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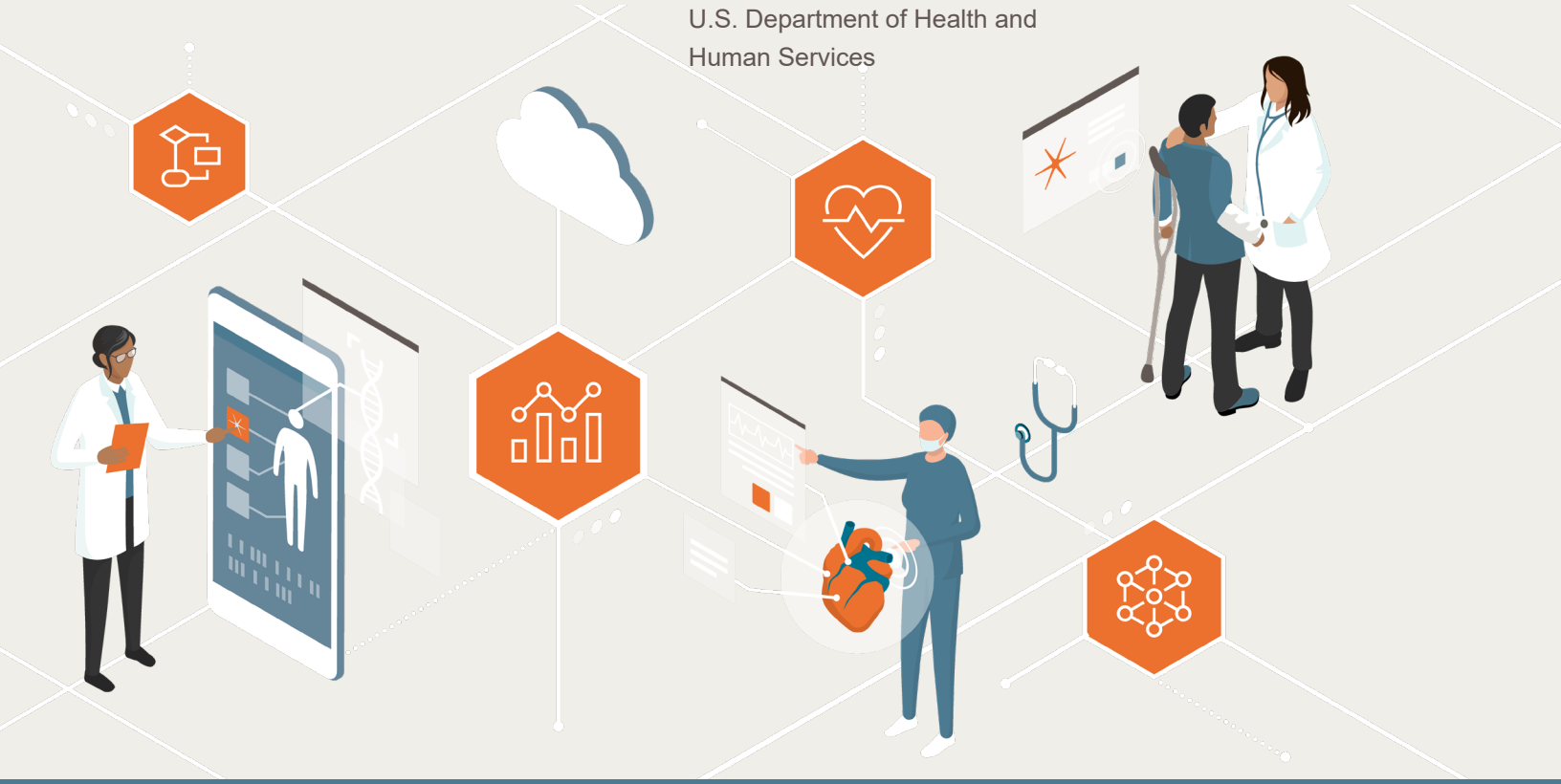

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Introduction and Purpose

In 2012, the Office of the National Coordinator for Health Information Technology (ONC) conducted a first of its kind National Survey on Health Information Exchange in Clinical Laboratories. The survey was conducted as part of the evaluation of the State Health Information Exchange (HIE) Cooperative Agreement Program, in collaboration with NORC at the University of Chicago (NORC). It focused on two types of laboratories: hospital and independent laboratories, including the large commercial laboratories LabCorp and Quest Diagnostics. The goal of the survey was to assess exchange capability and actual volume of electronic exchange of test results with clinicians and hospitals participating in the Centers for Medicare & Medicaid Services (CMS) Electronic Health Records (EHR) Incentive Programs. In 2012, 67 percent of clinical laboratories reported they had the capability to send structured test results to an ordering providers' EHR. Among clinical laboratories with the capability to send structured test results, four in five (80 percent) reported that they sent them to an ordering providers' EHR. [i]

For this report, ONC contracted with NORC to assess the current landscape of laboratory interoperability and explore the potential for updating the national survey of clinical laboratories. The purpose of this landscape assessment was to:

1. Assess how the current landscape of laboratory information exchange has evolved since 2012, with a particular emphasis on the standards for exchange,
2. Identify current issues in laboratory interoperability that warrant measurement,
3. Determine new areas of focus for a potential repeat survey, and
4. Provide recommendations on which aspects of the past survey would be relevant to measure versus those which are no longer relevant, including both the content and past methodology for conducting that survey.

This report summarizes our assessment of the interoperability landscape for ONC leadership and staff, as well as their relevant partners.

Background

ONC's 2012 National Survey on Health Information Exchange in Clinical Laboratories surveyed hospitals and independent laboratories, including the national commercial laboratories Quest Diagnostics and LabCorp. The survey's key areas of inquiry focused on general background information on each laboratory (e.g., ownership and size), its health IT systems and infrastructure, the standards used for exchange, volume of exchange, barriers to exchange, and status as to the adoption of specific implementation guidelines and regulations. Given the status of HIE at the time, the survey focused exclusively on test results.

Multiple technical and policy developments since the 2012 survey have shifted the interoperability landscape. Notably, new standards of interoperability for data exchange and terminology have emerged and gained acceptance, although challenges with the use of specific standards and interoperability remain. For example, several issues with the electronic exchange of laboratory data were detailed in a 2019 report from the Health Information Technology Advisory Committee (HITAC) Interoperability Standards Priorities Task Force (ISPTF). These include lack of consistent encoding of test results and orders, issues with the granularity of LOINC codes, availability of lab results for patients, and use of reference IDs for test results. In addition, the current COVID-19 crisis has highlighted the need to better understand public health infrastructure at the state and federal levels, with particular attention paid to infrastructure that supports communication and the rapid sharing of results via electronic laboratory reporting (ELR).

Given that there has not been a national assessment of interoperability of clinical laboratories since the 2012 ONC survey, NORC was contracted to understand how electronic exchange of laboratory data has evolved since 2012, with an emphasis on the use of standards (i.e., vocabulary and messaging standards) and challenges experienced. Due to the current public health emergency, ONC was also interested in understanding how information is flowing through the public health system (i.e., potentially from hospital and commercial laboratories to public health departments), as well as the electronic capability of public health laboratories and agencies.

This report summarizes our findings about the current interoperability landscape as it relates to laboratories. We document the use of interoperability standards and challenges experienced by hospital and independent laboratories, as well as the electronic exchange of reportable diseases and conditions to public health. Finally, the report provides ONC with recommendations for an updated national survey on HIE in clinical labs.

Methods

The landscape analysis consisted of a targeted review of the literature and interviews with a multi-disciplinary group of key informants. The literature review focused on three areas: 1) use of standard terminologies, messaging standards, and implementation guides; 2) electronic exchange capability of public health laboratories and ELR; and 3) updates to Clinical Laboratory Improvement Amendments (CLIA) regulations. We searched the grey literature for federal reports and resources, for example: HealthIT.gov, where we focused on reports published by the HITAC taskforces and workgroups; the Centers for Disease Control and Prevention (CDC) Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement Program; the ELR Task Force; and CMS CLIA resources. We also conducted Google searches and reviewed webpages of standards development organizations, such as Health Level Seven (HL7) International. While we were able to find multiple resources on standards and CLIA regulations through these websites and federal reports, information on public health laboratory exchange was sparse. We supplemented the grey literature search with a search of the peer-reviewed literature in PubMed and Scopus, using a combination of keywords and Medical Subject Headings (MeSH) Terms including “Health Information Exchange”, “Clinical Laboratory Information Systems”, “Pathology, Clinical/methods”, “Health Information Interoperability”, and “Public Health”. The search provided limited results on the topic of public health laboratory exchange.

For the key informant interviews, we recruited a convenience sample of experts from various organizations with direct knowledge of laboratory data interoperability. We conducted 20 interviews, sometimes speaking to several key informants on a single call. Our key informant group consisted of representatives from laboratory associations, hospital and reference lab representatives, HIE organizations, public health, HITAC members, and standards experts (Table 1). We developed discussion guides tailored to the key informants’ areas of expertise but covering similar themes across informants. The questions focused on evolving standards for laboratory exchange, vocabulary and messaging standards, adoption and use of these standards, exchange capability of laboratories with public health departments, sharing of laboratory data with patients, and potential implementation and regulatory considerations (e.g., CLIA requirements, among others). After each interview, we synthesized the notes and organized our findings by key themes. We analyzed the responses on a rolling basis to guide subsequent discussions with key informants and synthesized the findings into major themes to develop this report.

Table 1. List of Key Informants

Lab Survey Informants	Organization
Laboratory Associations/Clinical Laboratories	American Clinical Laboratory Association
	ARUP Laboratories
	Children's Healthcare of Atlanta
	Henry Ford Health System
HITAC Members	Sutter Health
	University of Utah Health
Federal Partners	Centers for Disease Control and Prevention
	Office of the National Coordinator
HIE Organizations	California Association of Health Information Exchanges
	CORHIO
	CRISP
	Health Current
	MyHealth Access Network
Public Health	Arizona Department of Health Services
	Council of State and Territorial Epidemiologists
Other SMEs	Regenstrief Institute
	RTI International
	Sujansky and Associates

Findings

Since the 2012 survey, the landscape for electronic health information exchange has evolved considerably. Federal efforts to advance interoperable exchange of data have focused on the increased use of standards, including LOINC and SNOMED. In the sections below, we highlight key findings from our environmental scan and key informant interviews. Findings are grouped into sections based on the major themes that emerged: the use of terminology standards, messaging standards, and implementation guidance, ELR, health information exchange organization (HIO)-facilitated lab results delivery, genetic testing, and patient access to lab results. Within each section, we discuss the current landscape, challenges, and opportunities for development.

Terminology Standards

The 2019 HITAC ISPTF report outlined the need for consistent encoding of tests and test result values. Specifically, the ISPTF recommended the use of LOINC codes for all test orders and results, and SNOMED for all observation values.[ii] These recommendations are consistent with the standards recognized in the 2019 ONC Interoperability Standards Advisory.[iii]

In 2012, use of LOINC and SNOMED among hospitals and office-based physicians was accelerating; however, little was known about use by laboratories. To assess laboratory capability to electronically send test results, the 2012 survey measured whether laboratories used structured vocabulary standards (i.e., LOINC and SNOMED) or local codes to report test results. Respondents were also asked about challenges with adopting LOINC for sending results. The 2012 survey did not cover electronic exchange of laboratory orders.

To assess the current landscape of standards-based electronic laboratory exchange, we explored the following key themes with informants: semantic interoperability, standards and methods of exchange, barriers to exchange, implementation guidelines and CLIA regulations. We asked informants to share their thoughts on:

- Additional lines of inquiry regarding using standard terminologies for results delivery,
- Feasibility of collecting more granular data on the use of LOINC and SNOMED,
- Challenges to using standard terminologies,
- Solutions to support consistent encoding of test results,
- The current state of standards-based ordering and need for measurement, and
- Adoption of emerging standards for laboratory data exchange and need for measurement.

Several key informants spoke to the issue of semantic interoperability, noting that LOINC and SNOMED were not consistently used. LOINC, in particular, was a major focus of our discussions, and several key informants described practical barriers to using LOINC due in large part to the complexity of

the standards. The challenges with using LOINC are of particular note given the recommendations from the ISPTF.

Extent of Coding. Key informants stressed that simply asking laboratories if they use LOINC or SNOMED for reporting results is an insufficient measure of use. Informants stated that it is unlikely that a laboratory has 100 percent of its tests encoded using LOINC/SNOMED, and more likely that they use standardized terminologies for most commonly performed tests by volume. To better understand the extent to which laboratory data is standardized, informants suggested asking laboratories to report on the proportion/volume of their test results encoded using LOINC and observation values using SNOMED. Key informants agreed that it would be feasible for laboratories to report on the proportion of tests encoded using LOINC and SNOMED.

A few informants suggested a granular approach to assess not only the extent of coding, but also how the standards are used. Specifically asking about: 1) encoding result components (LOINC); 2) encoding values for microbiology results (SNOMED); and 3) encoding the panel or order the results came from (LOINC); and 4) the frequency that these standards are used. This approach would also help address an issue one informant raised about interpreting the results of a survey. Because the most common tests make up the vast majority of a laboratories' tests by volume, simply assessing the percentage of a laboratories' menu that is encoded using standard terminologies could underestimate the overall impact of standardization. Finally, two informants noted that it would be useful to assess the use of these standard terminologies segmented by the specific type of testing a laboratory performs, i.e., chemistry, microbiology, genetic testing.

Challenges to Mapping LOINC Codes. The most frequently described challenge was the complexity of LOINC, and to a lesser extent the availability and timeliness of new LOINC codes. These challenges are amplified in smaller, facility-based laboratories and hospital laboratories, which typically have fewer in-house resources to support the mapping. Key informants emphasized the need to better understand the extent to which these challenges impact laboratories.

Granularity of LOINC Codes. The granularity of LOINC terms introduces challenges to applying the appropriate LOINC code, aggregating and analyzing data from different sources. One informant cited a study that found that among survey respondents, nearly 20 percent of LOINC codes were incorrectly selected, illustrating the extent of errors in LOINC code selection and raising concerns about the "safety, reliability, and utility of using LOINC codes for clinical research or to aggregate data."[iv] One informant noted that the lack of hierarchies within LOINC limits users' ability to group clinically similar codes for more efficient analyses of data from different sources. To do so, EHR

LOINC Code Granularity

The granularity of LOINC terms results in numerous codes.

- A recent search for "HIV" in the LOINC databased resulted in 403 LOINC terms.

Multiples codes can make it difficult to distinguish between codes, for example a test for HIV 1 and 2 antibodies.

- **LOINC 85037-0**: HIV 1 and 2 ab and HIV 1 p24 AG panel – Serum or Plasma by Immunoassay
- **LOINC 83101-6**: HIV 1+2 Ab and HIV 1 p24 Ag panel – Serum or Plasma by immunoassay

systems need a way to group LOINC codes together in hierarchies and determine which codes to keep separate because they are meaningfully different. Despite the granularity of existing LOINC codes, one informant cited examples where the level of granularity is still lacking (e.g., LOINC codes capturing the reagent use for the Polymerase Chain Reaction (PCR) assay).

LOINC Term Naming Conventions. In addition to the short, long, and fully specified LOINC names, LOINC has worked to create Display Names and Consumer Names to assist users more easily identify test names. Beginning in release 2.64, LOINC began to publish Display Names which are "clinician-friendly" labels for LOINC terms.[v] More recently, Consumer Names, intended for use in patient-facing applications, were published and are currently in alpha.[vi]

Based on a 2018 survey of LOINC users, 25 percent of respondents reported using the LOINC Display Name and 54 percent indicated a need for Consumer Names in the future.[vii] However, one national reference laboratory informant stated that the use of Display Names was likely limited, and that they were not aware of any laboratory using Consumer Names.

LOINC Consumer Names

Consumer Names can be unclear and confusing, for example:

- Gastrin 45 Min After 0.2 U/kg Secretin, Blood
- Beta-2 Transferrin Panel, S/P+CSF

Despite the availability of LOINC Display Names, a few key informants expressed concerns about how user-friendly these terms are and shared that there is a private-public partnership to improve the naming conventions used for laboratory test orders. The TRUU-Lab (Test Renaming for Understanding and Utilization) initiative aims to improve laboratory ordering practices through the creation of test names that are easy to understand and use.[viii]

Staff Resources. Laboratories may lack staff resources to properly maintain and code LOINC given the complexities of the standard. Informants indicated that there is no LOINC code training akin to other health care standards (e.g., ICD-10); however, there are resources available to help laboratory staff consistently use standard terminologies. Therefore, one informant stated that it may also be useful to know what, if any, resources laboratories are using (i.e., RELMA® (Regenstrief LOINC Mapping Assistance), the SNOMED website, or the Unified Code for Units of Measure (UCUM) website).

Similarly, a few informants noted that it would be helpful to ask laboratories how often they update/curate their LOINC codes, and how they ensure their codes are accurate, as the LOINC codes are very dynamic. Using outdated standard terminologies can lead to interpretation and interoperability challenges further downstream.

Source of LOINC Encoding at the Lab. LOINC is not the primary index for laboratory test menus, and as a result its use requires laboratories to map their proprietary codes to LOINC. Several key informants stated that coding further upstream (i.e., closest to the source of the result) can minimize data mapping challenges encountered further downstream. To support complete and accurate coding, the ISPTF recommended that instrument vendors and LIS encode data using LOINC. In some instances, the in vitro diagnostic (IVD) device used to perform the test will output results using a LOINC code. In other instances, the result is encoded within the laboratory information system (LIS), and in

others, the coding may be performed by middleware services. We heard from informants that among laboratories there is a high degree of variability in the systems and processes for conducting this mapping.

However, informants explained that the extent to which IVD device manufacturers have implemented this approach is unclear. IVD manufacturers may not support coding at scale because the manufacturers are not currently subject to any regulatory or certification requirements to encode results using LOINC. The ISPTF identified this as an opportunity to support further standardization, specifically calling for coordination with the Food and Drug Administration (FDA), the National Library of Medicine, and CLIA to establish mappings between the outputs of analyte devices and LOINC terms. This would also support recent efforts by the FDA to promote the use of LOINC in diagnostic device approval and oversight and in the delivery of clinical trial results.[ix] However, it may be difficult to use this survey to measure the availability of these devices in the marketplace and adoption because laboratories have multiple devices; this type of measurement may be better obtained directly from the device manufacturers.

Informants also noted that even in instances where manufacturers are using LOINC codes, these codes may be applied inconsistently, with little transparency since manufacturers view their LOINC catalogues as proprietary. For example, one informant stated that two separate laboratories running the same exact assay from the same vendor may use different LOINC codes, introducing heterogeneity in codes, and barriers to interoperability further downstream. Finally, laboratories may not rely on the data outputs—instead, key informants reported, laboratory staff sometimes manually modify the codes obtained from the vendors/manufacturers.

LOINC and Barriers to Interoperability. Several key informants representing laboratories expressed concerns about the utility of LOINC to achieve interoperability. These informants described limitations in how the standard is used and highlighted several real-world challenges with using LOINC. Requiring laboratories to encode test results using LOINC does not resolve the data mapping challenges encountered when the data are integrated into a patient's EHR. A LOINC code may post to the incorrect result line, or an incorrectly coded LOINC term could result in the wrong value being displayed for a particular result. A LOINC code may be dropped because it does not exist in the EHR, or results from multiple laboratories using different LOINC codes could all be charted to a single result line, leading to misinterpretation and risks to patient safety.

Limitations to LOINC for Encoding Laboratory Data. Key informants representing laboratories also challenged the use of LOINC as the best standard for achieving interoperability of laboratory data. Issues related to the granularity of LOINC terms coupled with the complexity of the standard, limit its adoption in both the laboratory and provider communities, and when adopted LOINC has resulted in high levels of data heterogeneity that presently limit use. One key informant suggested that SNOMED may be a more appropriate terminology for data retrieval and secondary data analysis.

Orders. The 2012 survey focused on results delivery and therefore contained no questions on electronic exchange for laboratory ordering. We asked informants if there would be value in expanding

the scope of the survey to include an exploration of the use of standard terminologies for orders. They agreed that there is infrequent use of standard terminologies, including LOINC, SNOMED, and CPT codes for laboratory orders. Informants stated that they would expect that most ordering providers use their own order catalogues and local codes. Likewise, most laboratories have their own testing catalogues. However, there was interest among the informants in quantifying the use of LOINC for orders by asking the laboratories about the volume of orders received that include a LOINC code.

UCUM. In addition to LOINC and SNOMED, several key informants touched on the use of UCUM. UCUM is a standard for representing measurement units. Key informants were uncertain about laboratories' knowledge and familiarity with UCUM, or whether it is widely used. One informant explained that UCUM is specified in several implementation guides (i.e., the laboratory results interface [LRI] Guide[x], US Core Implementation Guide[xi]) and new FDA regulations around clinical trials, which may suggest incremental growth in use. Informants generally agreed that there would be value in asking about laboratory knowledge of the UCUM standard and whether UCUM is used by laboratories.

Use of CLIA as a Policy Lever for LOINC and SNOMED. The ISPTF recommended using CLIA as a policy lever to enforce use of LOINC and SNOMED. This would involve either auditing or certification by CLIA. Informants suggested that if auditing or certification was ineffective, the use of these terminology standards could be a condition of payment by CMS. Some key informants spoke strongly in favor of using CLIA as a policy lever to improve coding consistency; however, given the challenges highlighted by key informants with using LOINC and SNOMED, laboratories may encounter significant barriers to compliance.

Messaging

To assess laboratories' capabilities to send information electronically, the 2012 survey asked about the specific messaging standard used to send results from the laboratory to the ordering providers' EHR. This included questions about the HL7 version used, challenges to exchange, and issues encountered concerning laboratory interfaces to deliver test results in a structured electronic format.

Informants agreed that HL7 remains the predominate messaging standard for laboratory interfaces. The two most commonly used versions of HL7 are versions 2.3.1 and 2.5.1. Informants reported that the majority of laboratories are still using version 2.3.1 despite the fact the majority of ordering providers using certified EHR technology can accept HL7 2.5.1 messages.

Informants also indicated that laboratories maintain hundreds and sometimes thousands of HL7 interfaces with ordering providers. There would be value in asking laboratories about the number of interfaces they have with providers, as well as the number of interfaces by EHR vendor, since each vendor may have different issues with HL7 and how the interface is configured. There is a need to understand the burden associated with setting up interfaces and maintaining these interfaces over time. One key informant suggested exploring specific case studies to understand the process of configuring interfaces with EHR systems and the challenges associated with it.

The Fast Healthcare Interoperability Resources (FHIR) standard has emerged as a novel standard for exchanging electronic health information. Since the 2012 survey predated FHIR, we asked informants whether we should expand the survey to include it. There was agreement among informants that FHIR is an emergent standard and that the adoption of FHIR within the laboratory community is low. Informants stated that there are no policy levers for laboratories to adopt FHIR, and consequently adoption of this standard may remain low. Several informants explained that laboratory adoption of FHIR is probably limited to a single use case—sharing of test results directly with patients, but that even this is likely limited, given laboratories' preference for this communication to come from the ordering provider.[xii,xiii] Informants suggested that it would be helpful to explore the use of FHIR in the following ways: 1) assess laboratory awareness of the FHIR standard; 2) for laboratories that are aware of the standard, what, if any, use cases are driving the laboratories' plans to develop their FHIR capabilities; and 3) teasing apart some of the gaps in FHIR that may be a barrier to adoption (e.g., the need for more robust FHIR resources that include relevant meta-data to capture the specificity of testing data).

Challenges with HL7 Interfaces. A key informant raised specific concerns related to HL7. First, HL7 interfaces are resource intensive to maintain. They noted limitations to using HL7 due to compatibility issues with legacy LIS. For example, HL7 specifications may have character limits on particular fields, and as a result, the legacy system code outputs are truncated. Another challenge raised was the variability in which segments (OBX, SPM) LOINC specimen codes are sent via HL7; these inconsistencies are a barrier to interoperability, an issue exemplified through practical challenges in electronic laboratory reporting during the COVID-19 pandemic. This may present other challenges to interoperability because it further limits the likelihood that the LOINC code will be used/integrated by the ordering providers' EHR. Finally, the use of unstructured data sent via HL7 also limits interoperability. One key informant provided examples of HL7 messages containing laboratory results sent in the NTE segment rather than as discrete data.

Implementation Guides

The 2012 survey instrument included a question to assess laboratories' use of the LRI implementation guide, which was required for Meaningful Use Stage 2. Since 2012, other laboratory implementation guides have been developed to help implement the use of standards. We asked a subset of informants about the need to include questions about laboratories' use of these newer implementation guides in an updated survey. The informants referenced three implementation guides that help to address some of the challenges to using LOINC: 1) the Integrating the Healthcare Enterprise (IHE) Laboratory Analytical Workflow (LAW) profile, which is designed to facilitate standard communication between LIS and analyzers or middleware; 2) the HL7 Laboratory IVD specifications, intended to create a common representation for a vendor to publish their internal LOINC code mappings; and 3) the HL7 implementation guide for laboratory orders from EHR (LOI).[xiv] Informants also suggested referencing the ONC Interoperability Standards Advisory (ISA) to identify other relevant implementation guides to include in the survey.

Public Health Electronic Exchange

Public health laboratories were not included in the survey sample in 2012. In addition, questions about electronic exchange of laboratory information to public health were not included in the 2012 survey. Some public health laboratories perform diagnostic testing, reference testing, disease surveillance, and support emergency response. Hospital and commercial laboratories send results to public health for reportable conditions. Given the current COVID-19 public health emergency, we felt that it was important to explore capabilities for the rapid exchange of laboratory results to public health.

Establishing Electronic Exchange at the State-Level. Based on the published literature, we found that electronic exchange capabilities between the state health department and public health, hospital, and commercial laboratories can vary across states.[xv] Within a state, electronic exchange capabilities may differ by metro area or locality, and multiple reporting systems may be operational. In some cases, large cities or counties may have their own reporting infrastructure. Finally, even states with well-developed electronic exchange systems can still have a significant proportion of reporting through mail, fax, or telephone.

States receive financial support from the CDC to establish electronic exchange. Broadly, the CDC supports the nationwide adoption of ELR, the automated messaging of laboratory reports. The CDC's ELC Cooperative Agreement Program specifically provides funding to improve the detection, prevention, and response to infectious diseases, including improving laboratory funding and advancing electronic exchange.[xvi] Funding is provided to support ELR to public health within 64 "jurisdictions". These jurisdictions consist of eight territories, five cities, one county, and all 50 states.[xvii]

In order to develop a comprehensive sense of the public health landscape, we gathered perspectives from the CDC, a state health department, and the Council of State and Territorial Epidemiologists (CTSE). Our discussions with the CDC focused on their efforts to collect data about electronic exchange to public health from ELC Cooperative Agreement Jurisdictions. Our discussion with a key informant at the state-level focused on how the health department received information from laboratories, the process of establishing ELR and capacity for electronic exchange, and use of standards (i.e., terminology and messaging standards). We also broadly asked key informants with a range of expertise about reporting to public health and specific topics or questions that would be of interest. All of our discussions with key informants touched on the topic of challenges. All of the key informants we spoke with felt that public health electronic exchange was an important topic to pursue.

CDC Data Collection from ELC Cooperative Agreement Jurisdictions. The CDC collects information on a quarterly basis from the public health department in ELC Cooperative Agreement jurisdictions. Consequently, CDC data collection primarily focuses on ELR to the health department from laboratories (e.g., public health, hospital, commercial, federal), as well as the electronic exchange capabilities of jurisdictions' public health laboratory (i.e., the state public health laboratory). Key informants from the CDC shared that approximately 89 percent of all reportable condition reporting from public health, hospital, commercial, and other laboratories (e.g., federal, VA) to health departments is electronic. However, the CDC includes reporting via Excel files and web portals as "electronic reporting"

in addition to transmission using HL7 2.3.1 and 2.5.1. Table 2 summarizes the information collected about the jurisdictions and the jurisdictions' public health laboratories (collected via REDCap).

For each jurisdiction reported by the health department, the CDC collects information about regulations within the jurisdiction for ELR (e.g., does the state require ELR, are both the test requestor and performer responsible for reporting), if interstate ELR has been established (i.e., a data exchange feed with another jurisdiction), if LOINC and SNOMED are required in ELR, and if local codes are used. The CDC also asks about the specific capabilities of the state's public health laboratory. This section includes several questions about the laboratory information management system (LIMS), the ability of the laboratory to use HL7, and the use of LOINC and SNOMED. The CDC also includes a question about the public health laboratory's capability for Electronic Testing, Ordering, and Reporting (ETOR), which allows facilities to electronically request that tests be performed at the public health laboratory.

CDC Data Collection

Through the ELC Cooperative Agreements, the CDC collects information on electronic exchange capabilities from public health departments in 60 of 64 jurisdictions.[xviii]

Based on discussions with key informants, the CDC does not collect information directly from hospital or commercial laboratories about reporting to public health as part of ELC quarterly reporting.

Table 2. Information Collected from ELC Cooperative Agreements Jurisdictions

Topic Area	Information Collected
Information on Jurisdictions	• The jurisdiction's ELR onboarding process. • If the site (e.g., state health department) has established an interstate ELR data exchange feed with another jurisdiction (bidirectional, unidirectional, or both), and if applicable which jurisdictions. • If state regulations require labs to report in ELR, and what measures are in place to ensure compliance. • If the jurisdiction requires dual reporting, meaning both the laboratory test requestor and laboratory test performer are responsible for reporting to the health department. • If the jurisdiction requires that LOINC and SNOMED codes be sent in ELRs, and if facilities are sending local codes.
Information on State Public Health Laboratories	• LIMS software and version used by the public health laboratory. • If laboratory instruments are interfaced with the LIMS, and which instruments are planned to be interfaced. • If the state public health laboratory is in the process of upgrading the LIMS or planning a LIMS upgrade. • If the public health laboratory can generate HL7 Messages and the HL7 format used.

Topic Area	Information Collected
	• If the public health laboratory uses any of the standard code sets: LOINC, SNOMED results, or SNOMED specimen. • If the public health laboratory is capable of ETOR. • If the public health laboratory has implemented or is implementing a web portal to support ETOR, and if this web portal interfaced into the LIMS.

Challenges with ELR. Several challenges with ELR were identified in the literature and during the discussions with key informants. This included challenges with establishing ELR, use of standards, and obtaining information like patient demographics, as well as broader challenges with meeting reporting requirements. Challenges highlighted by key informants across a range of disciplines are summarized below:

Challenges for Public Health Departments and Public Health Laboratories

- **Laboratories with a low volume of reportable conditions may not invest in HL7 interfaces due to the resources required.** The key informant at the state-level public health agency indicated that approximately 25 percent of laboratory reporting for surveillance was still manual (e.g., phone, fax, email) in their state.
- **Establishing ELR can be difficult without in-house expertise.** One key informant stated that the state public health laboratory did not have in-house expertise with electronic data exchange or HL7. Consequently, establishing ELR for the laboratory required significant time and resources required from the state health department.
- **Once HL7 messaging is established, laboratories may also encounter delays in upgrading to new HL7 formats.** Delays may be due to technical difficulties with HL7 messaging. For example, one key informant shared that a laboratory was currently delaying migrating from HL7 2.3.1 to 2.5.1 due to their feeds missing common data elements. The transition to the other format would not happen until this was resolved. More broadly, upgrades can be delayed because of the time and resources required.
- **ELR to public health may miss important data elements.** For example, one key informant highlighted a lack of specimen source reporting from larger facilities. For some laboratory reports, there are specific OBX segments the performing facilities should be reporting about where the specimen was captured (e.g., blood, serum), but this is often not included.
- **Obtaining patient demographic data is a significant challenge for public health.** This information is often not provided in laboratory orders. Even if demographic data are provided in the order, the information may get lost in the process of orders moving through several different reference laboratories before they reach the performing laboratory or are in the wrong section. Key variables such as race and ethnicity, as well as patient information necessary for contact tracing such as addresses and phone numbers are often unavailable.

- **Obtaining updated information about changes to tests is also difficult.** Laboratories are supposed to inform the health department if they update tests; however, it is unclear how often this reporting occurs and how well states are able to monitor updates to the test catalogue.
- **Once electronic exchange systems are established, semantic inoperability can be a challenge for reporting to public health.**[xix,xx,xxi] Health departments may have difficulty identifying the tests performed and may need to translate local codes. Consistency of LOINC and SNOMED use can be highly dependent on the directives of the state. A key informant stated their state health department required that standardized LOINC codes be included in the messaging so they can route the electronic messages to the appropriate downstream systems (e.g., surveillance systems for cancer, infectious diseases). They also highly encouraged the use of SNOMED coding for specimen data collection.

Challenges for Hospital and Commercial Laboratories

- **EHR vendor codes are insufficient to capture what is needed for reporting to public health.** A key informant shared that over time, hospital laboratories in their state found EHR vendor codes to be insufficient to capture what was needed for public health reporting (including sending information to public health laboratories). Consequently, meeting requirements for standardized reporting required a significant amount of time for communication between the hospital laboratories, public health laboratories, vendors, and state health departments.
- Commercial laboratories have trouble differentiating between reporting to public health laboratories and to the health department. For some conditions, samples are sent to a public health laboratory for additional testing. This creates confusion at the reference laboratory as they need to both send a report to the public health department and send the sample to the public health laboratory for additional testing.

The COVID-19 Response is Changing the ELR Landscape. Key informants indicated that the current ELR landscape is evolving due to the COVID-19 response. Due to expansions in COVID-19 testing, specifically point-of-care testing, the CDC is not aware of all of the laboratories performing tests and the types of settings where those tests are performed. Many of these sites do not traditionally send reportable conditions to the state health department. Consequently, laboratory results are being sent manually to the state (e.g., email, faxes, Excel files), often with incomplete information. There also may be underreporting from doctor's offices doing point-of-care tests.

The COVID-19 response has amplified issues with semantic interoperability. Per CLIA, laboratories have an obligation follow-up with the person who ordered the test. While the person who ordered the test and the performing laboratory have an understanding of what test was performed, this may not be the case downstream even at the health care system level. Public health has difficulty interpreting laboratory results without knowing what test was performed. This information needs to be harmonized as these issues can lead to over- or under-reporting of COVID-19 cases. Laboratories also stated that they were having difficulty meeting the different standards at the state and federal level, and that harmonization of these standards would facilitate laboratory exchange.

CDC informants shared that they anticipate additional data collection efforts (beyond the quarterly reporting from ELC Cooperative Agreement jurisdictions) directly from hospitals due to expansions in COVID-19 testing. Questions on this survey will include whether hospitals are reporting to the state and how, as well as questions about uploading data to a system housed at the Department of Health and Human Services. The instrument is currently going through the clearance process. Broadly, key informants stated that it would be valuable to gather the lessons learned from the COVID-19 response to better prepare for subsequent waves and future pandemics.

Gaps in Current CDC Data Collection. Our discussions with key informants identified several topics not currently addressed in ELC Cooperative Agreement quarterly reporting. These gaps include questions about public health connectivity with HIOs and more targeted questions about challenges. Some key informants indicated that there was interest in expanding or modifying current data collection efforts to reflect new and emerging issues for ELR. Table 3 summarizes the gaps we identified.

Table 3. Gaps in CDC ELC Cooperative Agreement Data Collection

Topic Area	CDC Activities	Information Gap(s)
Public Health Exchange with HIOs	Previously collected information regarding public health connectivity with HIOs, including methods for sending and receiving data. Questions were not carried into the current data collection cycle.	Many jurisdictions are exploring ways to connect with HIOs due to the current COVID-19 public health emergency. This topic should be revisited for future data collection efforts.
Public Health Challenges with ELR	Free-text reporting from jurisdictions provides limited information on challenges.	There are no targeted survey questions on challenges encountered by jurisdiction health department and public health laboratories in establishing ELR.
Hospital and Commercial Laboratories' Challenges with ELR	CDC does not collect information directly from hospital or commercial laboratories about reporting to public health as part of ELC quarterly reporting.	While some information may be provided in second-hand reporting from health departments, there are no targeted survey questions on challenges encountered by hospital and commercial laboratories in reporting to public health.
COVID-19 Response	The COVID-19 response is creating new complexities for electronic exchange. The CDC indicated that there are some plans for a COVID-19 specific survey.	COVID-19 focused work should ask about the lessons learned, potentially focusing on challenges associated with varying standards at the state and federal level and point-of-care testing.

Health Information Exchange Organizations

In the 2012 survey, we asked whether laboratories shared their test results electronically with ordering providers via an interface to HIOs. To explore this topic during our discussions with key informants, we inquired about how HIOs interact with laboratories, the number of laboratories they are connected with, and the challenges and barriers to exchanging data between HIOs and laboratories, both from a laboratory perspective and from an HIO perspective. We also asked if laboratories work with HIOs to submit data to public health and if they have considered leveraging the data from HIOs to help fill gaps in missing patient data.

Laboratory Exchange with HIOs. Several key informants noted the need to understand the extent to which laboratories directly participate with HIOs, as well as the differences in how laboratories interact with HIOs. Informants from HIOs highlighted the complexities in exchanging data, particularly with large commercial laboratories. Informants cited policies that required HIOs to collect additional authorization release forms from providers in order to receive results from commercial laboratories. These forms are in addition to existing Business Associate Agreements (BAA) the HIO has in place with participating providers. As a result, HIOs receive only a subset of available patient data from commercial laboratories i.e., where they have both the BAA and the signed authorization form from the participating providers. HIO informants did not report similar issues with hospital laboratories.

There are gaps in understanding what standards laboratories use to share data with HIOs. Key informants noted that it would be helpful to draw out the difference between laboratory exchange with "vendor driven networks" (i.e., the institutions using Epic and Cerner) versus traditional HIOs, and whether the laboratories directly participate in one or the other.

HIO Result Delivery to Ordering Providers. Informants indicated that there is variation in how HIOs use standard terminologies to support results delivery. In some cases, HIOs may encode laboratory results using LOINC. One key informant stated that approximately 60 percent of results are encoded using LOINC at the HIO level. One informant noted that HIOs may provide a service that maps laboratory results from standard terminologies to the proprietary formats used by the ordering provider before sending them the results.

Barriers to Exchanging Data with HIOs (Laboratory Perspective). Several informants representing commercial laboratories shared that there are potential patient safety concerns when results are shared with HIOs. They noted that often laboratory results go through several different statuses. As such, there are concerns with exchanging results with HIOs who may not have the ability to properly manage those differences. Since laboratories do not have access to patient charts, they prefer to send results back to the ordering provider to ensure that the patient chart in the EHR will be reconciled with any updated results. Some laboratory informants expressed concern about duplicate copies of results if both laboratories and providers send results to the HIO. These duplicate results may proliferate throughout the system. While there are potential benefits to leveraging the rich patient information available to HIOs, laboratories are primarily concerned with accurately matching test data to the right patient and sending the correct information. Additionally, based on their interpretation of CLIA regulations, some

informants noted commercial laboratories believe that their responsibility is only to the ordering provider. They also cited the interpretation that sharing data with HIOs is not considered a HIPAA treatment, payment, and healthcare operation (TPO) activity. Finally, laboratories cited that in some cases the fees associated with participating in an HIO discourages their participation.

Barriers to Exchanging Data with HIOs (HIO Perspective). In our discussions with HIO representatives, they emphasized that HIOs are well-experienced with handling laboratory data, and have good processes to manage different laboratory results, reconcile results from different sources, and use accession numbers to avoid duplicate results. They noted that laboratories narrowly interpret CLIA regulations, which do not restrict the flow of information from laboratories to HIOs. In addition, HIO representatives felt that laboratories were not forthcoming with their rationale for why they do not consider data sharing with HIOs a TPO activity. While HIOs charge hospital and commercial laboratories fees for participating in their networks, the payment models vary based on laboratories' ability to pay and the volume of information they provide to HIOs. As a result, some laboratories are not charged any fees while others pay based on the volume of laboratory results sent. HIO informants recommended asking commercial laboratories if fees deter their participation in HIOs.

HIOs and ELR for Public Health. Commercial and hospital laboratories may leverage HIOs to send data to state health departments, particularly for those laboratories that do not have direct interfaces to public health departments. For some hospital and commercial laboratories, the HIOs serve as the primary method to submit data to the state public health department. Several HIO representatives noted that the barriers created by commercial laboratory exchange requirements have been particularly amplified during the current COVID-19 pandemic, where an HIO may only receive a subset of reportable laboratory data (discussed above). Informants also noted that while public health departments may participate in and establish an interface with an HIO, health departments do not share disease surveillance data they receive directly from providers back with the HIO. HIO informants noted that data submitted for public health surveillance is governed by a different set of privacy policy which vary state by state. Specifically, they noted that public health departments are the only agency authorized to view and disclose the surveillance data reported to them which consequently impedes their ability to share that data with HIOs.

Use of Unique Reference IDs. The ISPTF report noted the lack of consistent use of unique reference IDs by vendors to send laboratory orders and results. Key informants explained that unique reference IDs help providers keep track of results over time and help with de-duplication of data. For example, when a patient visits their provider, the EHR often connects with other health systems and/or HIOs to pull data. The provider is asked to verify the data and input any new patient information. Without unique reference IDs to match the patient and the data, the provider may be asked to reconcile the data again during the patient's next visit, which is a laborious process. However, the issue of EHR vendors not using unique reference IDs to send laboratory orders and results was also viewed as an EHR and HIO issue, versus a laboratory issue.

Genetic Testing

The 2012 survey included one question on genetic testing inquiring whether labs conducted genetic testing or not. When the 2012 survey was fielded, genetic testing was limited to a few labs only. Key informants were asked about: 1) the current prevalence of genetic testing in all types of labs; 2) any specific questions related to genetic testing that labs should be probed on; and 3) whether there would be value in asking about genetic testing for a potential repeat survey.

Key informants confirmed that technological advancements in genomics (such as next-generation sequencing) now supports the capability for most laboratories to conduct genetic testing, including academic medical center labs and smaller laboratories. As such, genetic testing is far more common and warrants further lines of inquiry in the potential repeat survey. Major themes that emerged from the key informant discussions centered on being precise about the types of genetic testing we are interested in, challenges associated with structured reporting of genetic test results, limitations of LOINC codes, and the lack of standards due to the vast variability of genetic testing methodology and genetic variants.

Types of Genetic Testing. Several key informants suggested being precise on the type of testing in the survey (e.g., point mutation of PCR vs. whole genome sequencing vs. microchip array) when referring to genetic testing as it varies widely, both in terms of the methodology and the results received. Some informants suggested that genetic testing can be more appropriately referred to as molecular testing and be further broken down into categories depending on whether it is somatic testing, germline testing, constitutive testing, cytogenetics testing, or identity/parentage testing. There is wide variance in the results that come back to an ordering provider from different laboratories after thousands of genes are sequenced. As a result, the coding is complicated. Laboratories are strongly encouraged to conduct a separate validation of the genetic testing results due to this variability.

Challenges Associated with Use of Standard Terminology. Several key informants noted fundamental issues with LOINC due to the variability of genomics. For example, creating and assigning a LOINC code for results when we do not know how many variants exist per patient is impossible, especially when one can create custom panels instantly and can have thousands of genes sequenced at one time. A recent survey of participants from the College of American Pathologists Proficiency Testing Programs on LOINC code selection for commonly ordered tests found that even in cases of limited group of testing like coagulation testing, the wrong code is assigned close to 20 percent of the time.[xxii] Encoding of genetic test results gets further complicated with cytogenetics. Currently, the use of LOINC codes for genomics would require assigning 30-35 codes for a single variant result which may not be practical. An HL7 Clinical Genomics Work Group is focused on how LOINC can be used to code genomic results.

Reporting Format. Currently, most genetic test results are provided in a report style using free text and being transmitted as a PDF document. Because the results include an enormous amount of data, these results are often sent in a CD or DVD format. Informants also note that given how specialized genetic testing is, the interpretation of genetic test results often require support from laboratory professionals.

There was broad consensus from the key informants on the need to make genetic and molecular testing interoperable because they are highly varied, complex, and can differ between labs.

Patient Access to Laboratory Reports

The 2012 survey had one question related to patient access to laboratory reports, simply asking if laboratories were sharing results with patients. In 2014, CLIA 1998 was amended to allow patients (or their designated representatives) access to complete test results directly from laboratories (42 CFR 493, 45 CFR 164).[xxiii] The 2014 final rule also modified the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to allow for direct patient access to laboratory reports. This change to CLIA in 2014 impacted laboratories in 46 states and territories. The ISPTF report also provides several recommendations to support patients' access to data beyond orders and results (including clinical notes, goals, care plans, histories, and vital signs). They encourage sharing of data via application programming interfaces (APIs), mobile, and cloud technology; and using standard "patient friendly" order and result display names for patients based on LOINC standards. The task force recommends eventually requiring all resulting agencies to make results available electronically to patients either via CLIA regulations or payment incentives.

The topic of patient access to lab results emerged during our conversations with key informants and was noted to be a topic worth exploring further through the survey. Our conversations with key informants revealed that while certain hospital labs and major commercial labs share data with patients, the practice is not widespread. Additionally, the methods and capability of data sharing varies.

Use of FHIR in Data Sharing with Patients. Key informants noted that one reason for FHIR's popularity and expansion is due to its resources that support the ability to provide patient access to data. Major laboratories such as LabCorp and Quest have enabled data sharing with patients via an Apple Health app.[xxiv,xxv] However, the capability of laboratories to directly share data with patients may not be as widespread. The majority of laboratory data sharing with patients is indirect, in that most patients receive laboratory results through an EHR vendor based proprietary patient portal. In such cases, laboratory organizations are not involved in the process of data sharing with patients. Most recently, public comments provided by Quest Diagnostics in response to ONC's proposed rule for the 21st Century Cures Act included recommendations noting that sending results to patients, health information exchange, or other health information networks should occur from the ordering/attending provider as their primary health care provider. Since laboratories often have multiple test result status (e.g., interim, final, corrected results) multiple deliveries of the same data may impact the data quality or risk data breach. Therefore, patient results are sent to the patient provider's EHR system to appropriately manage laboratory result status, before sharing it with patients.[xxvi]

Creation of "Patient-friendly" Test Names. Conversations with key informants indicated that laboratories were not able to provide patients test results in a way that is easily digestible. One key informant spoke to efforts by LOINC to develop "patient friendly" consumer names for consumers and consumer health applications (in addition to display names for providers); however, these efforts are

still in early-stages. Laboratory test naming continues to be a challenge. Informants noted that the current naming conventions of tests often lead to clinicians ordering the wrong test or more tests than necessary, which can cause serious patient safety concerns.

Recommendations

The 2012 survey included questions about laboratory terminology standards, messaging, patient access to laboratory reports, and barriers to exchange. Our environmental scan and conversations with key informants indicate that these topics are still relevant for a follow-on survey. However, these conversations also suggest that more specific and detailed questions are needed to fully capture the current state of laboratory interoperability. Capturing the complexity of challenges using LOINC, for example, will need multiple survey questions with specific examples and detailed probes. Our conversations with key informants provided some guidance and examples for how to structure these questions.

Suggestions for Potential ONC Follow-on Survey. Overall, we identified ways to broaden previous survey questions and/or new areas of focus for terminology standards, messaging, HIOs, genetic testing, and patient access to laboratory reporting. We elaborate on these areas below.

Terminology Standards

Summarized in Table 4, recommendations for terminology standards largely focused on the use of LOINC and the granularity of LOINC.

Table 4. Suggestions for Terminology Standards

Recommendations	Probes
Expand upon the measurement of laboratory capability to send results in a structured format.	• In addition to asking about the use of LOINC and SNOMED, ask laboratories to report on the volume of test results encoded using LOINC and observation values encoded using SNOMED. • Explore the possibility of asking laboratories to report on the use of standards by type of testing performed. • Lines of inquiry could also include more granular questions about what, if any, standards laboratories use to encode test components, values, and panels. For laboratories that respond in the affirmative, ask laboratories to report on the frequency of standards use.

Recommendations	Probes
Expand questions about challenges with mapping LOINC codes, including assessing gaps in the standard.	• This could include adding the following challenges to what is currently asked: • Availability and timeliness of LOINC codes. • Granularity of LOINC codes. Specifically, if the level of granularity meets laboratories' needs, and whether laboratories receive feedback from their ordering providers about the level of granularity. • Lack of expertise to consistently encode LOINC. • Time and effort needed to use LOINC. • Lack of regulatory requirements for using LOINC. • Uncertainty about which LOINC code to use due to too many codes that appear to be similar. • Lack of best practices or guidance/resources available on using LOINC. • The level of difficulty laboratories have when encoding results using LOINC and observation values using SNOMED.
Ask laboratories where and how LOINC encoding occurs.	• Whether the LIS used by the laboratory encodes results using LOINC. • Whether the laboratory uses a third-party software to map LOINC. • If the laboratory manually maps LOINC codes.
Ask about the use of standard terminology for orders.	• Specifically, if laboratories receive any LOINC codes with orders. • For laboratories that respond in the affirmative, ask how often/what percentage of orders are encoded in LOINC.
For hospital labs in particular, explore if, and how, LOINC and SNOMED codes from performing laboratories are integrated into the EHR.	• Explore the use of a targeted set of questions to assess the challenges to integrating LOINC codes including the following: • Do you encounter challenges related to test results being charted to the wrong line? • Are you aware of reported LOINC codes being dropped because the code does not exist within the hospitals EHR system? • Do you use LOINC Display Names?
Assess how laboratories use LOINC to support interoperability.	• Specifically, inquire what, if any, value laboratories derive from LOINC, which may include compliance with government requirements, reimbursement/billing purposes, achieving interoperability, and/or enhanced analytics.

Messaging

Recommendations for messaging standards are presented in Table 5. These recommendations focus the types of interfaces and use of LOINC and SNOMED.

Table 5. Suggestions for Messaging

Recommendations	Probes
Ask about the volume and type of individual interfaces	• Ask about each of the interfaces each laboratory maintains with: 1) provider offices; 2) HIOs; and 3) EHR vendors. • Ask about the number of interfaces a lab supports.
Explore the extent to which LOINC and SNOMED codes are included in the electronic interfaces.	• Do laboratories transmit LOINC and SNOMED codes via an HL7 interface to public health departments, cancer registries, and others?

Public Health Electronic Exchange

Recommendations in this section focus on reporting for hospital and commercial laboratories. These topics are only partially covered by CDC data collection activities through free-text reporting from state health departments. Consequently, we have included reporting to public health from the perspective of hospital and commercial laboratories in Table 6 as a potential area of focus. Items focused on public health laboratories are included in the section on suggestions for the CDC.

Table 6. Suggestions for Public Health Reporting for Hospital and Commercial Laboratories

Recommendations	Probes
Ask about the use of HL7 messaging including the format used.	• Current use of HL7 messaging (including specific version). For laboratories using HL7 2.3.1, specifically ask if they are planning to transition to version 2.5.1. • For hospital laboratories, the extent to which ELR is submitted via web portal versus HL7 interfaces.
Assess the ability to provide demographic information in ELR to public health.	• What data elements are provided in the laboratory orders (e.g., gender assigned at birth, race/ethnicity)? • Where they provide demographic information in the HL7 message to public health?

Recommendations	Probes
For hospital laboratories, assess the use of LOINC and SNOMED codes	• Ask about the inclusion of LOINC and SNOMED when submitting ELR data to state health departments.
Explore the use of targeted questions to assess the challenges associated with ELR.	• Challenges with establishing interfaces with health departments. • For commercial labs, challenges in determining whether to route information to the state public health laboratory or the health department. • For commercial laboratories, challenges associated with current COVID-19 response such as differing standards at the state and federal level.

HIOs

Recommendations related to HIOs focus on two areas: questions for commercial and hospital laboratories about HIO-mediated result delivery (Table 7) and questions specifically for a survey of HIOs (Table 8).

Table 7. Suggestions for Commercial and Hospital Laboratories about HIO-mediated Result Delivery

Recommendations	Probes
Ask if laboratories work with HIOs to share results electronically	• Quantify the number of interfaces labs have with HIOs. • Ask if laboratories share full data or partial data with the HIO.
Determine the reasons for not sharing data for those that do not share information with HIOs	**Specifically probe the following reasons:** • Role of CLIA or other federal regulations in restricting them from sending additional data. • Patient safety concerns. • Technical challenges/limitations of HIO. • Fees associated with HIO participation. • Value derived as a data contributor only.
Ask about standards used to exchange data	• What, if any, messaging standards do laboratories use to exchange data with HIOs?

Table 8. Suggestions for the ONC HIO Survey

Recommendations	Probes
Assess validity of the challenges that labs cite in participating with HIOs	**This includes asking about:** • Concerns with patient matching. • Concerns with producing duplicate data. • Fees associated with HIO participation. • Exchanging data with HIOs not considered TPO. • Lack of perceived value.
Ask about the challenges that HIOs face in receiving data from labs	**This includes asking about:** • CLIA and other federal regulations. • Lab policies that require HIOs to execute multiple disclosure forms.
Ask if HIOs share public health data with health departments and CDC	• Ask if HIOs receive public health data from hospital and commercial labs, and whether they actually share that data with public health authorities.

Genetic Testing

Recommendations for genetic testing are summarized in Table 9. Recommendations focus on probing the types of tests performed, the use of LOINC and SNOMED, and the method and format of delivering results.

Table 9. Suggestions for Genetic Testing

Recommendations
• Ask about the specific type of genetic testing the laboratory is conducting. This could include questions to clarify whether it is somatic testing, germline testing, constitutive testing, cytogenetics testing, or identity/parentage testing, as well as a follow-on question asking whether laboratories are using LOINC coding for each type of testing. • Measure whether laboratories have the LOINC or SNOMED code for a particular genetic variant or a genetic order. • Assess the method and format for delivery of genetic testing results to ordering providers. For example, are laboratory results delivered in a PDF format or transmitted as narrative text in an HL7 message? • Ask if laboratories are familiar with the newer HL7 recommendations on how to send genetic tests,[xxvii] and if there are issues with specimens that they are not able to implement.

Patient Access to Laboratory Reports

Recommendations about patient access to laboratory reports (Table 10) focus on methods of sharing results with patients and changes to CLIA.

Table 10. Suggestions for Patient Access to Laboratory Reports

Recommendations
• Inquire if laboratories are sharing results directly with patients, and if so, how (e.g. proprietary portals, provider portals, patient-facing apps, mail/fax or other).

ONC Survey Development and Methodology. While the environmental scan was focused on potential areas of exploration for the survey, there were a few methodological considerations that emerged. These include:

- The development of a new survey will require additional conversations with subject matter experts to develop and refine questions that capture the nuances highlighted by key informants.
- Given that these topics are wide-ranging and at times highly technical, it will be important to identify individuals in the best position or role within laboratories to respond to the survey.
- A follow-on survey may be able to use publicly available Provider of Services files from CMS' Quality Improvement Evaluation System (QIES) to form a sampling frame for CLIA certified laboratories.

Suggestions for Leveraging CDC Data Collection Efforts. Based on information gathered from informants involved with reporting data to public health, we believe that the data collection activities through the CDC ELC Cooperative Agreement quarterly reporting provides sufficient detail on the ELR reporting capabilities of public health laboratories. The CTSE also indicated that they collect data on electronic exchange, but with a broader focus than ELR. Table 11 summarizes the topics of interest identified during our discussions with key informants that can be incorporated into existing data collection activities.

Table 11. Suggestions for the CDC

Recommendations	Probes
Structured data collection on challenges with ELR	**Ask about challenges associated with:** • Establishing interfaces with health departments. • Lack of resources and expertise.

Recommendations	Probes
Assess interaction between HIOs and labs	• Ask about public health connectivity with HIOs, including methods for sending and receiving data. • Ask if public health agencies and laboratories work with HIOs to share public health data.

Qualitative Work. It may be appropriate to further explore some of our findings through additional qualitative discussions instead of a survey format. One area is the use of LOINC. We have outlined specific suggestions for survey questions about using terminology standards. However, some of the nuances and complexities of using LOINC may only be fully captured through additional interviews with subject matter experts. Qualitative discussions will provide a more robust understanding about challenges to mapping LOINC codes and gaps in the standard.

In addition, key informants specifically stated that capturing lessons learned from the current COVID-19 response would be a valuable area for qualitative inquiry. It may be difficult to design survey questions that fully capture laboratory interoperability issues related to COVID-19 given that the response is on-going and evolving. Qualitative discussions that capture the lessons learned from laboratories could be used to help ONC develop targeted survey questions. Given that the CDC is currently developing a survey for hospital laboratories, this qualitative effort could focus on commercial laboratories and/or the difficulties state health departments are encountering with laboratory exchange for point-of-care testing. Table 12 summarizes areas we have identified for further qualitative work across several topics.

Table 12. Suggestions for Qualitative Work

Topic	Recommendations
Terminology Standards	• Ask about the use of LOINC, focusing on the nuances and complexities of using LOINC. • Ask about the challenges to mapping LOINC codes and the gap in the standards. • Explore the readiness of laboratories to implement the recommendation from the ISPTF that CLIA use its authority to require the use of LOINC and SNOMED as a condition of certification. This could include asking respondents about how they feel about this potential change and challenges they anticipate in meeting certification requirements, if necessary.
Messaging	• Understand the challenges with setting up interfaces and maintaining them over time. Explore specific case studies to understand the process of configuring interfaces with EHR systems and the associated challenges. • Assess knowledge of FHIR and explore the gaps in FHIR that may be a barrier to adoption. Ask about use cases driving laboratories' plans to develop their FHIR capabilities.

Topic	Recommendations
Implementation Guides	• Ask about the use of implementation guides: Integrating the Healthcare Enterprise (IHE) Laboratory Analytical Workflow (LAW) profile; HL7 Laboratory IVD specifications; HL7 implementation guide for laboratory orders from EHR (LOI)
Public Health Electronic Exchange	• Ask about the lessons learned from current COVID-19 emergency. • Probe challenges with varying standards at state and federal level. • Potentially focus on commercial laboratories and/or the difficulties with point-of-care testing.
Patient Access to Laboratory Reports	• Explore changes to CLIA regarding direct patient access to laboratory reports and how these results are rendered would impact laboratories. This could include questions about barriers or challenges to providing direct patient access as well as any efforts to create results that are accessible to patients.

Throughout the recommendations, we have highlighted several pathways for future data collection including a follow-on survey from ONC, CDC activities, and qualitative work. Additional qualitative work is most likely needed to both develop survey questions and capture some of the nuances related to use of LOINC and the current COVID-19 response. We also identified CDC data collection initiatives for public health laboratories. There may be an opportunity for ONC to coordinate with the CDC to develop new questions for quarterly ELC Cooperative Agreement reporting based on our findings. Table 13 provides a high-level summary of the data collection avenues by topic; some topics have multiple data collection pathways.

Table 13. Summary of Data Collection Avenues

Topic	ONC Survey of Hospital and Independent Laboratories	ONC Survey of HIOs	Qualitative Interviews	Case Studies	CDC ELC Cooperative Agreement Data Collection
Terminology Standards	X		X		
Messaging Standards	X		X		
Implementation Guides for Lab			X		

Topic	ONC Survey of Hospital and Independent Laboratories	ONC Survey of HIOs	Qualitative Interviews	Case Studies	CDC ELC Cooperative Agreement Data Collection
Orders and Lab Results					
Public Health Electronic Exchange	X		X	X	X
HIOs	X	X			
Genetic Testing	X		X		
Patient Access to Laboratory Reports	X		X		

Conclusions

Based on our analysis we have identified several topics for measurement in a potential repeat survey of clinical laboratories. These include questions that are specific and detailed enough to fully capture the complexity of the use of standardized terminologies and their limitations.

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