Surmounting Barriers to Healthcare Data and Information: U.S. Case Studies

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Abstract

Objective: This article reviews the progress of healthcare interoperability in three separate case studies in the United States. Interoperability, in the context of this article, is "the ability to share information across time and space from multiple devices, sources, and organizations," as defined by the IEEE (Institute of Electrical and Electronic Engineers). This is followed by recommendations for future policy work toward improving the standardization of heterogeneous data in the healthcare setting.

Methodology: A literature review was conducted on established interoperability systems in healthcare based on information obtained from journal publications, government and academy reports, published materials, and publicly available websites. Examples of interoperable solutions adapted to systems were provided at three levels of healthcare interoperability, as defined by the National Academy of Medicine: inter-facility interoperability, intra-facility interoperability, and point-of-care interoperability.

Results: This review reveals that adopting existing interoperability standards to clinical settings, even when prudent and tailored to a specific application, may lack scalability. Broader tasks in interoperability require customized solutions in conjunction with standards adapted to each health information system's infrastructure and objectives.

Conclusions: The development of custom solutions may be simplified under the recent development of the Trusted Exchange Framework and Common Agreement (TEFCA) framework, which greatly reduces data exchange friction in many healthcare contexts. In addition, funding middleware architectures to mediate data exchange between separate healthcare organizations may also be an effective strategy for consolidating healthcare data and improving information exchange.

Plain Language Summary

Enhancing healthcare globally is a challenge that requires improved standardization and communication if we are to achieve better outcomes and value in healthcare investments. Interoperability in healthcare—the ability of two systems to exchange and use health information—is lacking in the United States healthcare system and is one of the most significant barriers to enhancing data accessibility and achieving a greater impact of ongoing parallel efforts to improve patient quality of care.

Recognizing the importance of this issue, governments and health authorities have played a large role in promoting standards and interoperability in healthcare. However, many of these efforts focus on isolated geographic areas, specific segments, or medical specialties of the healthcare industry. Examples include billing for healthcare services, medical devices, pharmacies, or the medical Internet of things (IoT).*

What is lacking is the ability of these efforts and the standards that have resulted from them to interoperate. To this end, the authors reviewed three key case studies of how interoperability efforts may fall short. They explored the unique solutions adopted in each case, evaluating each solution's efficacy,

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* IoT: physical objects with sensors, processing ability, software, and other technologies that connect and exchange data with other devices and systems over the Internet or other communications.

sustainability, and impact. The article then spotlights future policy trend which caters to the growing need for an overarching vision and mechanism that transcend domain-specific boundaries in the United States to help unify data assets scattered across heterogeneous health information systems.

The issue of fostering interoperability arises in many disciplines, industries, and fields, including computer hardware and software, telecommunications, finance, defense, e-governance, public safety, climate control, healthcare, and railways. In the context of computer-based systems used in different sectors of the economy, mechanisms for enhancing interoperability frequently evolve under the aegis of many professional organizations, such as those given in Table 1.

While the need for electronic interoperability is increasingly pronounced at local, regional, provincial, national, and international levels, the mechanisms for attaining such interoperability between organizations that have traditionally made their own decisions have evolved slowly.

The change, in several cases, is driven by crises. For example, during the Grenada War, pilots in the air could not communicate with the soldiers on the field as they were using different equipment and frequencies. After the war, a concerted effort was directed toward enhancing interoperability across the forces.[2] An analogous problem has occurred in healthcare, but the interoperability issue has increased substantially at multiple levels.

Methods

This review examines specific examples of interoperability efforts at three levels of healthcare interoperability, as illustrated in Figure 1:

• Inter-facility (macro-tier) interoperability
• Intra-facility (meso-tier) interoperability
• Point-of-care (micro-tier) interoperability

When performing the analysis, the definition of interoperability published by the Institute of IEEE was "The ability of two or more systems or components to exchange information to use the information that has been exchanged."[4] Interoperability was said to be achieved when "little or no reworking of the software to accommodate the new environment" is required and when the "behavior/benefits in the new setting…are identical to those seen in the original setting."[5]

Results: Initiatives Within The United States

According to the Centers for Medicare & Medicaid Services (CMS), "under current law, healthcare expenditures in the United States are estimated at around \$6.8 trillion by 2027."[6] However, almost 25% of current expenditures can be attributed to "wasteful spending."[7] Much of the "wasteful spending" stems from administrative complexity, pricing failures, fraud and abuse, failures of care coordination, failures of care delivery, and overtreatment. A large portion of the wasteful expenditures is avoidable by taking full advantage of new electronic health records (EHR) and (Internet of things [IoT]—concepts that have risen to prominence in recent years. Despite the expansion of EHR and IoT concepts within healthcare systems, effective use of these evolving concepts requires standardization and communication between them. Despite the increasing adoption rate of EHR nationwide, each organization may have different clinical terminologies, technical specifications, and functionalities. These inherent differences make it difficult to not only exchange but also utilize the data meaningfully.[8] Therefore, lack of interoperability is one of the biggest barriers to achieving a greater impact of ongoing parallel efforts in different countries and relieving much of the pressure brought upon the healthcare system by "wasteful spending."[9]

To help combat the obstacles to achieving data accessibility and interoperability in the United States, the National Coordinator for Health IT (ONC) introduced the State Health Information Exchange (HIE) Cooperative Agreement Program in 2010, in which ONC provided \$548 million to help states and territories facilitate the exchange of health information amongst health organizations within their jurisdictions and ultimately encourage the exchange of information across states.[10] Overall, 56 states, territories, and qualified State Designated Entities received funding to increase connectivity into disparate health organizations that otherwise may not have exchanged information, improve the quality and efficiency of care, and promote continuity of care across state boundaries.[10] This was a major step in moving toward developing infrastructure that can be leveraged to support nationwide information exchange and interoperability.

Each HIE is characterized by inherent challenges in the quest to achieve interoperability. Different systems and organizations use their local codes and various medical term classifications and determine the mappings from one to another. This can be a painstaking, expensive process.[11] Furthermore, the quality of data flowing into HIEs has often been questionable, as described by healthcare

Table 1. Academic, commercial, and governmental organizations responsible for establishing interoperability standards in their respective industrial sectors

Professional organization	Activity
The Association for Computing Machinery (ACM)	A US-based international non-profit professional society for computing. ACM is the world's largest scientific and educational computing society. It has established rigorous codes for upholding the ethical development and responsible use of computing technology
Institute of Electrical and Electronics Engineers (IEEE)	A professional association for electronics engineering, electrical engineering, and related disciplines
National Institute of Standards and Technology (NIST)	An agency of the United States Department of Commerce whose mission is to promote American innovation and industrial competitiveness. NIST's Systems Interoperability Group develops infrastructure to ensure the robustness of health IT systems[1]
International Organization for Standardization (ISO)	This independent organization develops standard numeric codes to ensure the quality, safety, and efficiency of products, services, and systems. In healthcare, ISO codes deal with everything from environmental and energy management to information security standards
International Telecommunication Union (ITU)	ITU, part of the UN, develops codes to maintain the quality of information and communication technologies. For example, its standards ensure the high-quality reception of TV and radio programs that are free-to-air or satellite broadcasted
World Health Organization (WHO)	The WHO sets standards for disease control, health care, and medicines to improve the quality of health services
National Electrical Manufacturers Association (NEMA)	NEMA publishes more than a thousand medical imaging standards to ensure safety and interoperability in the use of medical imaging equipment. They're known for establishing DICOM (Digital Imaging and Communications in Medicine), which specifies a centralized way to transmit, store, and process digital medical images
World Wide Web Consortium (W3C)	The W3C publishes recommendations to optimize the interoperability, security, and privacy of web standards, the tech used to build websites

professionals as "garbage in, garbage out," making the aggregated data unusable.[12] Unfortunately, some providers do not want to go through an HIE, making it difficult for state HIEs to serve as a source of truth for the patients they serve in their respective states.[11]

Inter-Facility (Macro-Tier) Interoperability Case Study: Indiana Health Information Exchange

The Indiana Health Information Exchange (IHIE) has one of the largest inter-organizational clinical data repositories in the United States. The IHIE has connections to 117 hospitals across 38 different health systems, provides access to data for nearly 50,000 providers, and houses the aggregated data for over 15 million patients in the state of Indiana.[13] Its patient-centric model enables clinicians from different health organizations to avoid redundancy and easily access high-quality data in Indiana. To accomplish this, the Integrating the Healthcare Enterprise (IHIE) leveraged the existing infrastructure by five major regional health information organizations (RHIOs) that operate in the state: Healthbridge, HealthLINC, Indiana HIE, Med-Web, and Michiana Health Info Network.[14]

Three of the five RHIOs in Indiana already had developed interoperability that streamlines handling clinical messages.[14] This served as a basic foundation to construct more advanced interoperability amongst the health information organizations to support IHIE. As a result, IHIE is capable of providing meaningful use options that cover the entire state. A data flow diagram of the IHIE is shown in Figure 2.[15]

One of the problems that IHIE encountered was that the structure of incoming clinical data varied based on the EHR system from which the data originated, in addition to differing patterns of how clinicians input the data.[16] The IHIE initially leveraged Consolidated Clinical Document Architecture (C-CDA) documents for specific applications, which became a bottleneck for broader consumption and utilization.

Ultimately, IHIE implemented a data management vendor's technology to not only extract data from numerous health organizations in the state but also standardize, normalize, deduplicate, and enrich the aggregated data to utilize the data to improve the quality of care effectively. To effectively exchange information in healthcare, there must be a central control of language that maps one healthcare terminology to another. This ensures that the data ingested can be utilized in a meaningful way. The United States Core Data for Interoperability (USCDI) was developed during the pandemic for this purpose.

The technology to cleanse, de-duplicate, and enrich the data flowing into IHIE works in the background to standardize codified data and extract discrete data from any unstructured text, such as a prescription for a medication. More standardization in the data helps reduce "noise" for clinicians, who can then utilize high-quality clinical data to care for their patients.

Intra-Facility (Meso-Tier) Interoperability Case Study: Lahey Clinic

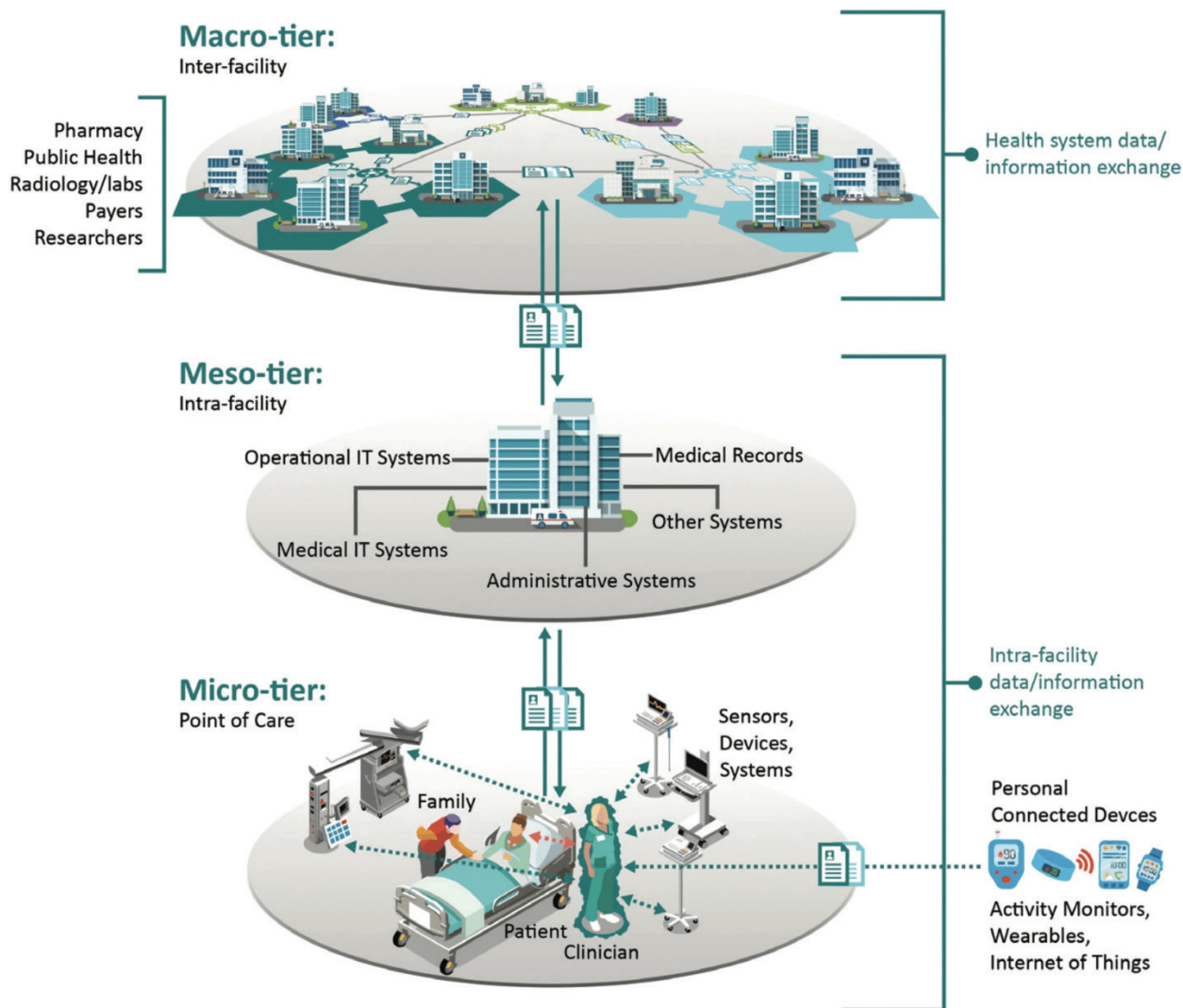The Lahey Hospital & Medical Center (formerly the Lahey Clinic [LC]) is a multispecialty group practice with

Fig. 1. Interoperability in the health ecosystem: inter-facility (macro-), intra-facility (meso-), and point-of-care (micro-) tiers.[3] National Academy of Medicine.

more than 1,400 providers. The department depended on imaging devices (e.g., visual field machines and optical coherence tomography units). These devices were manufactured by various companies and acquired at different times, resulting in specialists using different versions of the operating programs. Hence, managing images and attributing them to a patient and visit is difficult.

One major challenge LC's ophthalmology practices faced was that the clinical images were "confined in isolated databases associated with each instrument." Additionally, these databases were not consistently backed up in a fail-safe manner and were not integrated with LC's HIS to receive valid Abstract Data type (ADT) data, resulting in conflicting patient identifiers.

The LC needed a process for direct communication from one ophthalmic device to another, an access point where information could be stored/retrieved, and a valid association between a patient and their information.

Thus, LC implemented Medflow's standards-based image management system designed under the Integrating the Healthcare Enterprise (IHE) and Digital Imaging and Communications in Medicine (DICOM) frameworks. The software and hardware upgrades were costly, but the benefits derived from DICOM connectivity to the Medflow Management system were necessary.

With LC's new workflow, the higher-quality images are practically stateless and will still be available in the Enterprise Image Archive if the system is replaced. Furthermore, the images maintain meta-data of patient demographics, medical record numbers, and other useful information that remains identifiable even upon database corruption.

Point-Of-Care (Micro-Tier) Interoperability Case Study: The Oregon Clinic
The Oregon Clinic (OC) is an independent specialty physician organization with about 260 providers, 160
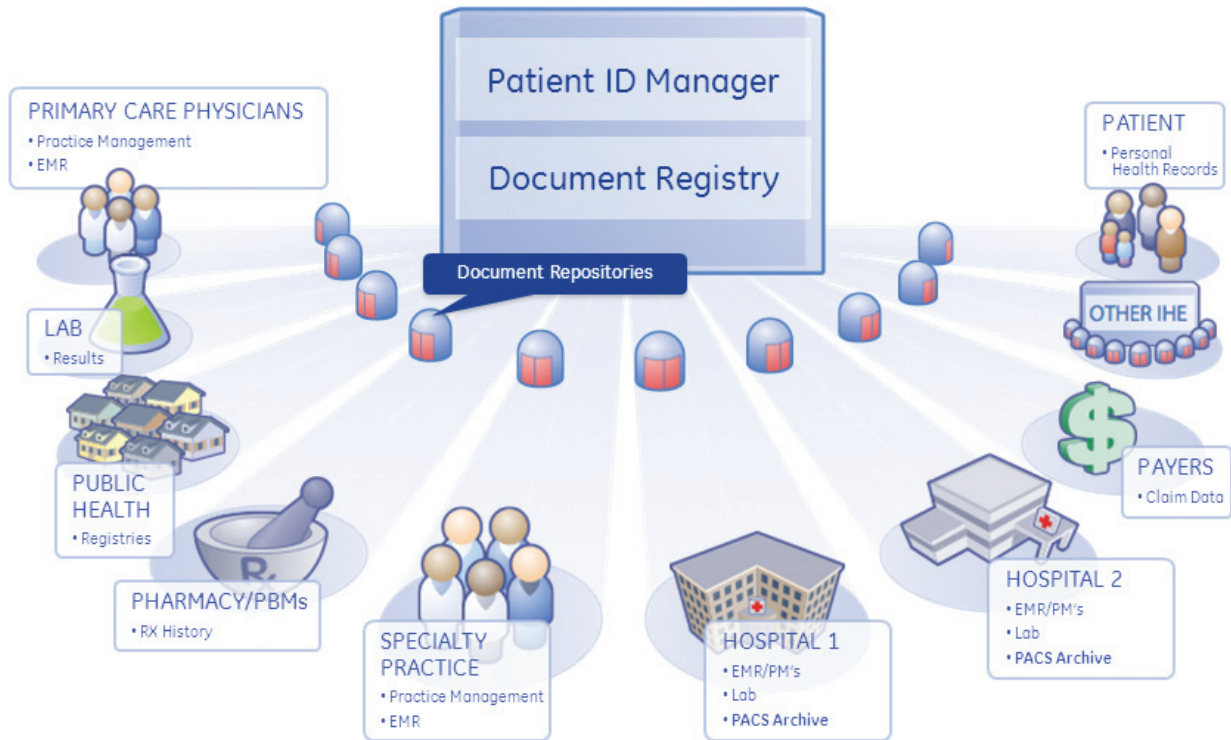
IHE Standards-based HIE

Fig. 2. Health information exchange data flow diagram.[15] HIE: Health Information Exchange; IHE: Integrating the Healthcare Enterprise.

physician shareholders, and 20 specialty practices. Many of its interoperability implementations have been applied to assist clinicians and patients at point-of-care. Accordingly, it is used as the case study for discussion here. In 2016, many hospitals within the clinic could not transfer information among each other on data query and exchange because they used different EHR platforms; the predominant platforms used were General Electric's Centricity and Epic. These providers would fax requests for documents and receive them days later, which increased the transfer of redundant requests. As a result, clinicians spent more hours sifting through faxed documents, and patients waited longer for their health records when visiting a different hospital within the clinic.

The OC could create an intermediate platform to interoperate between the two systems or replace all their current systems with Epic—a more costly and disruptive option. The clinic decided to move forward with Stage 2 of Meaningful Use with these goals:

1. Receive referrals as a C-CDA using direct messaging, and return a consult note as a C-CDA to the physician
2. Real-time bi-directional C-CDA exchange
3. Asynchronous provider-to-provider (P2P) communication

Collaborating with Epic, OC first developed a communication standard (SSL [Secure Sockets Layer] connections with IHE standards) between their hospitals and local healthcare system partners, Legacy and Providence. They also worked on C-CDA exchange with GE Healthcare and Qvera. Many specialist providers, however, were unsatisfied because data were still not readily accessible. Accordingly, OC began to engage them in the process by continuously asking for feedback throughout the implementation process until responses were predominantly positive. Furthermore, a key feature of the Qvera Interface Engine (QIE) that OC adopted is the inclusion of a workflow-driven forms module that allows user input; physicians can refine their query and request only the information that they want because the module turns the interface engine into a pinpoint search engine and routes documents into the workflow of the clinician's native EHR.

The OC successfully implemented its first goal of using C-CDA referrals using Direct Messaging, which reduced the burden of collecting data and verifying patient visits. The workflow is as follows: an external physician sends a C-CDA referral to a specialist at OC; a referral receipt message is sent back to the physician upon retrieval; the consult note is sent back to the physician if the query of the EHR

returns the correct appointment type. The second goal of bi-directional, real-time C-CDA exchange was integrated after GE, Epic, and Qvera utilized Carequality to publish clinical documents to a shared registry, where clinicians could query/retrieve documents from their respective repositories. The bi-directional sharing was possible through the IHE cross-gateway sharing infrastructure external communication adapter (XCA) profile. The last goal of asynchronous P2P communication still needs to be completed, but it will allow providers to communicate with specialists using minimal effort. An important use case would be a physician sending a patient's EHR to a specialist and asking whether or not the patient should be referred.

This new system significantly improved point-of-care by relieving non-clinical, clerical work that contributed to physician burnout. The exchanges, in particular, allow a physician to have immediate access to EHRs instead of waiting for documents to be faxed, significantly reducing both appointment times and emergency department (ED) length of stay. Furthermore, querying for only relevant information results in more productive appointments, which benefits the provider and the patient. The OC now processes over 90% of referrals using the C-CDA and Direct systems, and almost all referrals receive an automated chart note back from OC's specialists. Additionally, thousands of C-CDA documents are exchanged monthly on the bi-directional, real-time C-CDA exchange system.

Results: Policy Changes

Interoperability Policies During the Covid-19 Pandemic in the United States

The 21st Century Cures Act of 2016 prioritized interoperability, which is broadly understood as easier sharing of health information, to allow patients greater access to their health data and streamline the exchange of patient records among providers. With the temporary expansion of telemedicine, more devices than ever are storing and transmitting health data. The need for these devices to share data securely and without adding to the workload of providers is critical to ensuring that diagnoses and prescriptions for patients who have received telemedicine care are recorded in their health record and viewable by their primary physician.

On March 9, 2020, CMS and the Office of the National Coordinator for Health Information Technology (ONC) released final rules to promote interoperability. Among the proposed policies, two were set to be implemented by January 1, 2021. The first required payers to use an Internet-based tool known as an application programming interface (API) that allows patients to access their data. The second required payers to make their provider directory information available to the public via an API. Together, these policies enabled patients, application developers, device makers, and telemedicine companies to securely exchange patient data with providers.

Interoperability efforts were critical to aid in sharing contact tracer data and prevent the loss of critical data generated via telemedicine and remote monitoring during the COVID-19 public health emergency. When applicable, guidance was needed to ensure that data generated remotely during the pandemic was accessible by providers so that future diagnoses would be based on comprehensive, accurate health information. Enabling patients to take their data from telemedicine visits during the pandemic to providers, urgent care, or the emergency room is crucial to ensuring patient safety and improving outcomes during an infectious disease emergency. This would make it easier for providers to share information with vaccination and infectious disease databases.

Ensuring interoperability now is also necessary to continue the fight against the opioid epidemic. When Secretary Alex Azar of the Department of Health and Human Services declared COVID-19 a public health emergency, providers registered with the Drug Enforcement Agency "may now issue prescriptions without requiring an in-person medical evaluation first." Implementing nationwide interoperability as soon as possible will allow for the tracking of these prescriptions and can improve prescription drug monitoring program (PDMP) compliance.

During the public health emergency, CMS also issued a Health Insurance Portability and Accountability Act (HIPAA) waiver enabling providers to use non-HIPAA-compliant tools, such as Skype and Google Hangouts, to communicate with patients. (This applies to all patients regardless of where they get health coverage.) Without this waiver, doctors would be penalized for using these and other everyday conferencing and messaging programs. While the waiver has increased access to care, it is important to update private laws to ensure patient data remain secure and inaccessible to malicious individuals. One question facing the healthcare and telecommunications industries today is whether computer programs that use "reidentification techniques"—a form of digital cross-referencing—can take a person's data generated by systems that are not bound by HIPAA, such as general web-conferencing software and match it to deidentified patient information found in research databases.

The HIPAA was enacted in 1996, long before 98% of Americans were connected to high-speed wireless Internet, and allows patient data to be shared as long as it is de-identified. As health records were mostly exchanged between doctors' offices, hospitals, and insurance companies, HIPAA focused on setting privacy regulations and penalties for technology companies that offered services to healthcare providers. Today, health data are generated in many ways, from Internet browser search histories to fitness apps, and are used

by companies not bound by HIPAA. Furthermore, advances in artificial intelligence make it increasingly likely that deidentified patient records can be reassociated with patients. In a JAMA Network open article published in December 2018, researchers in the United States and China found that artificial intelligence could re-identify persons who participated in a National Health and Nutrition Examination Survey with physical activity data from wearable devices. Moreover, a recent study demonstrated that machine learning models and matching algorithms might identify individuals from deidentified patient records with 99.9% precision.[17]

With more patients using telemedicine during the pandemic, patients could access their data more frequently, using HEART-based frameworks (Happiness, Engagement, Adoption, Retention, Task success). Defining what third-party health companies can do with patient data is also necessary. With physicians practicing telemedicine across state lines and over various virtual platforms, state and federal health information laws must be reconciled along similar lines to facilitate interoperability.

Discussion: Designing Intermediary Platforms for Interoperability: Middleware Architectures

The mandate of APIs for simple and secure access to EHR data and provider information was a temporary solution to improve the ease of data access and exchange during the COVID pandemic. However, as the number of unique domains, applications, and standards in healthcare rapidly proliferate, there arises a need for a more sustainable and scalable approach toward improving interoperability.

Here is where middleware architectures come to play. The term 'open architecture middleware' refers to "a data exchange framework composed of open and standard components and interfaces" that allows new Laboratory Information Systems (LIS) and legacy EHR systems to communicate. Middleware has been successful in other industries, as proven by credit card point-of-sale terminals that can be connected across global retail chains and banks. This technology can also be extended to make disparate EHR systems interoperable. A middleware architecture solution is distinct from the solution that IHIE used to standardize incoming clinical data, although its objective remains the same: clean, standardize, and de-noise data from different EHR sources to facilitate simple and meaningful information exchange.

Here we focus on semantic middleware architectures, which are concerned with preserving the 'meaning' of concepts between disparate health information systems. Different semantic conflicts that may arise between systems include:

- Naming conflicts, when individual HISs develop their naming schema for their medical concepts
- Encoding conflicts when the same concept is represented by different coding constructs and unique identifiers
- Discrepant data conflicts, when the same medical concept is defined and represented differently between healthcare organizations

Architectures that ingest heterogeneous medical data from diverse sources and provide common meaning frequently have the following components[18,19]:

1. Ontological repository. Ontologies are working conceptual models of entities in a healthcare domain that can flexibly adapt to an architecture's needs. They provide a standardized representation of medical data, including medical class definitions and data types, all of which are needed to derive meaningful inferences. Due to the large volume of medical data and changing knowledge domains, engineering medical ontological models can be a complex task that requires continuous updates and maintenance. The most recent initiative for creating a central ontology has been the development of the FHIR OWL (W3C Web Ontology Language) Ontology, which is still in draft.[20]
2. Semantic Mappings Generation Module. Generalized semantic mappings between healthcare data and medical ontological concepts are created using string-matching algorithms, deep neural networks, or a combination. Research has shown the most promising results for using the latter method. Customized mappings will also need to be provided supplementarily to accommodate organization-specific concepts.
3. Semantic Mappings Storage Module. Semantic mappings may be stored in a novel data format, which will require the development of a translation engine to query and map different terms to their corresponding ontological entity.
4. Evaluation protocol. To evaluate the efficacy of the semantic mediation architecture, automated and manual verification methods must be devised to iterate on and improve the architecture.

The components and their interactions in a sample middleware architecture are illustrated in Figure 3.

Conclusions: Current Trends and Options

The digitization of the healthcare industry, spurred by increased adoption and use of mobile devices, the IoT, and electronic health records (EHRs), brought about a greater need for standardization of healthcare data. While there are ongoing parallel efforts to improve interoperability, existing standards lack lateral compatibility. As a result, many clinical organizations still struggle to operate
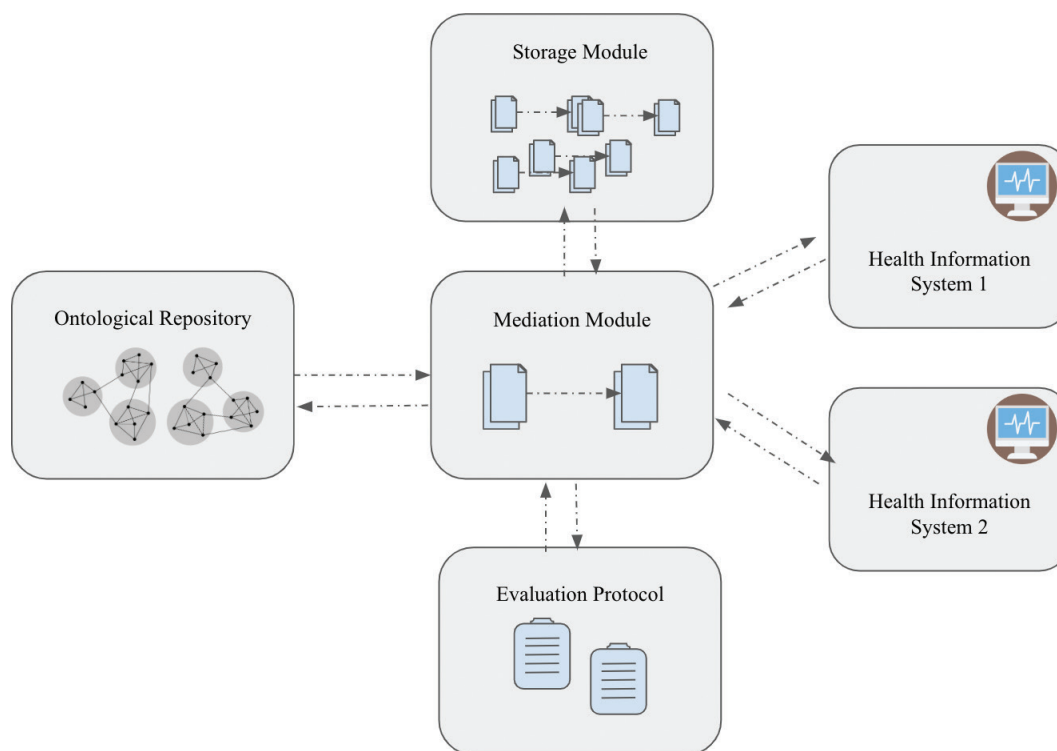
Fig. 3. Example middleware architecture.

with diverse healthcare information from different data streams.

The development of the HIE by the ONC (National Coordinator for Health IT) was aimed at addressing the lack of interoperability in the United States. However, each state's HIE faces unique challenges that hinder its ability to streamline and standardize data exchange.

The Indiana HIE (IHIE) was initially constructed to streamline clinical message exchange between health systems, but it struggled to adapt to the diverse clinical message structures being transferred. As a result, the IHIE adopted a separate vendor's technology to clean data before it was ingested into the system. The USCDI today, developed during the pandemic, streamlines data standardization and cleaning.

Lahey Clinic, another group practice with many different providers, struggled with homogenizing communication between ophthalmic devices so that medical images could be easily stored, retrieved, and associated with the corresponding patient in a fail-safe way. To this end, they chose to adopt a third-party image management system, Medflow, in conjunction with the IHE and DICOM frameworks.

The Oregon Clinic struggled to reduce the friction associated with EHR exchange between hospitals using different EHR platforms. As a result, they created an intermediary platform, in collaboration with Epic, that streamlined communication between providers using different EHR platforms, which was built on top of C-CDA and the Direct Standard interoperability frameworks.

Adapting and implementing solutions tailored to each clinic's unique needs is not a sustainable, long-term development of an interoperable healthcare system. In addition, the onset of the COVID pandemic in the United States hastened the need for a broader interoperability framework that could be adapted to multiple healthcare domains. While middleware architectures remain one promising solution, the arrival of the TEFCA technical framework, which went live in 2022, will aid in achieving interoperability at an even larger scale. By creating a common ground for interoperability across healthcare entities, TEFCA allows different users and disparate systems/networks to share data while securely meeting agreed-upon expectations and rules. This common agreement framework expectation is intended to leverage existing data formats where possible such as Consolidated Clinical Document Architecture (C-CDA) or via Fast Healthcare Interoperability Resources healthcare data standard with an application programming interface (FHIR APIs).[21]

The United States must implement effective policies and technologies that traverse organizational boundaries to bridge diverse healthcare information to address the shortcomings associated with the development of many isolated, inconsistent efforts at creating interoperable healthcare standards.

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