Communication and Electronic Health Records

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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
Outline

- Background
- Activities of CDC Informatics Team
- Institute of Medicine Report
- Error Reporting
- Questions for CLIAC Consideration
Background

- **CLIAC September 2011**
  - Lab test report elements: The absence of some test report information in the EHR may result in patient safety issues
  - EHR implementation: Communication issues are important and barriers may exist to safe and effective use of laboratory information
  - Committee Recommendation: "Implement a work group to outline the scope of issues related to communication of laboratory testing information and propose approaches to address these issues for discussion by CLIAC.”
CDC Informatics Team
Division of Laboratory Science & Standards

Project Lead
- Ms. Megan Sawchuk

Team
- Ms. Nancy Anderson
- Dr. Nancy Cornish
- Ms. MariBeth Gagnon
- Dr. Devery Howerton
- Dr. Ira Lubin
- Ms. Anne Pollock
- Ms. Elizabeth Weirich
- Dr. Barbara Zehnbauer
First step: Categorized CLIAC member comments and identified the following primary focus areas:

- Engagement of the laboratory profession
- Interoperability
  - Degree to which information can be successfully exchanged via an interface
- Usability & Contextuality
  - Degree to which information is conveyed as intended
  - Degree to which information can be interpreted in relation to other factors, e.g. clinical information, demographics, environment
CDC Informatics Team
Division of Laboratory Science & Standards

- Second step: Created “bubble chart” of major workgroups
  - Electronic Health Record (EHR)
  - Electronic Laboratory Reporting (ELR)

- CDC Informatics Team members monitor national activities and participate on a number of workgroups
Red ovals signify areas where additional lab representation may be needed.

Yellow stars indicate CDC Informatics Team staff participate.

* Workgroup for Electronic Data Interchange (WEDI) Open to public

Yellow stars indicate CDC Informatics Team staff participate.
ELR
Office of Infectious Diseases (OID)
CSTE/ELR Task Force
5 internal workgroups
Vendors and Large Laboratory Workgroup
ELR Standards Workgroup
Reportable Condition Mapping Tables (RCMT)

Office of Surveillance, Epidemiology, and Laboratory Services (OSELS)
Laboratory Science Policy and Practice Program Office (LSPPPO)
Laboratory Interoperability Cooperative (LIC)
Connect hospitals with public health
Public Health Laboratory Interoperability Project (PHLIP)
"Uber CoP" - Collaboration of APHL, OID, PHITPO and LSPPPO
ETOR = PHLIP + LIMSi, harmonize vocabulary for CDC/public health ordering & receiving

Clinical Decision Support CoP
Lab Messaging / Vocabulary and Messaging LabCoP (Facilitated by APHL/PHLIP)

Centers for Disease Control and Prevention (CDC)

Yellow stars: CDC Informatics Team staff participate.
Blue stars: Collaborate with liaisons for other projects as needed.
Red ovals signify areas where additional lab representation may be needed.
CDC Informatics Team Activities

- **ELR: Laboratory Community of Practice**
  - Standardizing SNOMED terminology for public health reporting
  - Develop standing committee to review SNOMED and LOINC changes

- **EHR: Standards & Interoperability Framework**
  - Laboratory Results Interface Initiative (Ambulatory)
    - Vocabulary
    - Implementation Guide Analysis
    - Validation Suite
    - Pilots

- **EHR: NIST Usability Guidance**
  - Reviewed and provided comments (NISTIR 7804)
Next step: Communication in Informatics Project

Logic Model

Engagement
- Forum to Engage and Coordinate Laboratory Efforts
- Laboratorians Participate Early In EHR/HIT Planning
- Regulations and Guidelines Incorporate Lab Input

Interoperability
- Support Harmonization (SNOMED & LOINC)
- Harmonized Interfaces
- Meaningful Comparisons of Lab Information

Usability & Contextuality
- Explore Innovative Information Display
- Results Interpreted Correctly
- Adverse outcomes reduced
VISION:

LABORATORY INFORMATION CONTRIBUTES TO OPTIMIZED HEALTHCARE DECISION MAKING.
Communication in Informatics
Team Project Proposal

- **Engagement**
  - Establish committee of laboratory professionals and experts
  - Implement communication plan
  - Facilitate national EHR/ELR workgroup participation

- **Interoperability**
  - Continue participation in CDC workgroups
  - Publish white paper on challenges and opportunities
  - Facilitate implementation of solutions

- **Usability & Contextuality**
  - Facilitate collaboration and exploration of innovative means to integrate laboratory information in the EHR
  - Integrate other CDC initiatives in collaborative efforts, including CLIHC™, LMBP, and Molecular Genetics Results Interpretation
Emerging Regulatory Landscape
Team Continuing to Monitor

- Office of the National Coordinator (ONC)
  - EHR Standards and Certification

- Centers for Medicare and Medicaid Services (CMS)
  - Meaningful Use
  - Patients’ Access to Test Reports
  - Accountable Care Measures

- Office of Civil Rights (OCR)
  - Privacy and Security
  - Patients’ Access to Test Reports

- Food and Drug Administration (FDA)
  - Mobile Medical Apps Guidance

- National Institute of Standards and Technology (NIST)
  - Usability Guidance
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<th>Agency</th>
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<th>Citation</th>
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EMAIL THE CDC’S INFORMATICS TEAM IF YOU KNOW OF EHR OR ELR ACTIVITIES NOT IDENTIFIED IN THIS PRESENTATION AND WHICH MAY HAVE NATIONAL IMPACT.

LABHIT@CDC.GOV
“Medicine used to be simple, ineffective, and relatively safe. Now it is complex, effective, and potentially dangerous.”

-Sir Cyril Chantler of the Kings Fund
Institute of Medicine Report

Health IT and Patient Safety: Building Safer Systems for Better Care

- Released November 8, 2011
- Recognizes unique intersection in time of rapidly evolving technology and healthcare reform
- Acknowledges there is limited data on the safe use of Health IT
- Offers a vision for better integration of safety science into a Health IT
- Identifies threats and opportunities in Health IT
  - Threats to patient safety include poor user-interface design, poor workflow, and complex data interfaces
  - Features that contribute to safe use include interoperability and usability

Institute of Medicine Report

- Health IT and Patient Safety: Building Safer Systems for Better Care
  - Makes 10 recommendations supporting concepts of:
    - Increased research and oversight by HHS, ONC, AHRQ
    - Free exchange of information and public reporting
    - New HealthIT safety council
    - Adverse event reporting and independent federal agency for investigations

- Recommendation 9a
  - "...If progress toward safety and reliability is not sufficient as determined by the Secretary, the Secretary should direct the FDA to exercise all available authority to regulate EHRs, health information exchanges, and PHRs.”

Reporting EHR Laboratory Information Issues

- **FDA’s MedWatch:**
  - EHRs and other HealthIT computer systems are medical devices
  - Adverse Event Report Forms (Mandatory and Voluntary):
  - Online Reporting (Voluntary Only):
    [https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm](https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm)
  - Mandatory reporting: Death and serious injury within 10 work days
Reporting EHR Laboratory Information Issues

- **EHRevent.org:**
  - [https://www.ehrevent.org/](https://www.ehrevent.org/)
  - Supported by iHealth Alliance, over 100 state and specialty medical societies and FDA liaisons
  - Entirely voluntary
    - Incident: An EHR event that reached a patient, whether or not the patient was harmed.
    - Near Miss: An EHR event that is not believed to have impacted a patient.
    - Non-Patient Issue: An incident or near miss that impacted staff, employee(s), visitor(s).
    - Unsafe Condition: A circumstance that increases the probability of an EHR event.
“Perfection is not attainable, but if we chase perfection we can reach excellence.”

-Vince Lombardi
Questions for CLIAC Consideration

COMMUNICATION AND ELECTRONIC HEALTH RECORDS
Questions for CLIAC Consideration  
Communication and Electronic Health Records

1. Does CLIAC have comments or guidance on the proposed Communication in Informatics project?

2. Are there other EHR or ELR workgroups or activities that should be included on the "bubble chart"?

3. Are there other databases in which healthcare professionals are reporting issues with laboratory information in the electronic health record?
References

- **ONC**
  - Clinical Decision Support

- **NIST - EHR Usability Framework**

- **FDA Mobile Medical Apps**
  - [http://www.fda.gov/medicaldevices/productsandmedicalprocedures/ucm255978.htm](http://www.fda.gov/medicaldevices/productsandmedicalprocedures/ucm255978.htm)

- **Council of State and Territorial Epidemiologists (CSTE) & CDC ELR Task Force**

- **CDC Communities of Practice (CoPs)**
  - [http://www.cdc.gov/phcommunities/](http://www.cdc.gov/phcommunities/)

- **Workgroup for Electronic Data Interchange (WEDI)**
  - [http://www.wedi.org/](http://www.wedi.org/)
For more information please contact Centers for Disease Control and Prevention

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