*a*LOINC[1] Order Code
S&I Framework Initiative
Final Report

[1] *a*LOINC refers to agreed upon LOINC® code.

4/30/2015

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[2] The findings and conclusions in this report are those of the S&I Wiki Workgroup and do not represent the official position of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry.

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Executive Summary

The Standards and Interoperability (S&I) Framework initiative, *a*LOINC Order Codes, launched in January 2014. The groups' charge was to provide a common order code value set for the Laboratory Orders Interface and Electronic Directory of Services Implementation Guides. The group addressed issues where Logical Observation Identifiers Names and Codes (LOINC®[3]) mapping of laboratory orders was problematic for laboratories. The key deliverables were: 1) development of the *a*LOINC Common Order Codes Value Set, 2) input to the Regenstrief Institute on guidance for comparing user panels to LOINC panels, 3) recommendations to the Office of the National Coordinator for Health Information Technology (ONC) on how to use LOINC for laboratory orders, and 4) recommendations to the Regenstrief Institute on content updates based on the review of laboratory order LOINC codes.

Recommendations

The group would like to offer the following recommendations to ONC on how to use LOINC codes for laboratory orders:

1) The purpose of the *a*LOINC Common Order Codes Value Set should be for identifying the most commonly ordered laboratory tests.
2) Best practices in LOINC mapping (map to what matches, request a new code when needed) should be applied to the *a*LOINC Common Order Codes Value Set. If a laboratory test does not match a corresponding test on the *a*LOINC Common Order Codes Value Set, the larger LOINC database should be searched for a more applicable LOINC term. If an appropriate LOINC code cannot be found for the test offered, a new LOINC code should be requested from the Regenstrief Institute using the process described at http://loinc.org/submissions/new-terms .
3) A major barrier to the development of an empiric list of common laboratory order (or result) codes is the lack of nationally representative data. To ensure that such a list can be updated efficiently, ONC should help facilitate the collection of national laboratory data to establish a list of common laboratory order (or result) codes.
4) Recommended guidelines developed by this group for comparing a user-defined panel to an existing LOINC panel are an attempt to provide flexibility and allow laboratories a mechanism for comparing their laboratory panel to a LOINC panel to determine equivalency. ONC, the Regenstrief Institute, and the National Library of Medicine (NLM)

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need to work with the laboratory community to address the need for more flexibility and enhanced guidelines.

5) We support the use of LOINC as the universal code system for laboratory orders. The best practice in messaging is to exchange both the local and the standard code. Further, we recognize that there will be some cases where an appropriate LOINC code does not exist for the test (such as a brand new test). ONC will need to keep this fact in mind on future efforts to standardize coding.
6) ONC should encourage the development of training aids utilizing the LOINC database supporting fields to help laboratories understand how to select appropriate LOINC codes for mapping.
7) ONC should promote collaboration between the Food and Drug Administration (FDA) and the Regenstrief Institute to develop a process where an instrument and/or reagent manufacturer would assign an appropriate existing LOINC code or submit a request for a LOINC code from the Regenstrief Institute during FDA's approval process (i.e., provided in the manufacturer's package insert or other mechanism that allows easy access to the codes in one location). The provision of manufacturer-specified LOINC codes would help standardize laboratory test mapping.
8) ONC should develop a process for standardization of laboratory test reporting that provides coordination between clinical laboratory efforts and public health test results.
9) ONC should ensure that the Regenstrief Institute has sufficient resources to provide a timely response to the anticipated increased demand for new LOINC codes.
10) A model should be developed for coding anatomic pathology and cytology tests, where a test may include several codes (specimen collection, processing, and interpretation) for orders and results. We recognize the test is for one analyte, therefore it is not a panel. However, if several codes are necessary, there may need to be a way to link all the codes for one test together. ONC and the Regenstrief Institute will need to consider how multiple codes for one analyte are recorded in a structured format which typically has one code per analyte.

Background

Electronic health record (EHR) usage has increased in the last five years[1,2] partly due to the Centers for Medicare & Medicaid Services (CMS) providing incentive payments to health care providers who adopt certified EHR technology and use it to demonstrate meaningful use of that technology. The CMS incentive program (often identified as Meaningful Use Stage 2) criteria focuses on the capacity to electronically capture health information. Specifically germane to this project is the Meaningful Use requirements for laboratory test orders and results. More than 30% of laboratory test orders must be generated using computerized order entry (CPOE) and more than 55% of all clinical laboratory test results reported as numeric or positive/negative values must be incorporated in a certified electronic health record (CEHRT) as structured data[3]. The federal government has invested an estimated $29 billion (as of the end of 2014)[4] in incentive payments that reimburse healthcare providers if they install an EHR system.

Without a standardized vocabulary, data transmitted from one electronic health information system to another may not be fully computable when it is accessed or received. This results in a receiver's system that may not be able to entirely process, parse, and/or present data to the user in a meaningful way. Additionally, EHR vendors cannot efficiently pre-populate order menus for clinicians or trend data over time making it impossible for EHR's to support clinical decision rules.

LOINC is a coding system for clinical and laboratory observations and events developed by the Regenstrief Institute. It is the required vocabulary for identifying laboratory test results and is the proposed vocabulary standard for identifying laboratory orders. With the publication of the meaningful use requirements and the need for healthcare providers and hospitals to qualify for the incentive payments, laboratories will be expected to provide laboratory orders and laboratory results that include LOINC codes and vendors will be expected to provide the capability for LOINC's usage. In its white paper on laboratory interoperability best practice the College of American Pathologists (CAP) Diagnostic Intelligence & Health Information Technology (DIHIT) Committee stressed the need for standardization of test definitions, names, and codes in laboratories and went on to suggest that to achieve such a standardized vocabulary "every laboratory would need a LOINCologist to oversee the development and deployment of LOINC in the laboratory information system (LIS) and interfaced systems."

The CMS Meaningful Use and the ONC certification rules have definitely increased the awareness of the need for standardized vocabulary to connect with other healthcare systems. One outcome of this awareness is the observed increase of U.S. LOINC users. However, mapping to LOINC can be a complex and resource intensive process.[5,6,7,8,9] Many laboratories lack personnel with domain expertise in vocabulary standards who are dedicated to support a health information system. Even with the best available automated tools, mapping to a standardized terminology often requires extensive review by domain experts. If mapping of LOINC to local laboratory codes is incorrect then there is no guarantee the values are interpreted correctly. Incorrect mapping can also result in patient harm due to loss of information or results being mapped to the incorrect tests in the display. To assist LOINC mappers, the Regenstrief Institute and the NLM have developed a nationally-

representative set of the LOINC Top 2000+ Laboratory Observations and a companion LOINC Mapper's Guide (both available at http://LOINC.org/usage/obs) with guidance to implementers about mapping local codes to LOINC. The NLM and the Regenstrief Institute collaborated with several organizations to develop an empirically based list of the most commonly ordered tests. The outcome of that process was the Universal Order Codes from LOINC (http://LOINC.org/usage/orders), a collection of codes accounting for the majority of the volume of five nationally-representative data sources.

Activities/Approach

S&I Framework Initiative – *a*LOINC Order Code

The ONC S&I Framework is a collaborative community of participants from the public and private sectors who are focused on providing the tools, services, and guidance needed to facilitate the functional exchange of health information. The S&I Framework has several initiatives related to laboratory interoperability including the Laboratory Orders Interface (LOI), the Laboratory Results Interface (LRI), electronic Directory of Services (eDOS), and Electronic Health Record System Functional Requirements (EHR-S-FR). Implementation guides for laboratory test orders[10] and results[11] interfaces are two of this collaboration's products. During the collaborative process for developing the Implementation Guides, there was a discussion on how LOINC order and result codes would be carried in the message. It was determined that laboratories should use the LOINC codes, when available. However, local codes may also be carried in the message when LOINC is not available or in addition to LOINC. The group also discussed the need to expand the list of Universal Order Codes from LOINC. A planning group was convened to develop a new S&I Framework initiative called *a*LOINC Order Code. The meeting announcement was published on December 10, 2013, and the initiative launched on January 8, 2014.

The use of non-standardized local codes or terminology to describe laboratory test orders varies widely among laboratories. Universal use of LOINC coding for laboratory order and result information in a structured and systematic fashion is an essential component of interoperability between providers, clinical laboratories, and public health laboratories. This project will focus on the enhancement and expansion of LOINC for commonly ordered clinical laboratory tests in ambulatory care settings and for tests ordered in the public health settings. This goal is for the Regenstrief Institute to publish up-to-date lists of clinical and public health Order Codes Value Sets that could be recommended for incorporation in EHR Meaningful Use (MU) stage 3 and to support certification requirements. The scope document is in Appendix A.

Analysis of Data

*a*LOINC Common Order Codes Value Set

Two national reference laboratories provided a comparison of the top 500 tests performed at their facilities to a combined list of the Regenstrief Institute's Universal Order Codes from LOINC and LOINC Top 2000+ Laboratory Observations. Codes thought to not be ordered in an ambulatory care setting and duplicate codes were removed from the list. Tests (with corresponding LOINC codes) were categorized into three different classifications; Order, Observation, or Both. All "deprecated" and "discouraged" LOINC codes were replaced with active LOINC codes from the RELMA database. The tests were divided into two spreadsheets, one for single stand-alone orderable tests and one for panels. The two spreadsheets make up the *a*LOINC Common Order Codes Value Set.

Participants on the weekly *a*LOINC Order Code Initiative conference calls were asked to compare the *a*LOINC Common Order Codes Value Set to the list of orderable tests in their laboratory. They were also asked to identify tests not on the list that should be included or tests that were on the list that should not be included (either because they are not performed in an ambulatory setting or not offered as a stand-alone orderable test). All lists sent in by the members were combined and compared to the *a*LOINC Common Order Codes Value Set and "new" single tests and panels were included based upon committee discussion. The vetting of the list continued weekly and each test and panel was discussed. Comments pertaining to the validity of tests and panels were noted and discussed. Comments or concerns included but were not limited to designation of observation only and tests discouraged by the Regenstrief Institute. A list of recommendations for NLM and the Regenstrief Institute to consider was developed. The List of Recommended Content Updates for the Regenstrief Institute based on the review of laboratory order LOINC codes is in Appendix B. The final resulting spreadsheet has a total of 1532 orderable tests contained under two tabs: single tests (1376) and panels (153). This spreadsheet is the initial *a*LOINC Common Order Codes Value Set. The *a*LOINC Common Order Codes Value Set is in Appendix C.

Report of the Indiana Network of Patient Care (INPC) Data Building a Common LOINC

The California HealthCare Foundation provided funds to the Regenstrief Institute to help with developing a list of the most commonly ordered laboratory tests. Data was to be collected from 10 different institutions in the INPC for the period of January 2011 to at least January 2013. The data fields extracted were: laboratory order code, order name, result code, result name, LOINC, units of measure, and any metadata (such as service location) indicating that an order was placed in an ambulatory care setting.

The list of order codes was reviewed and an attempt was made to identify those that represented panels and those that represented single tests. It was found that a small number of local panel codes (less than 1% of the total volume) from various institutions had been mapped to the Regenstrief Dictionary codes that represented classes of tests rather than true panels. For example, the term "Cholesterol Tests and Lipid Panels" is meant to be used for grouping a domain of tests rather than representing a specific panel. Such terms were excluded from the final set. A summary of the analysis is in Appendix D.

The data extracted from INPC represented 173,929,006 laboratory orders. The local tests from these 10 institutions were mapped to 3,538 Regenstrief Dictionary codes, of which 2710 were mapped to LOINC codes. 396 of the 3,538 Regenstrief Dictionary codes were mapped to LOINC codes contained in the Universal Order Codes from LOINC. Of the LOINC codes in the Universal Order Codes from LOINC, 242 were mapped to Regenstrief Dictionary terms in the INPC data set. The INPC list of order codes was condensed by aggregating the volume of any code mapped to the same LOINC code, producing 3,127 order codes. The table below shows the number of unique laboratory codes accounting for specific levels of the overall volume. As a corollary, while 635 Regenstrief Dictionary codes accounted for 99.5% of the volume, the remaining 2,903 codes

accounted for remaining 0.5%. This means, there is a very long list of tests with little volume (Table 1).

Table 1: Number of codes accounting for the top 90-99.5% of overall order volume

	Unique Regenstrief Dictionary Codes*	LOINC codes with aggregated volume and remaining unmapped Regenstrief Dictionary Codes*
Accounting for 90% of volume	50	37
Accounting for 95% of volume	117	93
Accounting for 99% of volume	435	356
Accounting for 99.5% of volume	635	527

*numbers are accumulative with increasing volume

MarketScan Data

CDC staff analyzed data from the 2012 Truven Health MarketScan® Laboratory Database. This laboratory database contains commercial payer and Medicare clinical laboratory results linked at the de-identified patient level to the same patient's healthcare claims. The laboratory tests are ordered in office-based practices and sent to a central reference laboratory. Central reference laboratories serve office-based medical practices where testing volume is not sufficient to support investment in a full-scale laboratory infrastructure. Blood, urine, and tissue samples are obtained at medical offices and shipped to a central laboratory for analysis. Since most tests are run on automated equipment with digital output, test results are entered routinely into electronic databases. Thus, the data is representative of pooled laboratory data from reference laboratories and includes laboratory tests performed in an ambulatory setting that produce a computer generated result. The data does not include laboratory tests performed in hospitals or in doctors' offices. The database includes 6.9 million unique patient enrollees for the last 5 years or approximately 17% of the enrollees who have at least one laboratory test result in addition to other claims data (Table 2).

Table 2: MarketScan

Enrollee type	Number (percent)
Commercial Payer Enrollees	109,469,096
Medicare Enrollees	8,644,677
Total Enrollees (Commercial Payer + Medicare)	118,113,773
Enrollees with at least 1 laboratory test	6,932,832 (17%)

The data contains 73,402,305 laboratory tests that are represented by 7,362 unique LOINC codes. The table below shows the number of unique laboratory codes accounting for specific levels of the overall volume in one year of data (2012) (Table 3).

Table 3: Number of codes accounting for the top 90-99.5% of overall order volume

% of volume	Unique LOINC Codes*
Accounting for 90% of volume	327
Accounting for 95% of volume	647
Accounting for 99% of volume	1595
Accounting for 99.5% of volume	2115

*numbers are accumulative with increasing volume

Review of Reference Laboratory Test Orders

A review of the laboratory LOINC order codes obtained from four large reference laboratories showed variation in selection of the LOINC code and name used by the laboratory. A comparison of these test lists to the *a*LOINC Common Order Codes Value Set demonstrated a close matching of codes with one of the laboratories. However, for two of the laboratories few to none of the codes matched codes on the *a*LOINC Common Order Codes Value Set. This may be due to the laboratory performing the test using a different method or reported with different units of measure. In other words the variation appeared to be due to variation in laboratory practice.

During this review we found a lack of consistency with the laboratories' choice of local test name. Each laboratory has business rules for applying the test names, but the business rules lack consistency throughout the US.

Conclusion of Data Analysis

The *a*LOINC Order Code group was asked to provide a value set of LOINC order codes for the most commonly ordered laboratory tests in an ambulatory setting. A commonly ordered laboratory test is defined as an order for a laboratory test which is highly likely to be included in the top 95% of a laboratory's orders by volume. However, these orders represent a relatively small proportion of the total laboratory tests that a laboratory may provide. For example, one member of the group reported that her laboratory provides a total of 1134 different laboratory tests (including individual analytes and panels), yet, 95% of the laboratory volume was comprised of only 211 of these tests. Orders for the remaining 923 tests combined comprised less than 5% of all laboratory orders. We found this to be true in the INPC data also. In the INPC data, 117 tests represented the top 95% of the 173,929,006 laboratory orders.

None of the data sets we were able to obtain were representative of a national sample of laboratory test orders. Therefore, it is not possible to make a meaningful comparison of the data sets. The *a*LOINC Common Order Codes Value Set is not based on volume information. INPC and MarketScan data were for different lengths of time. The INPC data is representative of laboratory orders, while the *a*LOINC Common Order Codes Value Set and MarketScan list are based on resulted test codes. If you look at only trying to match the LOINC code from one set to the other, a LOINC code that has high ranking in one or two sets may not be included in the third set. For instance, Creatinine in Serum/Plasma, LOINC code 2160-0, was the most requested test in the MarketScan data and ranked within the highest panel requested by INPC, but the code was not found in the *a*LOINC Common Order Codes Value Set. On the other hand, the *a*LOINC Common Order Codes Value Set contained Creatinine in Blood, LOINC code 38483-4, which was found in both of the other lists.

We conclude that while volume data for a small laboratory would have a small number of tests making up the top 95% of their volume, the tests in another laboratory will not be the same due to variation in laboratory practices. A national sample would produce a much larger list.

Lesson Learned

The group identified several challenges and opportunities that support our recommendations. In this section we have grouped our comments under five headers: Volume Data Comparisons; Differences in Order Codes and Result Codes; Use of Local Codes; Need for Training Products; and Coordination with Public Health Tiger Team.

Volume Data Comparisons

Obtaining a national sample of laboratory order data that is collected by a standardized approach, such as that used by INPC, would be beneficial. ONC may wish to consider finding a way to obtain laboratory order volume data, such as requiring institutions to include data in the attestation statement provided to CMS under the incentive rule. The *a*LOINC Common Order Codes Value Set we are providing may not be representative of a national sample. A list of common orders for single analytes based on using the same code for both orders and results may end up being quite a bit larger than this list due to the variability of test methods used across laboratories in the United States. If a national sample were obtained, trends may be identified that would result in a list of codes that will be used by smaller laboratories, another list that will be used by larger laboratories, or another in laboratories that do primarily specialty testing.

The list of common orders for panels may not include as much variation between laboratories since some are defined by CMS. The panels are represented by one order code and several normally resulted test codes or possible resulted test codes. The group recognized that with more users mapping and requesting LOINC codes, this homogeneity may get lost when laboratories try to make an existing panel code match a panel used by that laboratory. This can result in the request for duplicate codes for the same test. The Regenstrief Institute and NLM may need to work with the laboratory community to address needs for order panels that may be missing or which do not include all of the result elements that a particular laboratory may include in its panel. The group asked for more flexibility in matching the laboratory's panel to an identified LOINC panel. The outcome was the development of a guidance document containing business rules to apply when comparing a laboratory's panel to a panel already identified in LOINC. NLM and the Regenstrief Institute plans to incorporate these rules in the LOINC User's Guide. The Business Rules for Comparing a User-Defined Panel to a LOINC Panel Code are in Appendix E. Since our *a*LOINC Common Order Codes Value Set may not be representative of the methods employed by the laboratory that may use it for mapping purposes, we suggest this list be used only as a first review. If a LOINC order code matching the laboratory's test cannot be found, the larger LOINC database can be searched for a more applicable LOINC code. A new code may be requested from the Regenstrief Institute.

Another problem identified by the group was in the reporting of anatomic pathology. In anatomic pathology, there are several resulted codes representing multiple specimens or multiple analysis types attached to a single test order. One approach discussed by the group was to consider these tests as a panel. However, NLM pointed out that anatomic pathology tests do not meet the requirements to be designated as a panel, since they are not tests for multiple analytes. LOINC was

designed to handle a single result per test with a single code and was not designed for the degree of variability or complexity found in an anatomic pathology report. As such, orders for anatomic pathology tests are not easily amenable to existing LOINC order codes. A model may need to be developed for coding anatomic pathology and cytology tests, where a test may include several codes (specimen collection, processing, and interpretation) for orders and results. If several codes are needed, there may need to be a way to link all the codes for one test together

Differences in Order Codes and Resulted Test Codes

LOINC provides a set of universal names and ID codes for identifying laboratory and clinical observations[12]. The primary purpose of LOINC promotes interoperability by standardizing codes for equivalent laboratory and clinical test results between systems. For resulted tests, equivalency is determined by ensuring that multiple components of the laboratory test are similar (e.g., method, units of measure, timing before or after an event). LOINC was not natively designed to handle laboratory or clinical test orders which are specific to an analyte but usually not specific to method or units of measure.

One idea that was discussed was to use methodless codes, as is the practice in Canada. The Pan-Canadian LOINC Observation Code Database (pCLOCD)[13] Nomenclature Standard allows access, management, and storage of patient laboratory orders and resulted tests across the continuum of care through a jurisdictional Laboratory Information System. It is based on the international LOINC standard. The Canadians recognized the need to standardize the coding and naming of laboratory tests to prevent duplication when a patient visits different health care providers. Making test information widely available online ensures the timely access to laboratory test information that can impact clinical decision making. Canada Health Infoway provided a list of methodless codes for consideration by the group. The Canadian Test Order List is in Appendix F.

Currently the ordering provider selects the test to be ordered by name, not a code. Laboratories have adopted local names which are also not standardized. This makes computerized provider order entry difficult when faced with a single EHR-S interface. Inclusion of laboratory test specific information, such as method or unit of measure may further increase the difficulty of the provider selecting the right test for a particular analyte. Choosing the wrong test may result in delay of treatment and sometimes may result in patient harm. For some analytes (e.g., Human Immunodeficiency Virus or HIV), the ordering provider needs to know the method because one is used as a screening test (e.g., HIV ELISA), one is used as a confirmatory test only when the screening test is positive (e.g., HIV by Western blot), and one is used to monitor viral loads (e.g., HIV by reverse transcriptase PCR).

There will have to be a balance of allowing the provider to request a test using the test name they are familiar with and mapping of test names to a standardized list of codes. If the provider is suddenly faced with new test names it may result in ordering the wrong test, not understanding the

results reported back, or delay of receiving the results needed to diagnose the patient's condition. All of these issues raise concern for patient safety and risk of harm.

Use of Local Codes

The group was very concerned about the purpose of the initiative in developing a standardized set of common LOINC order codes and how the list would be used. The group did not want this list to be construed as a constrained value set. They decided to add a section to our scope statement that would address this concern. The following was added to the initiative's scope document on January 14, 2015:

Use of this Data

This project group recognizes the following as true statements:

- There are thousands of existing laboratory orderable tests used for clinical patient care.
- The LOINC database is dynamic and changing frequently.
    - NOTE: Checking the LOINC database for updates at appropriate intervals is recommended as part of good database maintenance.
- There is a relatively small fraction of total possible laboratory orders which comprise the majority of all laboratory test volume in the United States (so-called "common laboratory orders").
- LOINC order codes currently exist for some, but not all, of the common laboratory orders.

Given the above true statements, the group strongly advises that any implementation of LOINC order codes recognize the following:

- If a laboratory order matches one of the common laboratory orders with associated LOINC codes then the matching LOINC code should be used for the order.
- The absence of a LOINC order code should not prevent the use of a local code for ordering laboratory testing.
- However, this does not preclude any of the following:
    - Use of aLOINC order code for a non-common laboratory order.
    - Processing a laboratory order that does not contain an associated LOINC code.
    - Requesting a new LOINC order code.
    - Re-checking the LOINC order code database at a later date and updating the order with a subsequently available and appropriate LOINC order code.

Need for Training Products

Mapping of laboratory resulted tests to LOINC codes (an activity which has been in place longer than for orders) is not well understood and prone to error when performed by most individuals unless they are specially trained in terminology practices, particularly LOINC mapping. Conversely, mapping of LOINC codes to laboratory orders or resulted tests without an in-depth knowledge of the laboratory's test menu is similarly prone to error. Most laboratories do not have the financial resources to hire specialists in LOINC coding. Training aids may need to be developed to help

mappers or provide incentives for laboratories to train and/or hire individuals who will be able to accurately assign LOINC codes to orders and resulted tests.

Coordination with Public Health Tiger Team

The Public Health Tiger Team is developing a standardized approach for collection of resulted tests for reportable conditions and cancer reporting. They are coordinating three initiatives that will promote and strengthen public health by leveraging technologies and standards. The three focal initiatives that will be are: Structured Data Capture (SDC), Data Access Framework (DAF), and Health eDecisons (HeD).

The efforts of this group must be coordinated with clinical laboratory reporting. The efforts of clinical laboratories and public health should result in a selection of the same codes for the same analyte or test.

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