

The Laboratory's Role in the Development and Use of Electronic Health Records (EHRs) & Electronic Laboratory Reporting (ELR) of Public Health Information for Notifiable Diseases and Meaningful Use

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CLIAC Meeting

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The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Office of Surveillance, Epidemiology, and Laboratory Services

Laboratory Science, Policy and Practice Program Office



Outline

- ❑ **Background**
- ❑ **Purpose for CLIAC Discussion**
- ❑ **Introduction of Speakers**
- ❑ **Questions for CLIAC Consideration**

Background

- ❑ **The Health Information Technology for Economic and Clinical Health (HITECH) Act**
 - Enacted as part of American Recovery and Reinvestment Act of 2009 (ARRA)
 - Promotes widespread adoption and standardization of health information technology (HIT)
 - Unprecedented investment in HIT
 - Lightning speed advancement of regulations

Background (2)

- ❑ **The Office of the National Coordinator for Health Information Technology (ONC–HIT or ONC)**
 - Health and Human Services (HHS), Office of the Director
 - Federal Advisory Committees
 - HIT Policy Committee (HITPC)
 - HIT Standards Committee (HITSC)

Background (3)

□ **CLIAAC February 2010**

- Addressed perceived CLIA regulatory impediments related to test ordering, result reporting, and sharing of test information identified in HIT Policy Meeting of October 2009
 - Authorized person
 - Verification of test reports
 - Interoperability

Background (4)

□ Authorized person

- Recognized issues related to CLIA and HIPAA
- March 1, 2010 CLIA issued Survey and Certification Letter (CMS S&C-10-12-CLIA)

Background (5)

□ **Verification of Test Reports**

- Recognized current interpretation of CLIA perceived as requiring manual inspection of transmitted data
- March 1, 2010 CLIA issued Survey and Certification Letter (CMS S&C-10-12-CLIA)

Background (6)

□ Interoperability

- Recognized issues
 - Laboratory interfaces lack standardization
 - Vocabulary not standardized
 - Laboratory Information Systems (LIS) use different versions of HL7 and LOINC
- January 7, 2011 ONC created the Standards & Interoperability (S&I) Framework
 - Laboratory Results Interface (LRI) workgroup addressing ambulatory issues

Purpose for CLIAC Discussion

- ❑ Update CLIAC on HIT activities since February 2010 meeting**
- ❑ Identify issues currently facing laboratories as EHR and ELR implementation moves forward**
- ❑ Provide opportunity for CLIAC to advise HHS on laboratory-related EHR and ELR issues**
- ❑ Identify ways for HHS to better communicate information and engage the laboratory community**

Introduction of Speakers

□ Ms. Jodi Daniels

- Director, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology (ONC)
- Health Information Technology Policy

□ Mr. Jitin Asnaani

- Coordinator, Standards & Interoperability Framework, Office of the National Coordinator for Health Information Technology (ONC)
- Standards & Interoperability (S&I) Framework and Laboratory Results Interface (LRI)

□ Dr. David Booker

- Chair, Pathology Department, Trinity Hospital of Augusta, Georgia
- Electronic Health Records (EHR) impact on clinical laboratory

□ Dr. Seth Foldy

- Director, Public Health Informatics & Technology Program Office (PHITPO), Centers for Disease Control and Prevention (CDC)
- Public Health and Electronic Laboratory Reporting (ELR)

Questions for CLIAC Consideration

ELECTRONIC HEALTH RECORD (EHR)

Questions for CLIAC Consideration Electronic Health Record (EHR)

- 1. The CLIA interpretive guidelines for test ordering and result reporting were revised to facilitate the electronic exchange of laboratory information.¹*

Are there remaining gaps pertaining to CLIA that need to be addressed to support implementation of electronic health records (EHRs)?

¹ March 1, 2010 Survey and Certification Letter (CMS S&C-10-12-CLIA)

Questions for CLIAC Consideration Electronic Health Record (EHR)

- 2. The HHS certification criteria for EHRs at 42CFR170.302(h)(2) includes requirements for display of test report information as specified by CLIA at 42CFR493.1291(c)(1) through (7).*

Are these test report elements adequate for the correct interpretation and use of patient test results by a healthcare provider using an EHR? Is additional information needed for this purpose?

Requirements and examples on next slide

Questions for CLIAC Consideration

Electronic Health Record (EHR)

Requirements specified by CLIA at 42CFR493.1291(c)(1) through (7) include:

- *Patient name and ID number or a unique patient identifier and ID number*
- *Name and address of the lab location where the test was performed*
- *Test report date*
- *Test performed*
- *Specimen source, when appropriate*
- *Test result and, as 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*

Examples of other test report elements may include:

- *Elements required as part of the test request (specimen collection date and time, gender, age or D.O.B)*
- *Purpose of the test – e.g. screening, confirmatory, diagnostic*
- *Method of testing and limitations*
- *Reference ranges*
- *Critical result flags*
- *Unique considerations for interpretive reports*
- *Others?*

Questions for CLIAC Consideration Electronic Health Record (EHR)

3. *What enablers and barriers exist for the use of HHS-certified record systems in healthcare to display laboratory test results?*

Examples may include:

- *Cost*
- *Incentives*
- *Regulations*
- *Interoperability with healthcare information system interfaces*

Questions for CLIAC Consideration Electronic Health Record (EHR)

4. *In what areas can the laboratory community provide input with respect to the implementation of EHRs and ONC activities?*

Examples may include:

- *Harmonization of CLIA with HHS EHR regulations*
- *EHR functionalities that meet the HHS EHR certification criteria*
- *Oversight of EHR certification*
- *Quality measures for the effectiveness of laboratory test report displays*
- *Personal Health Records (PHR)*
- *FDA's draft guidance for mobile medical applications*
- *Others?*

Questions for CLIAC Consideration Electronic Health Record (EHR)

- 5. What mechanisms could be used by HHS to communicate information and provide opportunity for the laboratory community to contribute on issues related to the implementation of EHRs?*

Questions for CLIAC Consideration

ELECTRONIC LABORATORY REPORTING (ELR)

Questions for CLIAC Consideration Electronic Laboratory Reporting (ELR)

- 6. How can laboratories support hospitals and eligible providers in meeting the public health objectives in Stage 1 of meaningful use, namely the capability to submit electronic data to public health in the context of reportable laboratory results?*

Questions for CLIAC Consideration Electronic Laboratory Reporting (ELR)

- 7. Do the laboratory report elements provided by a certified EHR provide the data needed for electronic laboratory reporting of notifiable diseases to public health agencies? If not, what is missing?*

Questions for CLIAC Consideration Electronic Laboratory Reporting (ELR)

- 8. What issues related to public health electronic laboratory reporting are NOT addressed as part of HITECH Meaningful Use regulations that may need to be addressed in other ways?*

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