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Opinion

Interoperability: COVID-19 as an Impetus for Change

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Introduction

With lack of a clear nationally directed testing response, individual healthcare delivery organizations (HDO) have had to collectively perform the majority of SARS-CoV-2 testing in the USA. Independently, each institution has overcome numerous testing obstacles, while under considerable pressure to provide testing to the public. We have worked tirelessly to meet the exponential increases in demand, but broad access to testing remains limited, particularly at the scale needed to ensure a safe return to routine life.

Since the beginning of the pandemic, the international public health response has considered laboratory testing and rapid case identification to be paramount in the control of COVID-19 outbreaks (1). Accordingly, the number of available in vitro diagnostic (IVD) SARS-CoV-2 assays receiving Food and Drug Administration Emergency Use Authorization (FDA EUA) has increased dramatically since March 2020, several of which are CLIA-waived point-of-care (POC) and IVD devices (2). While the EUA pathway has expanded national testing capacity, pre-existing limitations of modern healthcare interoperability have made it difficult to leverage this for meaningful public health interventions (Table 1). The COVID-19 pandemic has highlighted the challenges that are involved with the documentation, distribution, and follow-up of diagnostic test results across disparate entities and, ultimately, has exposed an unfortunate duality regarding the interoperability of medical data within the USA: (*a*) to coordinate an urgent public health response healthcare interoperability is exceedingly important, and (*b*) healthcare interoperability in its current form is exceedingly lacking.

For example, consider an academic, CLIA-certified laboratory that is contracted by the state to provide COVID-19 testing for a nonaffiliated skilled nursing facility (SNF). In theory, the laboratory has the operational capacity to receive specimens and perform testing. However, this only covers the analytic phase of the process, leaving important unanswered questions for the pre- and postanalytic phases: (*a*) How is the SNF interfaced with the LIS/EHR so that tests can be ordered, collected, and barcoded? What if the SNF does not have an EHR? (*b*) How should the results be reported? Fax? Secure text message? Email? Patient Portal? Electronic interface? (*c*) Where should the test results be reported? To the patients only? To providers or nurses at the SNF? To county public health officials? Other HDOs? (*d*) Do current laboratory resulting technologies even enable such flexibility in reporting practices? (*e*) Last, given the observed variability of test performance across platforms and methodologies (e.g., specimen type, collection method, pooling of specimens, and POC versus main-laboratory testing), what coding information [e.g., logical observations identifiers, names, codes (LOINC), systemized nomenclature of clinical terms (SNOMED-CT), unique device identifier (UDI), etc.] can be incorporated into result reports that would allow patients and data-trading partners to accurately judge if a test result is sufficiently reliable for their purposes? (2, 3). It is arguable that solutions to these questions fundamentally depend on the exchange of data between disparate electronic systems. Indeed, throughout the pandemic we have seen varieties of interoperability components leveraged to address these challenges and support enterprise-level testing initiatives, all with variable success.

COVID-19 and Current Interoperability Efforts

In the early months of the pandemic, many HDOs could only order SARS-CoV-2 testing as send-out testing to state public health laboratories, largely because the federal regulatory agencies prohibited use of viral detection using laboratory developed tests (4). In many cases, this process was paper-based for orders and/or results, with uni- or bidirectional electronic interfacing between state and local laboratories being the exception, not the norm. Because state laboratories were inundated with high demand, many chose to batch their result transmission—e.g., faxing results the morning after overnight testing was completed. While this streamlined the resulting process for public health laboratories, it created substantial delays for providers receiving results and downstream medical decisions required for prompt

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patient management. Over the course of the pandemic, some improvement has been made in this regard, but still there is considerable reliance on fax-dependent processes for offering COVID-19 testing to entities outside of prepandemic delivery networks.

Conversely, Electronic Laboratory Reporting (ELR) interfaces are increasingly being used by HDOs for automated transmission of reportable disease results to local public health officials. ELRs are an example of a "direct interface," wherein results are transmitted point-to-point via a secure connection, commonly using messaging standards, such as Health Level 7 (HL7) or Fast Healthcare Interoperability Resources (FHIR). Direct interfaces are a powerful tool for communicating results between disparate entities but require substantial laboratory resources to build and are not easily scalable. The overhead of creating and populating new data feeds was encountered nationwide following recent mandates by the HHS to report COVID-19 related "ask at order entry" questions. These provisions placed stress on HDOs and laboratories to capture and transmit these novel fields, requiring a reallocation of resources that were already exceedingly limited (5).

A centralized and more scalable iteration of direct interfaces is the health information exchange (HIE) (6). An HIE generally requires only a single connection to each HDO for laboratory result information sharing. Currently, incentive programs exist to encourage laboratories to participate in local, state, or regional HIEs, with participation likely to increase as lessons are learned from COVID-19. However, HIEs require large resource investments and broad community interest among participating stakeholders. Subsequently, HIEs may not be widely available to leverage for data sharing during the current pandemic.

Vendor-specific HIEs (e.g., Epic CareEverywhere) and patient portals (e.g., Epic MyChart) also have been heavily leveraged during the pandemic. From a regulatory standpoint, the College of American Pathologists Laboratory Accreditation Program General checklist item GEN.41077 requires institutions to solicit laboratory director input on reporting external laboratory results in the primary reporting system (e.g., EHR). While traditionally addressed using an internal laboratory policy, external results have drastically increased in volume and now regularly bypass the LIS/clinical laboratories. Accordingly, the complexities associated with incorporating heterogeneous, outside laboratory results into the EHR becomes a broader institutional issue requiring both clinical laboratory and hospital leadership input. Further, a variety of technical solutions are required to ensure full information sharing, compliance with information blocking provisions, and to show data provenance standards are aligned with CLIA'88 (7). Even with full consideration of the aforementioned, it remains unclear from a laboratory or data-management standpoint what percentage of available COVID-19-related test results are captured by vendor-specific HIEs. HIEs in general rely on participation from all entities performing COVID testing, but there is currently no requirement to contribute. For vendor-specific HIEs, these data are further limited by the fact not all institutions use the same EHR vendor. Thus, a sizable portion of electronic health information (EHI) may be unaccounted for in a given institution's patient population, with no current way to audit for completeness.

Fortunately, some bright spots of innovation surrounding interoperability have emerged from the pandemic. Interoperability took center stage in New York State's response to the early pandemic, with the state and local government health departments collaborating with private tech companies and state-wide public and private laboratories to rapidly leverage technology expertise to deploy and communicate COVID-19 laboratory testing solutions (8, 9). In other areas of the country, HDOs were able to quickly setup ELRs, HIEs, or provider/patient portals to securely report results. However, this required substantial resources and strained information technology system infrastructure in coordinating the rapid expansion of a result reporting system at scale. At the start of the pandemic, it was clear that more centralized reporting mechanisms were needed to transmit clinical laboratory results and allow subsequent downstream actions (e.g., patient notifications) to be managed. However, this framework requires interoperability in the forms previously discussed, but that, for many regions of the country, was not preexisting or possible to develop given the current state of the available technologies.

Summary

Fundamentally, COVID-19 is a life-changing clinical use case demonstrating how interoperability is of enormous importance to the overall public good. It has become urgently apparent how our institutions exist in silos and are limited in the exchange of laboratory orders and results using the conventional approaches described here. We are hopeful that these realizations will drive healthcare interoperability into a period of resurgence, with particular emphasis on laboratory testing. Federal efforts such as the 21st-Century Cures Act (7) and Promoting Interoperability Programs are encouraging in that they are likely to bring interoperability to the forefront of laboratory operations and impact how laboratories receive and transmit EHI. However, initiatives set

Table 1. Common interoperability terms

Term	Definition
Interoperability	The ability of disparate computer systems or software to exchange data in an efficient and meaningful way
Electronic Laboratory Reporting (ELR) interface	The electronic transmission of data from laboratories to public health entities, primarily for the purpose of reportable conditions
Health Information Exchange (HIE)	A central data repository or network that facilitates the transfer of electronic health information (EHI) between all participating entities
Health Level 7 (HL7)	International messaging standard for the transfer of clinical and administrative data between software applications in healthcare
Fast Healthcare Interoperability Resources (FHIR)	A messaging standard that describes data formats and an application programming interface for exchanging EHI and electronic health records
Logical Observation Identifiers Names and Codes (LOINC)	International standard for coding health measurements, observations, and documents
Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT)	International concept-based system used to code and represent clinical content in a consistent terminology
Unique Device Identifier (UDI)	A unique numeric or alphanumeric identification code assigned to medical devices by the device labeler (e.g., device manufacturer)

forth by these provisions would benefit immensely from a multilateral focus and prioritization across nationally recognized laboratory medicine organizations and federal agencies. Laboratorians have a unique vantage point for assessing the shortcomings and complexities of data exchange within our field. With this experience, we can provide regulatory and governing bodies the valuable prescience needed to ensure a sustainable and meaningful direction for the development of future interoperability solutions.

Take Home Points

- Robust interoperability standards have been lacking to fully support public health testing initiatives in response to the COVID-19 pandemic.
- Local and national COVID-19 testing initiatives have utilized currently available interoperability technologies in a way that has highlighted areas in need of improvement.
- The COVID-19 pandemic has demonstrated that interoperability has major importance for the overall public good and should provide a large incentive for multilateral focus and prioritization within the laboratory medicine community at the national level.

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