

POSITION STATEMENT

Interoperability of Clinical Laboratory Results

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Introduction

With the widespread implementation of electronic health records (EHRs), many important details from a patients' clinical encounter are now recorded. This documentation has revolutionized medicine by empowering healthcare institutions to track patients' care via clinical and billing data. Easy access to these data has improved patient outcomes and reduced healthcare costs by enabling better-informed clinical care decisions.

Despite these developments, effectively sharing laboratory data remains a difficult challenge that will require the collaboration of stakeholders across the healthcare spectrum, bolstered and encouraged by thoughtfully developed federal policy and incentives.

Background

The federal government is implementing reforms that require payers and providers to remove barriers for patient data exchange across the healthcare delivery system. The 21st Century Cures Act cleared the ground for these reforms by mandating the creation of a regulatory framework that requires healthcare providers to grant patients greater access to their personal health information. To facilitate this objective, the Office of the National Coordinator for Health IT (ONC) has been tasked with the identification, assessment, and promulgation of the best available interoperability standards.

To be useful for interoperability, laboratory data must contain consistent and sufficient information and move through numerous data systems without the loss of meaning. A single healthcare provider may

ADLM POSITION:

The Association for Diagnostics & Laboratory Medicine (ADLM) supports efforts to improve the interoperability of laboratory test results between healthcare organizations and relevant stakeholders. Achieving broad interoperability will improve patient safety and clinical care efficiency, support public health, and facilitate groundbreaking research and innovative new diagnostics and treatments.

use different laboratory analyzers, laboratory information systems (LIS), and electronic health record (EHR) systems when treating a patient. These systems often do not consistently generate or capture the same information or transmit it in a standardized format. Throughout each step of the process, errors can be introduced either through human error, or simply because different systems are used by different organizations.

These gaps, exacerbated by the growing complexity of the healthcare system, have made achieving the interoperability of healthcare information a complex challenge

that goes beyond standardization of data formats. To ensure consistency across functions and between organizations, significant incentives will be required to compel stakeholders to adopt a common syntax for how data is recorded, transmitted, and interpreted.

Considerations

Data Elements

Most laboratory results are produced by a variety of instruments and methods. Test result report formats can range from paper documentation of manual tests to the transmission of electronic results by fully automated instruments. Many tests, performed with different methods or instruments return the same essential result, but in a different format or on a different scale. Similarly, different laboratories and clinicians may lack common standards for certain terminology and test names. For example, the term “Hemoglobin A1c” may be variously notated as “A1c” or “HgbA1c”. Harmonization of results and terminology are therefore crucial to allow for this information to be combined or compared.

A related issue is information about the test and how it is performed. Regrettably, data describing these differences are not always collected or reported in a consistent manner. Achieving interoperability will require that stakeholders define the necessary, standardized data elements to include with each test result and ensure that information can be aggregated and compared for research, analytics, and public health purposes. Metadata including the origin of a result, as well as information such as Unique Device Identifiers (UDIs), are crucial to achieve this goal.

Data Format

Currently, there is no systematic or consistent manner in which identical data elements can be structured even within the same standards. The *Logical Observation Identifiers Names and Codes (LOINC)* is a commonly used standard that can label the type of test performed. However, this coding system does not identify the specific testing method utilized by a laboratory. For example, LOINC can say if a test was performed using mass spectrometry, however not all methods under this category are the same. LOINC is unable to adequately describe those differences.

Such differences can be specified using UDIs, including the testing method, instrument, and calibrator material. UDIs and LOINC codes can be mapped together using the LOINC In Vitro Diagnostic (LIVD) standard, which was employed to monitor SARS-CoV-2 test volumes and results. Data standards exist that deal specifically with transmission of healthcare information, such as HL7/FHIR1, which

can facilitate exchange between each point of the provider ecosystem [\(1\)](#).

Unfortunately, the significant flexibility in how information can be structured within these standards paradoxically means that those interpreting the data cannot rely on a reasonable set of assumptions about what it means. This disconnect leads to limitations in the interpretability of data post-exchange, essentially creating a barrier for how that information may be used later. Overcoming this hurdle will require coordination between healthcare providers and other stakeholders to ensure the same information is structured and interpreted consistently.

Transmission and Compatibility

Ensuring the compatibility and fidelity of information being transmitted between organizations and use-cases is crucial for the purposes of interoperability. Progress has been made by EHR vendors to facilitate data sharing across organizations, and tools are being used to integrate health records across organizations that use the same EHR vendor [\(2\)](#). However, reliance on any single standard for laboratory data may prove unrealistic.

In order to further move the healthcare field toward the goal of interoperability, federal agencies should incentivize common data use practices and standards to underpin and connect all EHR or informatics software vendors’ and IVD equipment manufacturers’ new products. This could be accomplished by working with healthcare providers, manufacturers, and informatics vendors to identify the standards and practices appropriate for specific use cases and determine any adjustments needed to make the standards compatible. Coordination and policy incentives would be necessary to promulgate updated specifications and promote its adoption among relevant stakeholders.

Challenges

The benefits of sharing data may be insufficient motivation for many organizations inclined to retain it for proprietary purposes. Establishing a framework that fosters coordination is paramount to achieve the benefits of broad interoperability. Better informed clinical decisions and patient outcomes will yield long-term benefits by lowering healthcare costs and reducing duplicate or unnecessary testing and

other inefficiencies. With the input and participation of healthcare stakeholders, regulatory incentives to promote interoperability would benefit both patients and providers.

ONC has responded to this need by developing a rule that would prevent providers from blocking the transfer of information to other organizations except under specific circumstances (3). This rule could be bolstered though a proactive framework that promotes data sharing through financial or other incentives. Institutions that make interoperability a priority in their long-term strategic planning will be well positioned for future success if federal regulations prioritize interoperability as part of the shift toward value-based incentives for reimbursement.

Positions

ADLM supports efforts to promote greater interoperability of healthcare information. Clinical laboratorians are often at the forefront of the healthcare data ecosystem and can play a central role in the design, implementation, and testing of new approaches and tools to achieve interoperability. Richer and more consistent sharing and reporting of laboratory test results would improve understanding for patients and clinical providers, significantly improve patient safety and clinical care efficiency, support public health, and facilitate groundbreaking research and innovative new diagnostics and treatments. Achieving this goal will require significant coordination among stakeholders across the healthcare delivery system, including the federal government, industry, and professional societies.

Federal Policymakers

- ▶ Congress should continue to support the harmonization of clinical laboratory test results to ensure that information can be aggregated and compared across different settings
- ▶ HHS should fund pilot programs that support interoperability and include assessments of quality of care and the burden on clinical laboratories.
- ▶ HHS should incentivize common data use practices and standards for EHR or informatics software vendors' and IVD equipment manufacturers
- ▶ HHS should prioritize interoperability as part of the shift toward value-based incentives for reimbursement.

Healthcare Stakeholders

- ▶ Healthcare providers, manufacturers, informatics, and In-vitro diagnostic vendors, as well as payers should collaborate to establish and enforce a common framework for information standards and practices that are appropriate for specific use cases in healthcare settings
- ▶ Stakeholders should engage with federal agencies to shape effective policy incentives to promote the adoption of updated data standard specifications
- ▶ Stakeholders should collaborate in establishing standardized data elements, including test names, that ensure that information is structured and interpreted consistently across different settings and organizations.

References

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