USCDI version 5 Public Comments Andrea Pitkus 15/Apr24

Thank you for the opportunity to comment as a citizen, laboratory professional and health informaticist with a passion for laboratory data interoperability and usability for the provision of safer, quality healthcare for all. Laboratory data comprise > 70% of EHR data and utilized for clinical decision making, and are also vital for public health, including cancer and infectious diseases.

New Data Classes and Elements

1. Orders
    a. Comment: While I support the addition of orders including laboratory orders to USCDI, there are a few recommendations ONC may consider.
        i. Move laboratory orders under the laboratory class so all laboratory data elements are found together. The laboratory test order name often provides important details about the complete meaning of a laboratory "test" along with the result name, specimen type and other details within the Laboratory Class. It will help developer and non laboratory users find these laboratory related data elements more easily and not draw incorrect conclusions if it is listed elsewhere.
        ii. Add LOINC codes as the required terminology for laboratory orders, specifically order only LOINCs and those that are ord/obs, meaning they can be used for a term that serves as both an order term and resultable term.
        iii. The most detailed LOINC should be used pertaining to the test and as mapped by the performing laboratory.
        iv. Has ONC researched federal requirements for operational definitions about what defines an "order?" Regulations such as HHS and Clinical Laboratory Improvement Amendments (CLIA) regulations use different names and definitions for an order. Clarification is needed as to the ordering process (order as a verb) such as used with ONC's Clinical Provider Order Entry (CPOE) functionality versus order as a noun, the thing that is requested and or performed on a patient.
        v. The four main types of laboratory orders need to be supported in any implementation across the health ecosystem. A characteristic of orders is they don't have a value or units associated with them like a result does.

1. One is the single orderable and resultable, such as a Hemoglobin order (often built in the EHR or LIS order dictionary) that also may be built in a result dictionary where units are indicated. The same LOINC in this case is mapped to each (an ord/obs), but the two terms serving different purposes may have a unique order number and a different unique result number. This is the simplest test order.
2. Second is a simple order panel such as a Complete Blood Count (CBC), which is comprised of each individual result and its value. This CBC LOINC shows the structure and relationship between the CBC order and it's results (and their LOINCs): LOINC 58410-2 CBC panel - Blood by Automated count
3. Third is a reflex order, (CMS has definitions for reflex), but it is an order that may have additional testing performed usually additional orders and their results if certain criteria are met. A common one is a "UA If" or Urinalysis order where a culture order may be reflexed if criteria are met such as a positive leukocyte esterase result, positive bacteria, or White Blood Cells reported for the urinalysis. The physician does not order the additional order for the culture. Rather the laboratory reflexes (adds and performs) the culture order automatically. One of the most complex reflex orders is for Lupus Anticoagulant Studies as indicated here: LOINC 75881-3 Lupus anticoagulant aPTT, dRVVT and PT screening panel W Reflex. 5 levels of reflex orders may occur depending on what occurs with the patient's specimen analysis.
4. Fourth, is what some call profile, tiered, or one click physician orders, whereby a single EHR order is built that explodes out into one or more sub orders of the above. For example a stroke profile, may explode into a CBC, PT/INR, and Basic Metabolic Panel (BMP), each of these order panels with their own results and values that also need to be kept grouped together for their complete meaning and interpretation/use. Some EHRs will explode out these orders on the EHR side and transmit each order separately to the performing laboratory (as different specimens may be collected for each, etc.) In other cases, the top/parent order may be sent to the performing laboratory with

the specimens and the performing laboratory has each order built and for which specimen is accessioned.

vi. Clarity will help ensure there is clear understanding of what is the focus and appropriate functionality for that thing is available when referenced in future regulations, etc.

vii. There are different terms for orders used across the standards space as well. I use the term lab test order to be clear it is different than a lab test result and it's value. However, others call this a procedure, and others still call it an observation. Further, in FHIR lab orders are currently being represented as FHIR Procedure resources, FHIR Observation Resources and FHIR Service Request Resources with these different definitions and interpretations. Some have indicated all laboratory test orders will use FHIR Service Request, which is my recommendation. However, other lab orders such as biopsies or when surgical procedures such as a "colon resection" are used to collect specimens for pathology lab tests or cytology, the specimen collection procedure should be indicated via a FHIR Procedure in addition to the Service Request for the order on that specimen (e.g. Surgical Pathology). Clear delineation is needed to ensure the proper data elements are accurately capture, encoded and exchanged for interoperability.

viii. From a usage perspective, most EHRs determine their own naming convention for laboratory test order names, often physician preferred terms, instead of the performing laboratory's term. The performing laboratory, is the source of truth about the test names and details on the tests that they perform. Many of these details are found in the laboratory's test compendium/catalog/menu/ specimen collection manual (terms in regulation/accreditation requirements). This is typically a separate electronic system from the laboratory information system (LIS), laboratory information and management system (LIMS, used in public health), and electronic health record (EHR), and similar health information technology. CLIA indicates that the information needs to be at all the places where specimen collection occurs. CLIA does not indicate the how, so electronic versions as well as the paper telephone book compendium are acceptable.

ix. However, electronic transmission is more interoperable and there are several HL7 implementation guides for exchange of laboratory test compendiums.

1. The newest is FHIR Order Catalog with great examples of the common laboratory order types: HL7.FHIR.UV.ORDER-CATALOG\Examples - Laboratory services - FHIR v5.0.0
2. The second in HL7 version 2 format is the electronic Directory of Service (eDOS): HL7 Standards Product Brief - HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS), Release 2 - US Realm | HL7 International

x. Some usability issues/limitations:
   1. FHIR natively cannot handle tiered/parent-child relationships of more complex orders. However, it does have a notation where the top parent order can be indicated within Service Request and another Service Request can be utilized for each "child" order.
   2. Another major aspect of EHR order build and use is the accuracy of the orders. What is meant by that is are the order terms used in EHR CPOE order functionality even the terms for the test orders at a particular performing laboratory? Let's use fast food menus as an analogy for laboratory test order menus. One cannot order a taco at a burger chain as they do not have the supplies or even a taco on the menu. Similarly, not every laboratory performs every kind of laboratory test. They only perform what is on their menu. A provider may request a test they don't perform, and some even will go as far as collecting a specimen from a patient, but when it is received at such a laboratory it is rejected and patient harm and increased healthcare costs occur when it has to be reordered and recollected. This can also result in healthcare disparities if a patient cannot take off work again due to the provider error.
   3. Thus, additional processes need to be supported to ensure orders are interoperable.
      a. First, ideally all laboratory compendiums are electronic and in a standardized format. Given LISs in the US don't have FHIR functionality yet, they may or may not be able to support FHIR Order Catalog. Many do offer Excel or other compendium formats currently. A Phased approach may be needed. Keep in mind that since many laboratory compendiums are built in other IT

systems, any “certification” requirements may not apply to those systems. Also lab compendiums often contain additional test information such as the method or sometimes IVD test information that is not contained in the LIS or EHR. It also contains additional information about the types of specimen collection containers and additives that may not be in the LIS or EHR either. It has more than just the order. eDOS was reviewed by CLIA personnel to ensure it would be compliant with requirements at the time. It would be good to have FHIR Order Catalog and/or eDOS reviewed to ensure no changes are needed before adoption to meet CLIA requirements. If changes are needed, then the implementation guides are updated accordingly.

b. Once a laboratory is able to send their compendium electronically, the EHR needs to receive the e compendium and all details therein, including Ask at Order Entry questions (AOEs), their expected responses, and other test details necessary for providers to order. Some EHRs have an ingestion capability, but most are manual builds, with either HIT vendor “starter” catalogs of lab tests, or if transitioning from another vendor, an “import” of previous system catalog build, etc. This is usually a labor intensive process. Many EHRs in the US create their own test terms independent of the performing laboratory compendium terms and map them to the order number (or other unique identifier from the test compendium, what many call local codes) in the back end build process. Once a provider orders a “test” on a patient from a particular lab (dependent on insurance/contracts, etc.), that order number is sent in the message to the performing laboratory so they know what test in their compendium the provider actually wants even if they don’t request it by that name.
c. There needs to be a load and storage in the EHR of each performing laboratory’s lab compendium information. If there are 5 labs (the average ambulatory practice is

interfaced to 1-5 labs), then 5 need to be supported, including updates when tests may be deprecated, added (such as with COVID), or updated (with different test methods, etc.).

d. Each compendium's data, including laboratory test orders, need to be used in the EHR CPOE functionality for ordering by the provider. Functionality may vary by EHR vendor, but the performing laboratory's test name should be available to the ordering provider as the source of truth of what they are ordering and in the order message sent to the performing laboratory, whether directly or via intermediaries such as when a provider sends to a critical access hospital who then sends an order they don't perform to a reference lab. Some EHRs offer capability for providers to customize lab order test terms to what they desire, but still retain the performing test name in the back end that is sent in the message to the performing laboratory (or potentially exchanged with other providers for referrals, etc.)
e. Once the provider finishes the ordering process, each order should be electronically transmitted to the performing laboratory.
    i. With Meaningful Use this was not a requirement and some providers would use the electronic ordering of CPOE functionality, but print out lab test orders and send them with the patient specimen to some laboratories. This defeats the purpose of interoperable systems and creates undue burden on laboratories who have had to hire teams to perform manual data entry into their LIS or these orders.
    ii. A similar burden occurs with fax, phone, and paper based ordering that occurs. There are a variety of reasons why electronic ordering doesn't occur. In some cases, a tertiary care center will make orders for a patient to fulfill at their home institution, especially for chronic conditions. Depending on their volume or

budget to invest in the costs of interfacing, they may use non electronic methods. Flipping to the laboratory perspective, one major reference laboratory reports ~10% of their orders are not electronic, which can be extremely burdensome for them and result in patient delays when time and resources are needed to order these in the laboratory's LIS. It may have larger impact on public health labs and those with more limited resources.

iii. It is recommended that the EHR as a sender of laboratory orders and a laboratory LIS as a receiver to adopt HL7 version 2.5.1 Laboratory Order Interfacing (LOI) Implementation Guide for electronic exchange. It will be a heavy lift for some laboratories, but should be much easier for EHRs. Additionally, financial resources will be needed to support laboratory adoption, especially since most were ineligible for the over $35 billion in Meaningful Use incentives.

iv. As part of having a complete or acceptable order that is not rejected by the performing laboratory, many require Ask at Order Entry Questions (AOEs) to be addressed as part of the ordering process. Specimen Type and Source Site need to be indicated for many orders where they are lacking in the order name. For example a Wound Culture, can be ordered and swabbed from anywhere on the body. Often there is an AOE for the specimen source site. This should be indicated for the order and with as much detail as warranted (e.g. Left leg, not just leg.) Orders on body fluids need to indicate which body fluid specimen type was submitted, etc. These are important order details that frequently impact public health reporting were missing from many COVID orders, so many downstream impacts of accuracy with orders too.

2. Laboratory
    a. Test Kit Unique Device Identifier
        i. While I personally support the inclusion and use of device identifier information for test reagents and kits, there are also a lot of questions as to how this would occur across the variety of patterns with laboratory tests, and without unduly burdening clinical laboratories and others with it's collection and usage.
        ii. Health IT functionality is currently lacking for this new data element to collect, store, use, transmission, and receipt. While it is true some UDIs are available in the FDA GUDID website electronically and a number on IVD package labels in barcode format, it is unreasonable to expect that laboratory professionals will hand enter any and all that apply to their test. It would be error prone and extremely burdensome. They should be available in a structured electronic format that can be easily ingested by a laboratory information system and associated with each test result built. Next the association similar to standardized terminologies and code systems need to be exchanged with results.
        iii. Although there was a short term solution in HL7 messages for COVID tests where this was first required, there is not a long term solution for widespread exchange of this data element. Updated HL7 version 2.5.1 ELR, LRI, and EHR-S for receipt of laboratory data into the EHR implementation guides are needed with clear guidance for both senders and receivers.
        iv. As laboratory data are received into the EHR for interfaced systems, often the lab result name is renamed to the EHR preferred test name. Additionally, where multiple different lab results are received from different laboratories, a single EHR generic result term may be built instead of separate terms for each distinct test result. As a result, most EHRs are unable to support mapping to multiple different LOINC results, and instead map to only a single generic result. With device information, these specific details may all differ too by each test result and it's unclear how EHRs will handle them if they flow to a single test result. There is no generic UDI. These practices defeat the whole purpose of specific LOINCs and specific detailed UDIs. I fully support EHR updates to support each lab result distinctively. This may be a first phase of functionality needed by HIT to support future use of UDIs/Device identifiers. They will also need to store as many

UDIs as provided by the performing laboratory, which could be 1-10 or more depending on the complexity of the test. These would have to be transmitted to every laboratory data exchange, whether via an HIE, or to public health, clinical trials or research systems for a variety of purposes.

v. The next major concern is how will the most complex laboratory test examples and all the patterns that need to be supported. For a large number of laboratory test results, including some common ones, it is not a 1:1 match from a result and a single reagent and its UDI or device identifier. It's unclear how many laboratory test result reagents/ test kits do not have a UDI or device identifier as they do not exist for a number of laboratory results including laboratory developed tests (LDTs). Further info follows.
    1. There are many laboratory test results that are built in laboratory result dictionaries and mapped to LOINC codes, that may not have a UDI or device identifier. These include Ask at Order Entry questions that are reported as part of laboratory test order panels as results. For a 24 hour timed urine, they include the result for the total volume, the result for the hours of collection, and the final calculated 24 hour urine analyte rate. It would only be available for the spot urine result for the analyte, which may or may not be on the final report for the laboratory as some report it outside the LIS, and others only report the final calculated 24 hour urine rate. See this example from Mayo (codes tab delineates each result and its LOINC): CRT24 - Overview: Creatinine, 24 Hour, Urine (mayocliniclabs.com) What HIT functionality is needed to support? Is it for all these lab results or only some of them?
    2. Consider calculated results such as a creatinine/albumin ratio. Each is produced with a different reagent/test kit so 2 different UDIs/device identifiers are expected in most cases. HIT would need to support mapping both to the single test result, as well as all downstream systems, messages, etc. How would this occur?
    3. Another example is a estimated glomerular filtration rate (eGFR), which for most formulas relies on a creatinine result and patient demographic information for the final calculated result value. The National Kidney Foundation updated the

formulas to reduce healthcare disparities, with one formula relying on creatinine alone and the other relying on creatinine and cystatin c. The latter would utilize at least 2 reagent/test kit UDIs for each result. The former creatinine UDI/device identifier would be the same as the regular serum creatinine result and not provide any distinction across all the different eGFR formulas using creatinine alone (and still use other demographic information) for the different test result values produced by each. Yet there are different LOINC codes for eGFR distinguishing each formula based result. See CRTS1 - Overview: Creatinine with Estimated Glomerular Filtration Rate (eGFR), Serum (mayocliniclabs.com) and BMAMA - Overview: Basic Metabolic Panel, Serum (mayocliniclabs.com)

4. In another example, a test kit UDI/device identifier would be the same across 10-12 different lab results produced by it and additional information such as the distinct LOINCs for each result would be needed in conjunction to provide unique test result information. Consider one of Biomerieux's antimicrobioal sensitivity (AST) cards (reagent/test kit with a single UDI/device identifier): 23-VITEK-REVEAL-GN01-Flyer.pdf (biomerieux.com) Each antibiotic on the left is typically built as a separate lab test result, which would have it's own LOINC code, but the same single UDI would be used for each of them on the same card (test kit).
5. Lastly, some of the more complex test results may be from whole genome sequencing where multiple reagents (test kits) may be used for a single result. Stained slides are used with hematology differentials whether manually read or with automated methods, cytology for pap smears, microbiology with gram stains, and widespread in pathology with (H&E) stains for tissues. Each of these uses multiple reagents (test kits) for the generation of a single test result, whether manually read by a laboratory professional or pathologist or utilized in digital slide imaging and analysis. Consider An Intro to H&E Staining: Protocol, Best Practices, Steps & More (leicabiosystems.com). We see 7 different reagents utilized in the staining process. This does not even account for reagents used in the histology lab fixation process, to create the blocks

of tissue from whence slices are placed on slides and stained. As the Best Practices indicate, many aspects can impact the staining results and thus reading and interpretation of the slides for the test result reported. Would each result reported from such slides expect to have 7 different UDIs for each reagent(test kit) stored and mapped in the LIS or Anatomic Pathology LIS? Then transmitted and messaged to other HIT, whether the EHR or perhaps a reference laboratory? What if results and values from these slides indicate cancer? Would the cancer registry systems need to support these with their results (also see USDCI + comments on cancer data elements)? How about the EHR, clinical trials systems, research systems, etc.? What if these results were from a community hospital and the results need to be shared with an academic cancer center for further diagnosis or treatment decisions? As you can see there can be widespread impact across different HIT for different purposes.

6. In blood bank, a "simple" type and screen" may involve many reagents for the single blood type result reported, when one considers both the backward and forward typing processes where sera and antisera are used and that doesn't even account for more challenging case workups where additional reagents (testkits) may be involved. Multiple screening cells (reagent (test kit)) for antibodies are often used and each may have its own UDI, which are part of the "screen" portion of the results. See antibody-panel-l.jpg (1024×768) (slideserve.com) If a patient had a positive screen result for a "Little e" antibody (5th from the left), would all 10 screening cell UDIs as they are different "reagents" / test kits be reported for the single result? Keep in mind a number of LISs may consider each "result" in he patient typing row as workflow steps, recording each, for billing purposes and documentation, but not having capability to LOINC encode them nor UDI encode them. They may not even report them external to the LIS, but the final interpretation or just the ABO/PH Blood Type if a negative screen (performed but no antibodies identified). How would UDI reporting occur (on both positive and negative screening results)?

vi. One consideration on the usability, ONC may wish to make is to consider a phased in approach. The structure and modeling of tests in the high volume automated clinical laboratory will be quite different from pathology and genomics laboratories where many test kits/reagents may be involved in results. Many of the automated IVD vendors have UDIs for their test results. ONC may wish to consider a pilot to assess UDI availability and applicability across different laboratory areas as some may be much easier to implement and sooner, rather than later.

vii. Clear criteria need to be developed with a scope on use. For example, if 10 or 15 or 25 UDIs are involved, it would be too burdensome on clinical laboratories to apply and downstream HIT to support. Some have requested UDIs for quality control and calibrators to be reported for these reagents. While these are important for test quality and tied to many CLIA test system requirements, they would be too burdensome and costly for laboratories to try to include. ONC and other federal partners are strongly discouraged from this level of requirement for device identifiers/UDIs.

Thank you for your consideration of these laboratory focused comments during Medical Laboratory Professionals Week 2024 and their impacts on laboratory professionals providing quality, safe patient care across the country in a variety of laboratory settings such as small independent laboratories, reference laboratories, physician office laboratories, government laboratories (CDC, DoD, VA, etc.), public health laboratories (state, federal and local), blood banks, critical access hospitals, and academic medical center laboratories.

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