The Office of the National Coordinator for Health Information Technology

State HIE and Independent Lab Interoperability Resource Guide

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Version History

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1.0 Introduction

1.1 Background of the Independent Lab Collaboration for Interoperability

The interoperability[1] of patient laboratory (lab) results between clinical laboratories and providers is a top priority of the Office of the National Coordinator for Health Information Technology's (ONC) State Health Information Exchange (HIE) Cooperative Agreement Program and meaningful use (MU) stage 1 and stage 2 incentive requirements.

MU stage 1 requirements signaled the significance of lab results through a menu (optional) requirement for some structured results in the eligible provider (EP) and eligible hospital's (EH) EHR and the requirement for EH to "test" their ability to submit lab data to public health. MU stage 2 requirements further demonstrated the importance by "raising the bar" and making both of these requirements core and increasing the percentage of the measurement. MU stage 2 also added another menu item requiring EH labs to send structured lab data to greater than 20% of their clients. Beyond MU, increased demand for lab interoperability will come from the need to support new care / payment models, such as accountable care organizations and patient centered medical homes.

Studies have indicated that lab data constitutes as much as 70% of the clinically relevant information within an EHR and is a key factor for managing health status and chronic diseases over time. This relevance makes lab data a key component in clinical decision support and the efficiency and efficacy of patient care driven by health care reforms.

Enabling lab exchange is one of the Cooperative Program's priorities requiring grantees to assess the level of lab data exchange within their states and develop specific plans to improve these levels—particularly in rural or underserved areas. To monitor advancement, HIE grantees have been required to report on the progress made for connectivity to hospital-based, independent, and national labs.   While headway has been made with both hospital-based and national labs, very little exchange progress has been realized with independent laboratories to-date.

In late 2012, the leadership of ONC's Lab Interoperability Community of Practice (CoP) contacted leaders of the National Independent Laboratory Association (NILA) to evaluate and explore opportunities to collaborate on several interoperability challenges unique to independent labs. In January 2013, NILA leaders presented an overview of their organization to the CoP membership. Together, the groups brainstormed potential approaches to collaboration and began identifying some of the interoperability barriers for independent labs. As a result, a collaborative workgroup was chartered with the following overarching goal:

> *To advance the dialogue around lab interoperability between independent labs and state HIE entities by recommending mitigation strategies or solutions to common barriers in this space.*

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[1] Interoperability is the ability of two or more systems to *exchange* health information and *use* the information once it has been received.

The workgroup met periodically from March through July 2013 to identify interoperability barriers and potential solutions. Workgroup membership was voluntary and provided a balanced representation from both organizations.

Workgroup
Membership and Cont

Click here to access a roster of the NILA/State HIE workgroup membership on the American Association of Bioanalysts (AAB) public website. Click here to access the document the State HIE Program Health Information Technology Research Center (HITRC) website. Note the HITRC has restricted access.

1.2 Origin of the Resources

The workgroup leveraged and further refined the preliminary list of interoperability barriers identified by the larger CoP/NILA brainstorming session. These barriers were further elaborated upon and consolidated into a final non-prioritized list. With a workgroup member facilitating the discussion on each barrier topic, the group identified solutions and deliverables to be developed which would result in a set of resources to support lab interoperability and the unique circumstances of independent labs.

1.3 Purpose of the Resources

These resources may be used as a "companion" to the "Labs Over Direct: A Toolkit to Get Started" which is a planning and implementation guide for Direct Secure Messaging (DSM) pilots with labs. This toolkit focuses on the "pre-work" leading up to the chartering of pilots. Since many of the barriers identified were related to lack of a common understanding of the interoperability business drivers and technology, this resource provides self-contained educational presentations on these key topics. The tools included support connecting stakeholders and instilling a common understanding of the terminology, business drivers, and technical options for interoperability.

1.4 Intended Audience

These resources may be used to facilitate HIE outreach to independent labs. It may also be used to help independent lab leaders identify HIE activity and interoperability opportunities within their lab service area.

1.5 Key Barriers to Interoperability with Independent Labs

The table below represents the list of barriers, possible solutions, and deliverables resulting from workgroup collaboration. Section 2 of this document provides a detailed description of each barrier and the corresponding solution deliverable.

Table 1.5: Barriers and Possible Solutions to Key Independent Lab Interoperability Challenges

Independent lab and State HIE InteroperabilitBarriers and Possible Solutions

Barrier 2.1: Challenges for State HIE grantees to know who to connect with, and challenges for independent labs to know who to reach out to about HIE
- o   Clearly identifying who the independent labs are within each state.
- o   Share what the State HIE role is in supporting interoperability.

Solutions: Openly share contact information among NILA and State HIE memberships.
- o   Leverage the HIE inventory to identify services available within each state.

Barrier 2.2: Labs and HIE speaking different business languages
- o   What are MU Stage 1 & 2 requirements and what are their implications for independent labs and providers?
- o   What and why of Direct secure messaging?
  - ▪   CLIA requirements related to Direct for lab.

Solutions: Provide topic educational materials for NILA and State HIEs to build a common language
- o   MU Stage 1 and 2 education materials.
- o   Direct secure messaging and CLIA guidelines.

Barrier 2.3: Understanding the Use cases for independent labs and their business value
- o   Why there is an increasing demand for interoperability (MU driver)?

Solutions: Document lab specific use cases for lab interoperability.

Barrier 2.4: LOINC coding/mapping within independent labs
- o   Variable LIS support for LOINC cross references.
- o   Challenges of local codes and benefits of LOINC standardization.
- o   Awareness of the different State specific strategies for LOINC services.

Solutions: Provide information on the different levels of State HIE services to support LOINC coding
- o   Provide overview materials of the different LOINC support strategies use by States.
- o   Leverage the HIE inventory to identify services available within each state.

Barrier 2.5: Lack of Laboratory information system (LIS) vendor support for interoperability
- o   Expensive, non-standard interfaces to EHR vendors.
- o   Limited support for Direct integration for results or orders.
- o   Many in-house developed/supported LIS systems.

Solutions: Survey lab membership for LIS and interoperability information
- o   Start a NILA group conversation with the most common LIS vendors.
  - ▪   Define the memberships technical and business requirements for their LIS vendors.
- o   Research opportunities to engage LIS vendors at a national level for interoperability support.
- o   Provide educational updates and contacts on current / evolving lab interoperability standards.
- o   Provide role awareness and contact information for the Standards and Interoperability (S&I) Framework.

Barrier 2.6: Slow adoption of Direct as a low-cost interoperability solution for independent labs .
Solutions: Continue the NILA and State HIE collaboration and identify pilot partnerships.

2.0 Overview of Interoperability Barriers and Solutions

2.1 Identifying Independent Labs to Start the Interoperability Conversations

Barrier 2.1: Challenges for State HIE grantees to know who to connect with, and challenges for independent labs to know who to reach out to about HIE
    o   Clearly identifying who the independent labs are within each state.
    o   Share what the State HIE role is in supporting interoperability.

Solutions: Openly share contact information among NILA and State HIE memberships.   ▪   Leverage the HIE inventory to identify services available within each state.

The State HIE Lab Strategy Inventory provides a state-by-state overview of grantee approaches to advance lab exchange and interoperability, as well as state contact information. It illustrates how grantees around the country are leveraging State HIE Cooperative Agreements Program dollars to address gaps and increase the utilization of HIE services in support of EPs and EHs meeting MU requirements. In reviewing this information, independent labs will have a better sense of grantees' role and how they are supporting the electronic exchange of structured lab data.

In June 2013, the ONC Lab CoP/NILA workgroup identified and vetted a list of predefined attributes that directly enable lab exchange and/or impact the ability to electronically exchange lab data. State HIE grantees reported on which attributes they are currently supporting or enabling, as well as the implementation status of their architecture and services (e.g., planning, testing, or operational). ONC also reviewed other data sources and implementation reports to improve the quality of the data. The inventory includes the following attributes:

- HIE infrastructure
    - Direct secure messaging (DSM)
    - Health information service provider (HISP) delivery notification functionality
    - Clinical data repository
    - HL7 interface engine
    - Lab hub
- Lab services
    - Lab ordering
    - Lab results delivery
    - Electronic lab reporting (ELR) to public health
    - Immunization reporting to public health
    - Syndromic surveillance reporting to public health
    - Logical Observation Identifiers Names and Codes (LOINC) strategy/service
- Consent model
    - Opt-in
    - Opt-in with exceptions
    - Opt-out
    - Opt-out with exceptions

- o Other
- Capacity building programs
- Technical assistance programs
- Supplemental lab strategy information
- Contact information of the current State HIT Coordinator

The self-reported data provided in the inventory is considered valid as of July 2013. However, independent labs are encouraged to contact the states and/or territories they operate in directly for updated information and to learn more about opportunities to participate in HIE efforts. A couple of other quick notes:

- Data in the inventory reflects exchange activity occurring within State HIE grantee operated or enabled (funded or supported with HITECH cooperative agreement dollars) entities.
- The inventory seeks to capture a majority of grantee lab-related strategies and services, however it is not considered comprehensive.
- Blank fields in the inventory indicate either the grantee did not respond OR the approach/strategy is currently not applicable.

State HIE Grantee
Lab Strategies Inven

Click here to access a copy of the State HIE Lab Strategy Inventory on the AAB public website. Click here to access the document on the State HIE Program HITRC website.

State HIE Lab Strategy Inventory Presentation

The State HIE Lab Strategy Inventory presentation slides are a users' guide to interpret the data captured in the inventory. A description for each attribute is provided along with links to additional online resources and tools with more detailed information. The second half of the slide deck includes graphics illustrating an analysis of selected data points to depict trends identified in grantee lab strategies and approaches.

Lab CoP NILA
WG_Lab Strategies In

Click here to access a copy of the State HIE Lab Strategy Inventory presentation on the AAB public website. Click here to access the document on the State HIE Program HITRC website.

2.2 Labs and State HIEs Speak Different Business Languages

Barrier 2.2: Labs and HIE speaking different business languages
- o What are MU Stage 1 & 2 requirements and what are their implications for independent labs and providers?
- o What and why of Direct secure messaging?

> - CLIA requirements related to Direct for lab.
>
> **Solutions: Provide topic educational materials for NILA and State HIEs to build a common language**
> - o MU Stage 1 and 2 education materials.
> - o Direct secure messaging and CLIA guidelines.

Independent labs have not often had the level of exposure and close association with MU requirements as hospital-based labs. Since hospitals are included in the MU incentive plan for certified EHR) technology (CEHRT), their labs' leadership is well aware of the provider interoperability requirements. In addition, because labs often use the same information technology vendor as their hospital system, their laboratory information system (LIS) would automatically be included in much of the MU requirements upgrades. Independent labs do not have this MU incentive association and often are not necessarily fully aware of the requirements being placed on their provider clients. In the absence of a suitable interoperability offering for providers from independent labs, provider clients could change their lab service relationship to another lab that is able to provide interoperability with their EHR solely driven by the goal to achieve MU and ultimately receive their incentive payments. This provider client business driver has created an opportunity for independent labs to secure their clients through offering an interoperable solution, or lose lab market share by not responding appropriately. The resources include an educational presentation on the topic of MU requirements for lab interoperability that may be used to facilitate a common understanding.

Meaningful Use and
Lab Related Requirem

Click here to access a copy of the MU Stage 1 & 2 Requirements for Lab Interoperability presentation on the AAB public website. Click here to access the document on the State HIE Program HITRC website.

The ability for a provider's EHR to send and receive patient information using DSM is a MU stage 2 requirement. DSM is a low-cost, secure, scalable, and standardized solution that helps labs send test results to providers electronically where there are no existing point-to-point interfaces.

HIEs and labs planning interoperability using DSM must ensure that their HISP(s) is/are compliant with the *Direct Applicability Statement for Secure Health Transport v1.1, which* is **also a Meaningful Use Stage 2 requirement**.

Applicability+Stateme
nt+for+Secure+Health

Click here to access a copy of the Applicability Statement for Secure Health Transport v1.1 on the AAB public website. Click here to access the document on the Direct Project website.

In addition, to be compliant with the Clinical Laboratory Improvement Amendments (CLIA) guidelines, labs are responsible for delivering reports to the Final Report Destination, and must assure timely and predictable delivery. In order to achieve this level of delivery assurance, DSM implementations must also comply with the *Delivery Notification Implementation Guide (IG) v1.0.*

Implementation Guide
for Delivery Notification

Click here to access a copy of the Delivery Notification Implementation Guide v1.0 on the AAB public website. Click here to access the document on the Direct Project website.

DSM with the Delivery Notification IG enables labs to transport results in a way that meets CLIA requirements and can help labs stay competitive in an evolving marketplace. As such, the simple, cost-effective tools enabled through the Direct Project open standards and specifications are an appealing delivery mechanism for electronic lab results.

To facilitate the awareness of these interoperability requirements and solutions, the resource includes an educational presentation on the topic of DSM and the Delivery Notification IG to ensure CLIA compliance.

Overview of Direct
Messaging - MU and C

Click here to access a copy of the Direct Secure Messaging and Delivery Notification presentation on the AAB public website. Click here to access the document on the State HIE Program HITRC website.

2.3 Understanding Use Cases for Independent Labs and their Business Value

Barrier 2.3:   Understanding the Use cases for independent labs and their business value
   o   Why there is an increasing demand for interoperability (MU driver)?
Solutions: Document lab specific use cases for lab interoperability.

Lab interoperability use cases featuring DSM have been well documented by the Lab CoP and State HIE grantees. In collaboration with NILA leadership, workgroup participants validated these use cases and attempted to determine if there were unique characteristics and business drivers for independent labs compared to hospital or larger national labs.

One unique observation with independent labs is that they prioritized Order Entry (OE) as a higher value use case. This priority is in contrast to hospital-based and large national labs which may already have OE capability through point-to-point interfaces, integration hubs, or portals.

The table below depicts the key DSM use cases for lab interoperability.

Table 2.3: Independent Lab Use Cases and Unique Business Drivers for DSM

Independent Lab Use Cases and Unique Business Drivers for DSM	
Use Case	**Business Driver / Value**
Lab orders from a provider to the independent lab.	Fewer integration resources are a key differentiator for independent labs as compared to larger national labs and hospital labs. Many national and hospital labs already have interfaces and portals for their key business clients. For this reason, OE has a higher priority for independent labs to compete with the "ease of business" offerings of their competitors and to secure their clients loyalty.
Results reporting from the lab to the ordering provider.	Similar to OE, independent labs must remain competitive and protect their markets. MU 2 requirements for discrete results in a providers EMR will also increase this demand/expectation for clients. Independent labs can leverage DSM as the low-cost interoperable solution for result delivery including low volume clients.
Lab orders from another lab to a "specialty" lab.	Providing an electronic option for lab-to-lab ordering can streamline operations and reduce errors. If the referring lab is a larger hospital or national lab, they will likely favor an electronic option similar to their other OE/RR transactions.
Results reporting from a "specialty" lab to a referring lab.	Providing an electronic option for lab-to-lab ordering can streamline operations and reduce errors. If the referring lab is a larger hospital or national lab, they will likely favor an electronic option similar to their other OE/RR transactions.
Result reporting from an In-vitro Fertility (IVF) lab to a patient's primary care or OB/GYN provider.	Many of the NILA member labs are IVF labs which have a unique result reporting workflow. Many patient orders originate from an internal clinical specialist. When the patient has completed treatment with the IVF lab and clinical specialist the resulting reports may need to be sent to the patient primary care or OB/GYN provider. DSM offers a low-cost solution for these potentially low volume transactions.

2.4 LOINC Coding / Mapping for Independent Labs

Barrier 2.4: LOINC coding/mapping within independent labs
- o   Variable LIS support for LOINC cross references.
- o   Challenges of local codes and benefits of LOINC standardization.
- o   Awareness of the different State specific strategies for LOINC services.

> **Solutions: Provide information on the different levels of State HIE services to support LOINC coding**
> - o   Provide overview materials of the different LOINC support strategies use by States.
> - o   Leverage the HIE inventory to identify services available within each state.

The MU stage 2 core requirements for ELR by EHs and critical access hospitals (CAH) to Public Health Agencies (PHAs) dictates the use of LOINC coding in the electronic submission of this information. State HIEs have chosen differing roles in support of LOINC coding and data submission. Some state HIEs have chosen to just serve as the facilitator of education on the topic of LOINC coding to providers while other states have created host of services to take the burden of LOINC mapping off of the providers. This latter approach also supports many state's plans to create a central repository of clean "normalized" clinical data for the purpose of population health analytics.

Independent labs are challenged with understanding the requirement of their state public for reporting and the various roles and services offered by their state HIE. One solution to this barrier was the creation of an informative presentation of the different LOINC strategies that states are using including specific case studies on a few states.

Workgroup
Deliverable_LOINC De

Click here to access a copy of the LOINC Deep Dive presentation on the AAB public website. Click here to access the document on the State HIE Program HITRC website.

In addition, the State HIE Lab Strategy Inventory spread sheet provides a state-by-state classification on the level of LOINC services being provided by each state HIE.

State HIE Grantee
Lab Strategies Invent

Click here to access a copy of the State HIE Lab Strategy Inventory spread sheet on the AAB public website. Click here to access the document on the State HIE Program HITRC website.

2.5   Lack of Laboratory Information System (LIS) Vendor Support for Interoperability

> **Barrier 2.5: Lack of Laboratory information system (LIS) vendor support for interoperability**
> - o   Expensive, non-standard interfaces to EHR vendors.
> - o   Limited support for Direct integration for results or orders.
> - o   Many in-house developed/supported LIS systems.
>
> **Solutions: Survey lab membership for LIS and interoperability information**
> - o   Start a NILA group conversation with the most common LIS vendors.
>   - •   Define the memberships technical and business requirements for their LIS

vendors.
- Research opportunities to engage LIS vendors at a national level for interoperability support.
- Provide educational updates and contacts on current / evolving lab interoperability standards.
- Provide an overview of the Standards and Interoperability (S&I) Framework and lab interoperability guidance.

Many independent labs use different LIS systems than their hospital-based counter parts. Since independent labs have been further removed from the MU interoperability technical and business implications as mentioned in Section 2.2, their LIS vendors have not been required to respond to a demand for this interoperable functionality—either for MU certification requirements or from their independent lab customers. In addition, many small independent labs operate using home-grown LIS systems.

Due to the high-throughput workflow of a lab, in order for a lab to consider DSM as a low-cost solution for delivering structured results to their clients, LIS systems must enhance their systems to closely integrate DSM into their result reporting workflow functionality.

Independent labs need to work together to formalize the request for interoperability requirements to their LIS vendors. In such an effort, one consistent message from many independent LIS customers is more effective than a single request. A possible solution to this barrier is for independent labs to identify who the most prominent LIS vendors are within their community, and collectively request these functional enhancements. To facilitate this process, the NILA leadership created a survey of their membership to identify the LIS vendors and level of interoperability functions of their members. Information from these surveys will be used to develop the list of most prominent LIS vendors in order to target the requirements requests.

NILA Results   CRB Results
Summary Data_All_13Summary Data_All_13

Click here to see a sample survey used to identify LIS vendors and level of interoperable functionality for the National Independent Clinical Labs (NILA) and here for the College of Reproductive Biology Labs (CRB) sample survey on the AAB public website. Click here to access the NILA survey and here to access the CRB survey on the State HIE Program HITRC website.

The Standards and Interoperability (S&I) Framework is an approach adopted by the Office of Science & Technology (OST) to fulfill its charge of prescribing health IT standards and specifications to support national health outcomes and healthcare priorities. The S&I Framework is a collaborative community of volunteers from the public and private sectors who are focused on providing the tools, services and guidance to facilitate the functional exchange of health information.

To date, there are three sets of standards and guidance to facilitate the exchange of laboratory orders and results between labs and providers known as LRI, LOI and eDOS.

S&I Framework and   LRI IG Overview CoP
Interoperability Standa   one-pager.pdf

Click here to access an overview of the S&I Framework and the LRI, LOI and eDOS guidance and here for the two-page executive summary of the LRI implementation guide (IG) on the AAB public website. Click here to access the overview and here to access the executive summary on the State HIE Program HITRC website.

In addition, S&I Framework leadership has been working closely with members of CLIA to develop a CLIA compliant Implementation Guide for Direct and to harmonize LRI and LOI specifications with CLIA requirements. These efforts will make it easier for LIS vendors to create LRI/LOI and CLIA compliant interfaces at a lower cost.

2.6 Slow Adoption of Direct as a Low-Cost Interoperability Solution for Independent Labs

Barrier 2.5: Slow adoption of Direct as a low-cost interoperability solution for independent labs .
Solutions: Continue the NILA and State HIE collaboration and identify pilot partnerships.

To further facilitate the lab interoperability goals of the ONC State HIE Cooperative Agreement Program and to support removing barriers to independent labs in achieving interoperability with their provider clients, the workgroup proposed several ongoing roles:

- Continue to "*advance the dialogue around lab interoperability between independent labs and state health information exchange entities"* through continued collaboration among leadership and members.
- Formally solicit and align willing participants of each membership to participate in executing these solutions and resources and leveraging other supporting tools for this purpose
- Launch DSM interoperability pilots with independent labs and their provider clients.
- Stay current on evolving lab interoperability standards and perhaps participate in Standards and Interoperability Framework (S&I) workgroups.
  - For more information about these workgroups, visit http://wiki.siframework.org/.
  - Labs and HIEs should leverage these standards when working with exchange partners to ensure they are taking advantage of the most current exchange standards and features.
- The American Recovery and Reinvestment Act of 2009 (ARRA) provided for the creation of an HIT Policy Committee and an HIT Standards Committee under the auspices of the Federal Advisory Committee Act (FACA). Stakeholders may stay aware of HIT Standards and Policy activity by visiting the FACA committee information site at http://www.healthit.gov/FACAS/.

3.0 Additional Resources

3.1 Labs Over Direct Toolkit

In February 2013, the Lab CoP published the "Labs Over Direct: A Toolkit to Get Started." The toolkit is a "how to" guide, drawing from the experiences of the six lab pilots (Alaska, Florida, Guam, Hawaii, North Carolina and West Virginia) to help grantees better understand the key steps and sequences to get to production quickly and accelerate lab interoperability. The toolkit is broken down chronologically, from initiating pilot planning to evaluating lessons learned. We encourage you to use the templates, tools, and resources in this toolkit which were developed primarily by the lab pilot teams and subject matter experts.

Labs Over Direct_A
Toolkit To Get Started

Click here to access a copy of the "Labs Over Direct: A Toolkit to Get Started" on the AAB public website. Click here to access the document on the State HIE Program HITRC website.

3.2 Frequently Asked Questions (FAQs)

Why should I start a labs Over Direct pilot?
The delivery of lab results over Direct is fast, simple, secure, and cost-effective. As Direct is integrated into a greater number of EHRs for MU 2, labs will be able to send results directly to a physician's EHR, saving time and resources.

The use of Direct for labs is a secure, scalable, standardized and valuable means of health information exchange.

What is CLIA, and what impact does it have on lab results delivery?

The Clinical Laboratory Improvement Amendments (CLIA) were passed by Congress in 1988. These amendments established quality standards for all lab testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. There are currently over 225,000 labs registered with CLIA. The Division of Laboratory Services (DLS) is responsible for implementing the CLIA program. New York and Washington are the only two states exempt from CLIA as their regulations meet or exceed CLIA.

To ensure that Direct was a viable option for CLIA certified labs, ONC formed a workgroup including labs, accrediting agencies, and CLIA. This group was tasked with identifying any regulatory or operational issues with Direct that would inhibit CLIA compliance. From there, the workgroup developed mitigation strategies and established guidance around the implementation of Direct for lab results delivery.   These technical mitigation strategies are addressed in the *Delivery Notification Implementation Guide v1.0* and in section 2.2 of this

resource document. Guidance from CMS on this topic is expected to be released as an FAQ letter in the Fall of 2013.

What guidance is available on this subject?

The Direct Project's Implementation Geographies Workgroup formed the Lab Reporting Over Direct subgroup to develop the Delivery Notification IG. This guide explains how to implement the necessary notifications within Direct. The guide also details how to request destination delivery notifications, what constitutes a delivery "success" or "failed" notification, and the responsibilities of each HISP during the exchange.

What is delivery notification and why does it need to be implemented?

Delivery notification in Direct is a method used by Security/Trust Agents (STAs) to provide a high-level of assurance that a message has arrived at its destination. The delivery notification is needed because the delivery of lab results over Direct initially presented a risk because reliability and timeliness needed to be confirmed in order for labs to be CLIA-compliant. The guidance issued by the workgroup stated that STAs that receive a Direct message **must** acknowledge successful receipt and trust verification of a Direct message by sending a delivery notification with a processed disposition. The delivery notification ensures that the CLIA criteria are met and that the labs can remain CLIA-compliant.

When is delivery notification applicable?

Delivery notification is applicable when there is a HISP-to-HISP communication in both a single and a dual HISP environment. This is because the sending HISP cannot determine when delivery to the destination (via the receiving HISP) has succeeded.

Even in a single HISP environment (when the sending and receiving HISP use the same STA) the IG states that the STA SHALL notify or indicate back to the sender successful or failed delivery to the destination." Further, during "post-handoff—regardless of whether the sender and receiver share the same STA or are served by two separate STAs—the sender's STA SHALL notify the sender of the successful or failed delivery of the original Direct message by delivering a positive or negative delivery notification message as defined in the IG.

Are there any potential security issues related to delivery notification?

Delivery notification messages are only supposed to be sent after security and trust have been verified, and are themselves Direct secure messages.

The use of X.509v3 standards for public key infrastructure (PKI) certificates enable Direct users to create trust policies that enable network encryption by the use of digital certificates, public and private keys and certificate authorities. The content encapsulated in the messaging protocol is secured using the Secure/Multipurpose Internet Mail Extensions (S/MIME) protocols. The S/MIME protocol supports the capability to encrypt the message as targeted to only the destination endpoint. This encryption is mandatory in the Direct Project specifications to protect the confidentiality of the message. For more information on the security of Direct, visit the Direct Project Security Overview.

What is the difference between 'Delivery Notification' and 'MDN'?

Always cite the Direct Delivery Notification IG and not just the message disposition notification (MDN). The MDN is part of the delivery notification implementation guide specification which also defines how to request an MDN, what events it should be used to report (e.g. success and failure of delivery to the edge system or mailbox) and what to do if the MDN (or the DSN) is not returned to the sending HISP/STA. Implementation of MDN alone, without implementing the full set of requirements in the Delivery Notification IG, does not meet the CLIA delivery requirements for lab results.

What is the actual definition of "delivered to final destination"?

Where the Delivering Notification IG is concerned, successful persistence into the recipient's mailbox would constitute successful delivery, and hence the generation of a positive delivery notification (i.e., dispatched MDN).

Why should I use a MOU?

The objective of the memorandum of understanding (MOU) is to define the responsibilities of the participants and in what situations the data can be used. This goes above and beyond BAA language.

Does CLIA support Direct secure messaging as a transport for electronic reporting of laboratory results?

CLIA's position is that Direct with the Delivery Notification IG for reporting lab results aligns with regulations and requirements.

3.3 Useful Links and Resources

The Direct Project web site

http://wiki.directproject.org/home

Link to Direct Applicability Statement for Secure Health Transport

http://wiki.directproject.org/file/view/Applicability%20Statement%20for%20Secure%20Health%20Transport%20v1.1.pdf/353270730/Applicability%20Statement%20for%20Secure%20Health%20Transport%20v1.1.pdf

Delivery Notification Implementation Guide:
http://wiki.directproject.org/file/detail/Implementation+Guide+for+Delivery+Notification+in+Direct+v1.0.pdf

Direct Project Java Reference Implementation: http://wiki.directproject.org/Java+Reference+Implementation and http://wiki.directproject.org/message/view/Java+Reference+Implementation/59341528

Standards and Interoperability (S&I) Framework web site

http://wiki.siframework.org/

3.4 State HIE Leadership and NILA Leadership Contact information

NILA Independent laboratory website and leadership contact information
http://www.aab.org/aab/NILA.asp

State HIE leadership contact information (HIT Coordinators)
http://statehieresources.org/contacts/