COLLEGE of AMERICAN PATHOLOGISTS

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The College of American Pathologists (CAP) appreciates the opportunity to comment on *A Shared Nationwide Interoperability Roadmap*, released by the ONC in January. As the leading organization with more than 18,000 board-certified pathologists, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. The CAP's Laboratory Improvement Programs, initiated 65 years ago, currently has customers in more than 100 countries, accrediting 7,600 laboratories and providing proficiency testing to 20,000 laboratories worldwide.

INTRODUCTION

The CAP supports the high-level goals of the Interoperability Roadmap. The CAP believes that the widespread adoption of interoperable EHR systems will improve health care quality and increase the efficiency of care, benefiting physicians, patients and payers alike and enabling vitally important new coordinated care models.

It continues to be the case that the vast majority of pathologists' practices use laboratory information systems (LISs), not certified EHRs. LISs are highly specialized systems that are required and engineered specifically to support laboratory operations in pursuit of patient testing and interoperability with EHRs. Further, LISs are focused on managing data relative to biospecimens and subsequent diagnostic testing, while in EHRs documentation relative to patient encounters is the focus. Most eligible providers (EPs) and hospitals will need to rely on data that pathologists and their laboratories generate. Thus, as LISs have special functional and interoperability requirements that differ from EHRs, ONC should ensure that regulations and certification are applied to LISs rationally.

CAP appreciates that the Nationwide Interoperability Roadmap describes a path for achieving the Federal Health IT Strategic Plan's second goal, i.e., advance secure and interoperable health information. We support standards and vocabulary development efforts and have been intimately involved in several ONC laboratory standards projects. Further, CAP is the original creator of SNOMED Clinical Terms® (SNOMED CT®).

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Currently, the College offers standardized cancer protocols via the CAP Cancer Protocols and Cancer Biomarker Reporting Templates.

In addition, we are encouraged with discussions regarding the implementation and use of LOINC and UCUM (Unified Code for Units of Measure). However, these standards, in addition to SNOMED CT, have not been widely implemented in laboratory settings. SNOMED CT has a longer history with pathology, but even that terminology is not commonly used outside of anatomic pathology. We think it is important further field testing of SNOMED CT, LOINC and UCUM be conducted to fully understand the capabilities and limitations of each and to determine the extent and correctness of use across enterprises.

While CAP agrees that both private and public stakeholders need to take immediate action to improve the interoperability and safety of health IT, we believe the Roadmap is unclear as to how these actions will be prioritized or what role each stakeholder should play. Additionally, there are conflicting sections where the ONC states they feel action should be taken by the private sector, yet within the same section, ONC lays out prescriptive actions they will take by pushing federal reimbursement and policy levers. This theme is threaded throughout the document.

We include comments on specific sections of the Roadmap below.

EXECUTIVE SUMMARY

Principle-Based Interoperability: Working Toward a Long-Term Vision with Near-Term Wins

The Roadmap states that it "focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017". CAP believes that 2017 is too short of a timeframe to accomplish the vision and recommends that ONC extend the proposed timeframe based on current functional capabilities.

The ONC Data Brief titled *Health Information Exchange among Clinical Laboratories* reports that "Two-thirds of clinical laboratories reported the capability to send structured test results to an ordering practitioner's EHR. However, one in five laboratories with this capability did not report exchanging structured test results. When examining the electronic delivery of structured test results based upon the volume of test results sent, we estimate that over half (58 percent) of test results that were processed in 2012 by hospital and independent laboratories were sent electronically to ordering practitioners. The two most common challenges reported by clinical laboratories for sending test results electronically in a structured format were high subscription rates for exchange services providers (19 percent) and the lack of harmonization of industry accepted

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standards (17 percent)."[1] Thus, even within the clinical laboratory, there continue to be issues with electronic exchange of clinical structured data and more time will be needed to establish the necessary capabilities and standards for national interoperability.

Current Context

CAP agrees that HHS should "consider where additional guidance may be needed to clarify the current legal framework, including Health Insurance Portability and Accountability Act (HIPAA) Rules, to effectively support individual privacy in a learning health system". Many security and privacy considerations in HIPAA are out of scope and archaic and may cripple innovative technologies and HIT business models. Further, we believe that standardizing the best practice form, content, and usage contexts of data use agreements should be part of the clarification of HIPAA.

Critical Actions for Near-Term Wins

We recommend that ONC consider alternative standards besides C-CDA 2.0, such as ONC's Structured Data Capture model which does not allow data conversions and forced coding for transmission purposes. SDC is a model that allows software to implement the technology once, and then it can be used for future content without the need for re-programming.[2]

ROADMAP INTRODUCTION

Interoperability Vision for the Future

We agree with the Care Providers listed on page 17, and recommend that these other authorized individuals and institutions be specifically called out: FDA, CDC, central cancer registries, public health departments, including local health departments. These institutions may not be intuitively thought of when reviewing this list.

Why a Learning Health System

We find Figure 4: The Health IT Ecosystem as a Learning Health System to be confusing. The diagram seems inaccurate in many places and adds little to our understanding. For example, CDS is not generally targeted at patients, but rather to physicians who can interpret the often complex recommendations. There may be algorithms that generate recommendation support appropriate for patient consumption, but this is not the usual usage of the term. CDS for patients potentially can result in unintended adverse consequences and it must be studied and optimized for every

[1] http://www.healthit.gov/sites/default/files/onc-data-brief-14-testresultexchange_databrief.pdf

[2] D'Amore, J. D., Mandel, J. C., Kreda, D. a, Swain, A., Koromia, G. a, Sundareswaran, S., … Ramoni, R. B. (2014). Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative. Journal of the American Medical Informatics Association : JAMIA. doi:10.1136/amiajnl-2014-002883

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disease and patient population before putting it into practice. For these reasons, we recommend that ONC not include this figure.

A SHARED NATIONWIDE INTEROPERABILITY ROADMAP

Rules of Engagement and Governance

Shared Governance of Policy and Standards that Enable Interoperability

We request clarification of the following statement: "The public and private sectors also must establish a mechanism for compliance and accountability to governance criteria. In instances where the process has established consensus criteria that require additional reinforcement, ONC or other federal agencies will consider creating implementation specifications for the criteria that could be adopted through existing public programs." Does this statement refer to the possibility of enhanced certification programs, voluntary or required?

In regards to patient access to their laboratory results, we believe that more thorough investigation of possible scenarios should be further explored. For example, how will individual access and correction by patients or other individuals be monitored and controlled, if allowed? Will individuals/patients be permitted to annotate or alter a laboratory test result? Mandating short time frames for release of certain types of results (e.g. surgical pathology) can lead to patients seeing potentially life-changing or complex results prior to their physician seeing them and/or counseling them about it. This can lead to undue patient suffering.

Supportive Business, Clinical, Cultural and Regulatory Environments

A Supportive Business and Regulatory Environment that Encourages Interoperability

While duplicate laboratory and imaging tests could be wasteful, there is some value in ensuring that correct tests are undertaken, especially if they have not been previously. This can save downstream costs that may end up being much greater than the direct savings from reduction in such tests.

Pathologists have continued to be an integral part of care coordination under new value-based payment programs. As EHRs and HIEs become more common, a key role for pathologists is to design the format for laboratory results in the EHR and HIE making the format as actionable as possible. As laboratory data stewards, pathologists in these new payment models either have taken, or are looking to take on, a leadership role in making data more accessible and more actionable by other physicians throughout the care team. As HHS tests new models of care, we believe that medical professional societies should be engaged to standardize content, develop reimbursement models and related quality measures and to promote uptake.

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CAP believes that new payment models will depend on robust HIE that is multi-directional and interoperable so that the laboratory is not just viewed as a source of data but instead as follows:

Pathologists' easy access to patient data across the patient's EHR; and
Other clinicians' easy access to readable and actionable data from the laboratory.

Indeed, a CAP White Paper, *Contributions of Pathologists in Accountable Care Organizations: A Case Study*[3] found that key to ACO's success is a "health information technology system that allows providers to access information about the patient across different care setting and allows for implementation of the payment and care delivery reforms." Importantly, the paper also notes that in settings with robust coordinated care and HIE, the laboratory data is used to implement population health management programs, communicate and assess the effectiveness of standardized laboratory order sets, and present laboratory results in a way that makes it easier and more efficient for the clinician to provide appropriate care to the patient. In their current operations, pathologists typically utilize LISs and anatomic pathology information systems (APIS) that enable them to receive test orders, track test status, and report test results and provide interpretive reports. These test results and interpretive reports are then typically transmitted by interface in the EHR.

Individuals are Empowered, Active Partners in Their Health and Health Care

In a previous section, the Roadmap defines a learning health system as focusing on improving "the health of individuals and populations" and "generating information and knowledge from data captured and updated over time – as an ongoing and natural by-product of contributions by individuals, care delivery systems, public health programs and clinical research…" whereas in this section the Roadmap states "a learning health system is person-centered…". These definitions seem at odds with each other, and we request that the ONC further clarify the definition of an LHS.

Care Providers Partner with Individuals to Deliver High Value Care

We appreciate that the Roadmap calls for providers to engage with an expanded set of interoperable workflows in Table 4, Category D4. However, we recommend that ONC add Electronic Public Health Reporting and Submission, including reporting to cancer registries to this category. This would enhance workflows for providers and would help to improve the overall health of the nation by electronic timely reporting.

CAP requests clarity on how incorporation of interoperability into the training of new providers and into continuing professional education would enhance the mission of interoperability for health care.

[3] http://www.cap.org/apps/docs/advocacy/white-paper.pdf

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Certification and Testing to Support Adoption and Optimization of Health IT Products and Services

Stakeholder Assurance that Health IT is Interoperable

We note with interest the following statements: “A diverse and complementary set of certification and testing programs will need to be in place to achieve a nationwide learning health system…” If ONC pursues certification of subspecialty systems, we strongly encourage that the appropriate subspecialists are included in the development the certification criteria.

Core Technical Standards and Functions

ONC should recognize and support the efforts being undertaken by Integrating the Healthcare Enterprise’s (IHE) Laboratory domain with regards to the completed Laboratory Analytic Workflow (LAW) profile and the Laboratory to Clinical Communication (LCC) profile (in development) and encourage the testing (via Connectathons) and use of these profiles by the medical laboratory industry members.

Consistent Data Formats and Semantics

We agree with the statements that “electronic health information is not sufficiently structured or standardized and as a result is not fully computable when it is accessed or received” and “The meaning of information must be maintained and consistently understood as it travels from participant to participant.” This is particularly evident in anatomic pathology reports. However, at this time, the complexity of anatomic pathology, genomics and some clinical pathology reports do not readily lend themselves to standardized structured reporting, other than for cancer reporting. As a result, there is a need to support flexible means of displaying and formatting complex pathology (molecular, etc.) reports; for instance, through the support of PDF. Patients have been harmed by serious formatting issues which lead to misinterpretation when reports have crossed to electronic health records and been reformatted. However, laboratory information systems and electronic health records should also allow structured information in a PDF to also be transmitted as discrete data in addition to the PDF. This will help electronic health records retain their abilities to consume the information in a way that may promote safe secondary uses of the data. Work needs to continue for these types of cases before an agreed upon standardized structure is considered final.

CAP agrees with the statements “public and private stakeholders should advance standards that are scalable, high performing and simple” and “Semantic interoperability is the ‘ability to automatically interpret the information exchanged meaningfully and accurately in order to produce useful results as defined by the end users of both systems.’ This includes, but is not limited to: Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) for problems or conditions, RxNorm for medications and

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medication allergies, or Logical Observation Identifiers Names and Codes (LOINC) for laboratory tests and CVX for immunizations."

The requirement for the use of LOINC for laboratory orders is certainly not simple. Many laboratories do not have sufficient expertise or time to identify and maintain the proper LOINC codes in the laboratory information systems that are expected to be transmitted to the EHR. It is also unclear to what level of detail LOINC codes should be assigned in order to be useful for data analysis. Further field testing using LOINC across a wide range of clinical labs needs to be conducted to better understand the nuances of sharing what is considered comparable LOINC codes. We also recommend that LOINC codes should be provided by the manufacturers of the tests or the instruments which run those tests.

Regarding the Common Clinical Data Set on p. 80 of the Roadmap, in order to definitely identify a patient, we recommend the consideration of incorporating primary (biological) identification of patients to ensure true interoperability. A person's identity can only be established by who he/she is - biologically. A number of robust, reliable biometric identifiers are available. We should be identifying, and matching, patients based on their biometrics. Two unrelated patients with identical names and birthdates (a common occurrence) will be clearly distinguished by their biometrics. On page 95, ONC refers to biometric identification of patients but fails to identify biometrics as the primary way we should be identifying patients. Instead, the Roadmap refers to an "additional identity attribute". CAP believes that biometrics should be our primary patient identifier. Well established biometric identifiers include fingerprint, iris pattern, face recognition, palm vein pattern, and several others.

We agree with the following statement: "However, stakeholders have also made it clear that there remains value in the documentation and exchange of some unstructured data, such as a physician note that is typically documented as free text in a system."

To reiterate, the ability to collect, transmit and store unstructured data is especially important for genomic reports as well as numerous anatomic pathology reports. Software vendors must continue to support these types of unstructured data and be able to correctly display the information in the EHR.

While ONC acknowledges the role of IHE as a collaborator in many ways, we suggest specifically adding IHE activities and profiles as a reference to others. CAP is most actively involved in IHE Laboratory and IHE Anatomic Pathology profiles and activities which are developing technical profiles pertinent to interoperability. We also suggest including the following ONC S&I Framework initiatives in the list:

- ONC S&I Framework – a LOINC Order Code Initiative
- ONC S&I Framework – EHRs Functional Requirements IG LAB

Regarding "ONC S&I initiative - Structured Data Capture (SDC) including, but not limited to, a standard for the structure of Common Data Elements (CDEs)", we do not think this

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is a truly accurate description of SDC - CDEs use the ISO 11179 specification which is optionally used by SDC, but is external to SDC.

CAP recommends that ONC's Structured Data Capture Initiative should continue to be further advanced for inclusion as a component of nationwide interoperability. SDC allows standardized data sets to be completed in data entry forms (DEF) at the point of care, and to be transmitted unchanged to another system, so that the data sets and DEFs can be used in their original (unchanged) forms, exactly the same as at the point of care.

We recommend that ONC consider adding the following statement to the 2015-2017 timeframe in Table 10: Critical Actions for Consistent Data Formats and Semantics, J4. Vocabulary approach:
All laboratory test kit manufacturers and laboratory instrumentation manufacturers should specify LOINC and/or SNOMED CT value sets required for reporting applicable testing results in the package insert and/or electronic reference material for the tests.

Secure, Standard Services

We agree with ONC's statements regarding the development of public API's for national interoperability. We emphasize that there be publically-accessible documentation for the standard APIs that should be centrally stored and made available to all health IT developers.

TRACKING PROGRESS AND MEASURING SUCCESS

CAP believes it is important to have metrics to monitor and measure success. An available data source to measure progress of sending and incorporating standardized structured data could be the state and national cancer registries programs. CAP is involved in a project with the California Cancer Registry to standardize structured cancer data capture transmission, receipt and analysis with the expectation that the registry database can then serve as a center for cancer health information exchange and analysis. This has the potential to serve as an example for a nationwide rollout and implementation.

Gaps in Measurement

ONC encourages measures that possess some key characteristics and uses the term "person-centered" as one of these characteristics. We request clarification from ONC on the meaning of this term and recommend a definition be given. We also find this statement confusing: "Identifies important results that can be used to improve health, or that have meaning for individuals about how well the system is moving around the data about them" and request clarification on the intent of the message.

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Measurement Actions

The Roadmap states that "ONC, after soliciting feedback from stakeholders and the public, will update measurement strategy to reflect feedback and determine a core set of measures that will be used to track progress over the short-term."

CAP believes a core set of measures will be difficult to complete because such a set of measures will vary for every disease type. For example, cancer reporting requires a separate panel of data elements to be collected for most every cancer type. The determination of such data element should be made by expert panels supervised by professional medical organizations. We have considered the technical mechanisms for standardizing, collecting, transmitting, and querying such information and have been actively participating in ONC's Structured Data Capture initiative. We recommend adoption of SDC for such complex data sets that tend to change rapidly over time.

Although professional organizations may be able to provide content standards, it is inadvisable to introduce a large set of new content standards precipitously for the purposes of assessing clinical quality. Such standards need to be phased in according to a timeline that is determined in consultation with professional medical organizations.

APPENDIX H: PRIORITY INTEROPERABILITY USE CASES

CAP recommends the following use cases be prioritized:
Priority #1:
41. Providers and patients receive electronic laboratory results from laboratory information systems (LISs) inside and outside their organization

Priority #2:
13. Providers and patients have access to genomics testing and data which, when combined with clinical information about patient goals allows the personalization of care and therapies.

Priority #3:
#37 – Individuals regularly contribute information to their electronic health records for use by members of their care team.

Priority #4:
27. Data for disease surveillance, immunization tracking and other public health reporting are exchanged automatically.

In addition, CAP recommends cancer registries as a new use case for ONC to consider in that currently cancer registries receive data that is not standardized.

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CONCLUSION

The CAP appreciates the opportunity to comment on this draft version of the Roadmap and as a leading laboratory organization looks forward to working with ONC as it finalizes the Roadmap to not only address pathologists' concerns but also to advance interoperable EHRs to improve care for our patients. Should you have any questions on our comments, please contact Mary Kennedy, Director, Clinical Informatics Initiatives at (847) 832-7261 or via email at mkenned@cap.org.

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