The Office of the National Coordinator for Health Information Technology

Laboratory Reporting Tiger Team Presentation to CLIAC

August 22, 2013

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Workgroup Charge

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Background

- Historically, the variability in interface standards, clinical vocabulary, and Electronic Health Record (EHR) system technology coupled with the lack of EHR standardization, testing and certification required verification of test result presentation (e.g. "visual verification") for each laboratory reporting interface between a laboratory and each implementation of an EHR. This is currently he only practical method for laboratories to ensure patient safety and laboratory best practice. However, this practice, as implemented, presents a significant barrier in terms of cost, implementation time and ongoing maintenance when establishing electronic interfaces between clinical laboratories and EHRs.

Discovery Phase (completed)

- Review the current status of interface standards, clinical vocabulary, testing methodologies and certification processes with regard to EHRs and ambulatory laboratory testing at a level of detail that will allow the development of a proposed timeframe and scope of effort for the Action Phase

Action Phase (completing report)

- Provide specific actionable steps regarding standards, testing, certification and policy that, when implemented, will minimize the time, cost and operational impact of establishing new laboratory to EHR interfaces in the ambulatory care environment while maintaining or improving the quality of the presentation of laboratory results to the Authorized Person.

CLIA Guidance (S&C-10-12-CLIA)

Issued March 1, 2010 – FAQ section – Number 6

If all interfaces or electronic communication software used between a laboratory and an EHR system are identical, is verification of accuracy of test result transmission required at all sites which use this interface? If a laboratory has multiple sites interfaced to an EHR/HIE that utilize different interface software, do they all need to be checked?

- CLIA does not prescribe the means by which a laboratory would test the accuracy and timeliness of their test report transmissions. Laboratories utilize varying test methods/devices for this testing, including manual and automated methodologies/devices.

- Each laboratory, its test systems, and processes are unique; therefore, laboratories must devise their own methods to check for the accurate and timely transmission of test results. This may include identifying means of checking the accuracy and timeliness of intermediate systems through which test results travel to reach the authorized person or their designated agent.

- Further, **extensive laboratory oversight experience has demonstrated that devices do not always work properly in the field. This necessitates the testing of every interface to ensure that that interface is operating as it should**. The protocol, method, and frequency for verifying the accuracy of an electronic test result transmission through an interface to an EHR/HIE to the authorized person are determined by the laboratory. Again, we would not anticipate the need for visual inspection of each interface/terminal within an EHR installation.

Current Verification Process (typical)

For each provider's EHR

1. Laboratory and provider's EHR vendor agree on standard transaction requirements
2. Establish physical connectivity and lower level transport
3. Verify basic exchange of test information
4. Laboratory sends test messages with a range of tests and result types
5. Provider generates a screen print for each "test report" and send the screen prints to the laboratory
6. Laboratory verifies accuracy, completeness, usability of test information (including any translations) as well as the availability of all CLIA required information
7. Gaps are identified and reported to the provider/EHR vendor for correction
8. Steps 4-7 are repeated until all "test messages" are displayed in an acceptable manner

Conclusion:

Expensive and time consuming process that tests a limited subset of all test reports for an individual EHR, typically, at one point in time.

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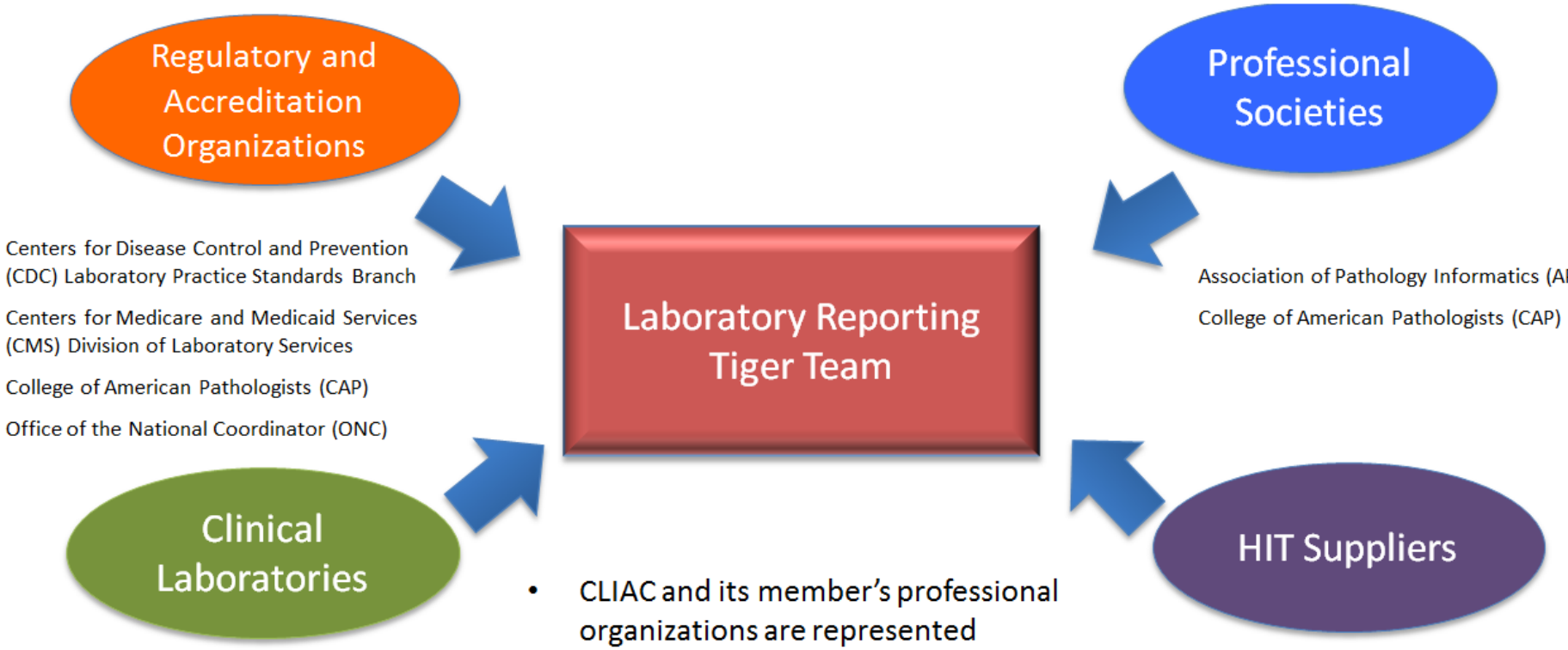

Centers for Disease Control and Prevention (CDC) Laboratory Practice Standards Branch

Centers for Medicare and Medicaid Services (CMS) Division of Laboratory Services

College of American Pathologists (CAP)

Office of the National Coordinator (ONC)

Association of Pathology Informatics (API)

College of American Pathologists (CAP)

- CLIAC and its member's professional organizations are represented multiple times (CLIA CDC CAP API)
- At least 6 Pathologists are in regular attendance

Cleveland Clinic
Emory University School of Medicine
Henry Ford Health System
LabCorp
Nebraska Methodist Hospital
Quest Diagnostics
Weill Cornell Medical College / New York Presbyterian Hospital

Cerner Corporation

Epic

Meditech

Sunquest

Participants

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ONC
- Robert Dieterle (Lead)
- John Feikema

CMS/DLS
- Daniel Cajigas
- Karen Dyer (Co-Lead)

CAP
- Dr. Victor Brodsky
  Weill Cornell Medical College / New York Presbyterian Hospital
- Julie Cantor-Weinberg
- Helena Duncan
- Gregory Gleason
- Dr. Walter Henricks
  Cleveland Clinic
- Mary Kennedy

CDC/LPSB
- Dr. Nancy Cornish
- MariBeth Gagnon
- Anne Pollock
- Megan Sawchuk

API
- Dr. Alexis Carter
  Emory University
- Dr. J. Mark Tuthill
  Henry Ford Health System

LabCorp
- David Burgess
- Don Chase
- Cindy Johns

Nebraska Methodist Hospital
- Dr. Thomas Williams

Quest Diagnostics
- Gregory Lovell
- Ken McCaslin
- Virginia Sturmfels

Cerner Corporation
- Dorthi Blair
- Gaby Jewell
- Dr. John David Nolen

Epic
- Craig Newman

Meditech
- Ellen Hawrylciw
- Joe Wall

Sunquest Information Systems
- Laurecia Dailey-Evans
- Megan Schmidt

Workgroup Goals

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Overall

Reduce the time and cost to implement and verify (e.g. visual verification) laboratory result reporting interfaces, in the ambulatory environment, while maintaining the accuracy, completeness and usability of laboratory test result information viewed by the authorized person for safe and effective interpretation.

Execution Phase

Provide recommendations regarding the following subject areas to achieve the overall goal

- Standards
  - Use of and changes to Implementation Guides for Laboratory Reporting Interface (LRI), Laboratory Orders Interface (LOI) and electronic Directory of Services (eDOS)
  - Use of standard clinical vocabulary for laboratory testing
- Testing and Certification
  - NIST validation suite use cases and data sets
  - NIST usability framework
  - EHR certification requirements
- Policy
  - Guidance from CMS regarding CLIA
  - FDA guidance regarding laboratory testing and transfusion software
  - Accreditation Agencies' relevant policies
  - CMS's Conditions of Participation in regard to authentication of interpretive reports
  - ONC requirements for EHR certification and CMS requirements for meaningful use

Subject Category and Leads

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Policy

- Co-leads: **Karen Dyer** and **Julie Cantor-Weinberg**
- Participants: **Dr. Victor Brodsky, Daniel Cajigas, Helena Duncan, MariBeth Gagnon**
- Guidance from CMS regarding CLIA
- FDA guidance regarding laboratory testing and transfusion software
- Accreditation Agencies' relevant policies
- CMS's Conditions of Participation in regard to authentication of interpretive reports
- CMS requirements for meaningful use and ONC requirements for EHR certification

Standards

- Co-leads: **Dr. Victor Brodsky, Dr. Alexis Carter, Dr. JD Nolen**
- Participants: **Mary Kennedy, Virginia Sturmfels, Craig Newman, Robert Dieterle, Cindy Johns**
- End-to-end delivery notification and data integrity
- Clinical vocabulary for laboratory testing
- Existing, emerging, evolving or new recommended standards

Testing and Certification

- Co-leads: **Dr. Mark Tuthill** and **Robert Dieterle**
- Participants: **Greg Gleason, Anne Pollock, Craig Newman, Megan Sawchuk, Dr. Walter Henricks**
- NIST validation suite use cases and data sets
- NIST usability framework
- LRI/LOI/eDOS Implementation and Behavior Guides

Special Sub-workgroup

LOI/LRI Regulatory Issues

- Co-leads: **Robert Dieterle** and **Karen Dyer**
- Participants: **Dr. Alexis Carter, Dr. Mark Tuthill, Dr. JD Nolen, Dr. Victor Brodsky, Mary Kennedy, Anne Pollock, Maribeth Gagnon, Megan Sawchuk, Daniel Cajigas, Helena Duncan, MariBeth Gagnon, Kenneth McCaslin, Virginia Sturmfels, Cindy Johns, Freida Hall, Craig Newman, John Feikema**
- Formed from the Laboratory Reporting Tiger Team membership
- Review all S&I Laboratory Initiatives and provide feedback on regulatory issues
- Recommend appropriate EHR and LIS behaviors constant with CLIA regulations, accreditation standards, patient safety and clinical laboratory best practices
- Analyze CLIA regulations and make recommendations regarding specific MU3 requirements and best practices
- All recommendations are reviewed by the Laboratory Reporting Tiger Team

Successes

Meaningful Use Stage 2 EHR certification

- Test Report definition
- CLIA required elements and best practice elements
- EHR behaviors for certification

Cancel test behaviors

Reflex and add-on testing definitions and behaviors

Results status and succession

Behaviors guide

Description of Laboratory Test Report for EHR Certification

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When testing compliance with the 2014 Edition electronic health record certification criterion, adopted at **45 CFR §170.314(b)(5)**, EHR technology is required at **§170.314(b)(5)(ii)** to display the data elements that include, as a minimum, the information specified in **§170.314(b)(5)(ii)** [42 CFR 493.1291(c)(1)-(7)].

For the purposes of paragraph 170.314(b)(5)(ii), a laboratory "test report" is meant to comprise all of the data elements specified at 42 CFR 493.1291(c)(1)-(7). Such data is meant to be concurrently displayed in their entirety by the EHR technology under test and the content must be presented in a human readable format.

When all of the required data elements cannot be concurrently displayed in their entirety (for example, due to complexity or IT limitations), additional electronic display screens are permitted. When multi-page electronic display screens are utilized, they should follow these characteristics:

- Identify individual electronic display screens unambiguously as part of the same report and as belonging to the specific patient
- Indicate on each electronic display screen the continuation of the report on additional display screens
- Provide additional information with ideally no more than two motions for electronic displays, e.g., hover, click, scroll, pan, zoom

Other presentations of laboratory information may be present in the EHR technology such as a flow sheet or summary reports.

Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition [45 CFR 170.314(b)]

Clinical Laboratory Improvement Amendments of 1988 [42 CFR 493.1291]

Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation. [45 CFR 170.102]

Examples

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CLIA required elements and best practice elements

- Required 42 CFR 493.1291(c)(1-7)
- Best practice additions from CLIA regulations and laboratory best practice

EHR behaviors for certification

- Matching to patient /order
- Store and/or display required and best practice information, for example:
  - Patient name
  - Patient identifiers
  - Gender / Age
  - Specimen information

Cancel test behaviors

- Provider cancel including lab status indicators
- Lab cancel
- Appropriate cancel transactions and notifications

Reflex and add-on testing definitions and behaviors

- Provider add-on
- Reflex testing as defined by agreement between lab and provider
- Includes Microbiology use case

Report Succession

The group believes that basing EHR behaviors regarding result "succession" on changes in the status is problematic at best. The definitions of the status codes and their use by both laboratories and EHRs is subject to local interpretation and their use for any purpose other than display can lead to significant patient safety problems.

Proposal:

- Result Report / Status Change Date/Time (*last change date/time*) must be updated by the laboratory with any change in any associated information (e.g. patient or specimen demographics, result, interpretation(s), ...).
- *Last change date/time* is solely used to determine report succession by the EHR
- **Status indicators are only used to display the status of the order and result respectively on the current version of the report in the EHR**.
- If *last change date/time* is:
  - **greater than or equal to** the current *last change date/time* associated with a previously received report, then the EHR must replace the report with the new version
  - **less than** the current *last change date/time* associated with a previously received report, then this is an error and should be evaluated as soon as possible to determine the cause.
- Exception for lab systems that "must" report in "Requisition Snapshot":
  - **equal to** -- the current *last change date/time* associated with a previously received report, then the EHR should ignore the received report and not update it in the system. This must only be used by trading partners that agree and have methods in place to ensure that updated reports (Orderables) are not sent with the same *last change date/time* when changes have occurred and provide for a process to "replay" a result that ensures the EHR can update a previously failed or partially failed report.

Laboratory Validation Interface (TBD)

Laboratory

LIS or HIS system

LIS analyzes the response for appropriate EHR behaviors

LIS requests Validation Transaction

EHR responds with Validation Transaction for specific Order

EHR consumes, translates and stores result information

EHR

Physician office

EHR collects display versions of data and populates validation transaction

LIS Functionality (elicit, receive and analyze)

- Send indicator that this transaction requires a validation response
- Ability to receive and consume the response message
- Analyze that the response demonstrates appropriate EHR behaviors

Functionality on EHR side (consume, respond)

- Recognize the validation message indicator
- Generate and send the response message

Preliminary Recommendations

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Standards

- Reliable delivery of test results (Delivery Notification)
- Support PDFs for complex reports
- Support for Laboratory Validation Transactions (TBD)
- Recommendations regarding Test Report display usability
- Recommendation regarding the use of clinical vocabularies such as LOINC, SNOMED and UCUM

Testable Behaviors (Required and Best Practice)

- Consuming reported data
- Displaying information in the Test Report
- Saving information required for validation of EHR behaviors

EHR Certification and Testing

- Use cases and test data to validate support for all common data types, limits and common usability problems
- Focus on the "Test Report"

Policy

- CLIA guidance to ensure that laboratories that adhere to the recommendations and use the new procedures satisfy CLIA EHR interface validation requirements

Next Steps

Complete and present recommendations to ONC and CMS/CLIA

- Update standards
- Create/update Behaviors Guides
- Expand NIST certification use cases and test data
- Create Laboratory Validation Interface Guide (TBD)
- Provide CLIA policy guidance

LOINC Orders Effort

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Goal:

To create a standard LOINC definition for 90 % (by volume) of ambulatory test orders

Participants

ONC
- S&I Workgroup
- Open to all stakeholders
- Input to LOI / eDoS Initiative

CDC
- Provides workgroup leadership

NLM
- Provides clinical and standards leadership
- Provides analytical support

Regenstrief Institute
- Supports LOINC
- Provides expertise in establishing new LOINC codes

CHCF
- Provides funding for data collection
- Part of ongoing support of laboratory standardization initiatives

Conclusion

- The Laboratory Reporting Workgroup
  - Provided guidance for MU2 EHR certification
  - Delivered recommendations regarding standards for both laboratory reporting and laboratory orders that are now part of the respective implementation guides
  - Is preparing final recommendations that will substantially enhance reliability, improve patient safety and reduce cost when electronically receiving and incorporating laboratory test results in a certified EHR