand this lab report in my EHR. The lab screwed it up. I need to call the lab.

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



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Concerns for Laboratories Regarding EHR Interfaces

- Laboratory responsibility for transmission and validation of laboratory results to EHR; compliance with federal and state laws
- Limitations in EHRs in laboratory test order and result handling
- Lack of control or involvement in the EHR management at physicians' sites
- Poor process design resulting in laboratory testing problems being blamed inappropriately on the laboratory
- Expenses of interface implementation and maintenance

PAP FLUID CERVICAL SCREENING [48918220] 8/11/2005 Reviewed

CYTOLOGY REPORT: Specimen #: SPECIMEN SUBMITTEDA: CERVICAL,SCREENING,FLUID**********FINAL DIAGNOSISA. CERVICAL,SCREENING,FLUIDSATISFACTORY FOR INTERPRETATION.NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY.INFLAMMATION.This specimen has been analyzed by the an automated imaging and review system, which assists the laboratoryin evaluating cells on ThinPrep Pap tests. Following automated imaging,selected fields from every slide are reviewed by a cytotechnologist ***Electronic Signature**********CLINICAL DATADate of Last Menstrual Period:7/5/05Menstrual History:PREGNANT: 5.6 WEEKS.

- Example of unpublicized “nonstandard” view of Pap smear result in EHR – garbled text
- Not widely used; was not known to lab at time of interface validation

Operational Considerations in LIS-EHR Interfaces

- Maintenance of EHR settings related to laboratory tests
- Change control and communication (e.g. test definition updates)
- Troubleshooting and client support
- Training of EHR users in test result viewing and (eventually) test ordering
- Handling of corrected results
- Monitoring or quality of service
- Client site contact and engagement

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

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*

Implications for laboratories of poor CPOE process design:

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

"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.
- Management of laboratory orders and results exchange with EHRs presents challenges and opportunities for pathologists and laboratories.

"Meaningful Use" and the Laboratory Summary

- The time is now to assess the impact of Meaningful Use (MU) regulations on our laboratories, practices, and institutions.

- Pathologists and laboratories need to be proactive in dealing with issues of laboratory information management in the EHR – be persistent!

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