Understanding National Interoperability Frameworks and Networks

HIMSS℠

Acknowledgements

This piece was written by the members of the 2023 HIMSS Interoperability Committee with major contributions from **Dr. Holly Miller** (Committee Chair), **Min Chen, Ph.D.** (Vice-Chair), **Marilee Benson**, **Dr. Steven Lane**, **Maria Moen**, **Jeff Nicholson**, **Fatima Rahman**, **Harm Scherpbier**, **Rob Havasy** and **Sarah Bell** (HIMSS Informatics Strategy). The Committee also thanks everyone who contributed chapters on the Networks and Frameworks, including **Lisa Bari** and the **Civitas team**, **Jay Nakashima** and the **eHealth Exchange team**, **Scott Stuewe** and the **DirectTrust team**, **Alan Swenson** and the **Carequality team**, **Paul Wilder** and the **CommonWell team** and **Mariann Yeager** and the **Sequoia team**.

Table of Contents

Introduction

The exchange of information in the American healthcare system has evolved in the last sixty years, mirroring the transformation of the healthcare delivery system. Moving from a largely siloed model of isolated individual providers toward somewhat more of a distributed and team-based model. The early paradigm of handwritten notes in paper charts has given way to significant electronic data capture and exchange. The advent of electronic health records (EHRs) marked a significant leap forward, offering a digitized version of a patient's medical record. Interoperability ensures electronic health information (EHI) is accessible to an authorized interdisciplinary care team and additional authorized healthcare constituents, including, of course, the individual to whom the data applies, or their designated representative.

At the beginning of 2024, we stand on the cusp of the next evolution in interoperable healthcare delivery: The Trusted Exchange Framework and Common Agreement (TEFCA), a National Framework championed by the Office of the National Coordinator for Health Information Technology (ONC). TEFCA aims to create a single 'on-ramp' to nationwide connectivity for patients, providers, and all authorized healthcare constituents, simplifying the process of sharing health information privately, securely, and efficiently. This Framework represents the collective ambition to achieve an interconnected health system where data informs care at the point of service and contributes to a larger ecosystem of health intelligence that benefits all. The journey toward interoperability has been long, but with the foundation of TEFCA, we are poised to enter a new era of healthcare communication and collaboration.

The Healthcare Information and Management Systems Society (HIMSS) was formed in 1961 as a reaction to the emergence of computers and information systems within hospitals and healthcare management. As the foremost convener of healthcare information technology professionals, our members are the architects and drivers of the information technology revolution in healthcare. On the eve of TEFCA, our Interoperability Committee decided to look both backward and forward from our unique vantage point to briefly document how we arrived at this point and where these new tools might take us. We are grateful that you are joining us on this journey.

Interoperability Overview

Safe, efficient, effective care requires communication across the individual's care team regardless of whether those members are within a single organization or across multiple organizations. For years, organizations used faxes to communicate. Then eFaxes which could be received directly into a specific patient's Electronic Health Record (EHR). Faxes and eFaxes, as simply text, require extensive data entry to keep the patient's chart up to date. Not only is data entry burdensome and time-consuming, but it is also prone to errors potentially leading to patient harm.

Throughout the history of EHRs, true interoperability required discrete data, meaning that every data element has an associated standardized machine-readable code. When the recipient EHR receives a document with coded data the system, following provider review, can automatically incorporate this data into the patient record. Interoperable, discrete data not only improves safety but can also dramatically decrease clinical burden and improve clinician, staff, and patient satisfaction. Patients can avoid continually filling out identical forms for information when they go to a new caregiver if prior data is interoperably received by the new EHR and incorporated into the new provider's system. Then, in review with the clinical staff, the patient can verify the information received.

Early Attempts – New Challenges

The 1960s saw the first health information technology (HIT) systems developed to automate administrative workflows such as order entry, scheduling, and billing. The first electronic medical records (EMRs) in the United States followed in the 1970s. Organizations deployed these EMR systems to replace paper forms and related processes for capturing, storing, and retrieving patient data, primarily within one practice or hospital.

In these early days, EMR systems were highly biased toward documentation speed rather than the collection of discrete, structured, computable data. In their quest for digital solutions, healthcare facilities sometimes developed homegrown systems tailor-made to suit their users' requirements. Other organizations purchased EMRs from various disparate vendors. These early EMR systems brought new challenges with their minimal capture of discrete data and the proliferation of EMR brands. Each EMR, with its unique architecture, protocols, and standards, created silos of information. The limited exchange of information between different organizations, when necessary, was facilitated through point-to-point interfaces – custom-built connections that allowed two systems to communicate or through faxing information. As the number of systems and local data standards increased, however, maintaining these interfaces became an expensive, unscalable logistical nightmare.

Standards Emerge

Recognizing these challenges, industry stakeholders came together in 1989 to develop global health data standards as **Health Level Seven International (HL7)**. HL7, with its focus on creating a comprehensive framework for the exchange, integration, and retrieval of electronic health information, quickly gained traction. Its protocols, encompassing various aspects of healthcare data exchange, from administrative data to clinical information, became the gold standard for healthcare data interoperability. The successive generations of HL7 standards, each more refined and comprehensive than its predecessor, allow health data, irrespective of its source, to be exchanged between and integrated into compliant systems. Numerous organizations sprang up within and around HL7 to advance the cause of standards-based health information exchange.

Federal Interest and Standards Enable Scale

One of the earliest efforts to support broad health information exchange was the Community Health Management Information Systems (CHMIS) program formed by the Hartford Foundation in 1990 to provide a centralized data repository in seven communities. Similar initiatives -- Community Health Information Networks (CHINs) and Health Information Exchanges (HIEs) proliferated in the mid-1990s to share data between providers more cost-effectively. While largely industry-driven, these interoperability efforts received significant federal interest and support.

The **Health Insurance Portability and Accountability Act** (HIPAA) of 1996 marked one of the earliest federal forays into healthcare data. While at its core, HIPAA focused on assuring that individuals could maintain their health insurance as they moved between jobs, it also provided new federal standards for protecting the privacy and security of medical records while facilitating the electronic exchange of health information. In HIPAA, the Department of Health and Human Services (HHS) required the adoption of certain transactions to exchange health care data electronically. HIPAA-covered entities conducting these specified transactions must use ASC X12N or NCPDP standards. Recognizing the transformative potential of digital health records, HIPAA sought to balance accessibility and privacy. By establishing standards for protecting health information and delineating patients' rights over their data, HIPAA laid the groundwork for a future where digital health data could be exchanged with confidence while safeguarding individuals’ privacy rights.

A new generation of federal efforts emerged in the wake of the 1999 Institute of Medicine (IOM) report, "To Err is Human," which identified medical errors, many addressable via information technology, as a significant threat to the health of all Americans. 2004 was a pivotal year for healthcare IT, beginning with A 2004 Executive Order from the Bush administration that created the **Office of the National Coordinator for Health Information Technology** (ONC) within HHS. Also in 2004, the Agency for Healthcare Quality and Research (AHRQ) Health Information Technology Portfolio funded grants and contracts to improve healthcare decision-making, support patient-centered care, and improve quality and safety. This funding included a State and Regional Demonstration (SRD) project, which provided grants to six states to develop regional Health Information Exchanges (HIEs).

ONC established the **Nationwide Health Information Network** (NwHIN) in 2004. A critical network component was a trust model to provide a common foundation for privacy and security obligations, accountability, and governance across the diverse ecosystem of federal, state, and local policies and laws. One of the significant results of this work was the Data Use and Reciprocal Support Agreement (DURSA), published in January 2009. That same year, the Social Security Administration and MedVirginia were the first organizations to share live data as NwHIN pilot partners. Over time, the NwHIN evolved into a public-private partnership known as the eHealth Exchange.

The **Health Information Technology for Economic and Clinical Health (HITECH) Act**, enacted in 2009 as part of the American Reinvestment and Recovery Act (ARRA), represented a significant federal push toward the widespread adoption of Electronic Health Records (EHRs). With a budget allocation of nearly $30 billion, the Act sought to accelerate the pace of Certified EHR Technology (CEHRT) adoption, facilitate health information exchange, and improve patient outcomes.

In 2009, ONC also launched the **State Health Information Exchange (HIE) Cooperative Agreement Program**, which provided funding to all US states and territories to build capacity for exchanging health information across the health care system within and across states. This program led to a diversity of approaches to supporting regional interoperability. Many regional organizations renamed themselves Health Information Organizations (HIOs) to avoid the ambiguity inherent in the term HIE, which can serve as either a verb or a noun. Some are now redefining themselves as Health Data Utilities (HDUs) to better describe their role in supporting and managing critical local exchange workflows. In 2023, there are only three states with no active HIO, and two states, California and Texas that each have more than ten.

The **Direct Project** began in 2010 (when about 20% of doctors were using EHRs) as a public/private partnership to create a simple mechanism for interoperability among EHRs and other systems. This effort developed the Direct Standard for data exchange in 2011. Direct Secure Messaging is used to send sensitive healthcare information to a specific receiver, with a Direct account, over the open internet. Direct utilizes digital certificates and a Public Key Infrastructure (PKI) to encrypt the contents of a message, meaning only the intended recipient can decrypt the message.

Also in 2010, CMS introduced the **Meaningful Use (MU) Program** to incentivize healthcare providers and hospitals to adopt and use EHRs meaningfully. The MU requirements, rolled out in stages, outlined specific objectives healthcare providers needed to achieve to qualify for financial incentives. Several Stage 1 meaningful use objectives involved health information exchange, including electronic prescribing, exchange of clinical care summaries (which required the documentation and exchange of Problems, Allergies, Medications, and Immunizations (PAMI) as discrete data), integrating laboratory results into EHRs and reporting of immunizations and syndromic surveillance data to public health departments. Meaningful Use Stage 2, which began in 2014, included several new interoperability requirements including allowing patients to access their health information online and requiring all CEHRT to support the Direct Standard.

Interoperability Quantitative Results

While early efforts to document the clinical and financial impacts of interoperability often had difficulty quantifying the benefits of health information exchange, recent studies with more rigorous designs have demonstrated fewer duplicated procedures, reduced imaging, lower costs, and improved patient safety[1] as well as decreased unplanned hospital readmissions[2]

The Office of the National Coordinator for Health Information Technology (ONC), in coordination with the American Hospital Association, tracks the adoption and utilization of health data interoperability through periodic surveys:

1. In 2019, about 65% of physicians engaged in some form of HIE consisting of finding, sending, or receiving information. An overwhelming majority (over 75%) of physicians who engaged in HIE

experienced improvements in quality of care, practice efficiency, and patient safety due to HIE. Office-based physicians electronically finding or querying patient information increased by over 40 percent from 2015, reaching 49%. [Pylypchuk Y., J. Everson, D. Charles, and V. Patel. (February 2022). Interoperability Among Office-Based Physicians in 2015, 2017, and 2019. ONC Data Brief, no.59. Office of the National Coordinator for Health Information Technology: Washington DC.]

2. In 2021, more than 6 in 10 hospitals engaged in key aspects of electronically sharing health information (send, receive, query) and integrating summary of care records into EHRs, a 51 percent increase since 2017. About three-quarters of hospitals participate in HIEs and about 35 percent participate in both HIEs and national networks. [Pylypchuk Y., J. Everson. (January 2023). Interoperability and Methods of Exchange among Hospitals in 2021. ONC Data Brief, no. 64. Office of the National Coordinator for Health Information Technology: Washington DC.]

While highlighting the progress, these surveys have also highlighted areas that need attention, such as the challenges faced by smaller clinics and rural and safety net hospitals with barriers to data exchange between different Health IT systems.

21st Century Cures Act and Beyond

In 2016, **The 21st Century Cures Act's** definition of interoperability called for "all electronically accessible health information" to be accessed, exchanged, and used "without special effort on the part of the user." It also required that HHS develop or support a trusted exchange framework and common agreement (TEFCA).

The ONC's Cures Act Final Rule of 2020 sought to prevent information blocking and foster a culture of data exchange. The rule defined Information Blocking as a practice by an "actor" likely to interfere with accessing, exchanging, or using electronic health information (EHI), except as required by law or specified in an information blocking exception. The rule applied the law to healthcare providers, developers of certified health IT, and HIEs/Health Information Networks (HINs). By defining what constitutes information blocking and outlining penalties for non-compliance, the Cures Act Final Rule sent a clear message: the seamless exchange of health information was not just a clinical or business imperative but a federal mandate. In implementing the Cures Act Final Rule, HHS determined it would develop a new framework for national exchange rather than rely on the existing national framework and component networks. This new framework, anticipated to be operational in 2024, will rely on designated Qualified Health Information Networks (QHINs) to broker exchanges between network participants and sub-participants. ONC designated the first five QHINs in December 2023. They are eHealth Exchange, Epic Nexus, Health Gorilla, Konza, and MedAllies.

Interoperability Methods

Different health information frameworks and their participating networks support specific methods of exchange:

1. **Directed Exchange** allows data to be sent from one entity to another, e.g., to support referrals, discharges, care coordination, results delivery, and public health reporting.
2. **Query-based exchange** allows those seeking information to request this from a data holder, either the original source, such as a healthcare provider, through federated exchange, typically facilitated by a health information network (HIN), or from a centralized system, such as a regional HIE/HIO.
3. **Consumer Mediated Exchange** leverages the individual's rights under HIPAA to access and obtain a copy of their health information and share it with others.

"Push" and "Pull" Use Cases

Medical practice requires sending and retrieving information to or from other care constituents. Informaticists refer to these conditions as "push" and "pull". A query *pulls* information from another system, or information can be *pushed* from the source system to an individual or team utilizing a different system. Clinicians can readily understand the utility of both "push" and "pull" use cases. For example, a primary care physician (PCP) refers a patient to a specialist and wants the specialist to have all the necessary information for the patient before the encounter. The PCP "pushes" the information to the specialist. Once the specialist has completed the consultation, it is "pushed" back to the PCP and reconciled in the PCPs system. Conversely, a patient arrives in the emergency department (ED) in a facility where the patient has no prior medical records in their EHR system. The ED doctor queries to "pull" the patient's records into their EHR system to treat them safely and appropriately. These examples illustrate how both "push" and "pull" clinical use cases are essential for interoperability leading to safe, efficient, cost-effective healthcare. Based on HL7's clinical data architecture (CDA), the Direct Protocol pushes CDA summary and other documents interoperably to the patient's care team across Direct Networks to diverse certified EHRs that adopted this capability. DirectTrust provides a trust framework for Direct Networks called Health Information Service Providers (HISPs).

As Direct is a "push" network, several national networks and frameworks have evolved to satisfy the need for "pull." They include eHealth Exchange and CommonWell, which are both networks and all Carequality Implementer Networks working under the Carequality Framework.

Under the TEFCA Framework, QHINs will offer "push" and "pull" with a roadmap to national Fast Healthcare Interoperability Resources (FHIR) at scale. The FHIR standard is a specification for exchanging healthcare data electronically. FHIR utilizes API-based exchange and is adaptable to exchange specific healthcare data resources, not necessarily entire documents.

Networks and Frameworks

In 2001, with the advent of electronic prescribing, proprietary networks were developed to connect prescribing providers, pharmacies, and payers. In 2008, Epic Systems, an electronic health record vendor, implemented functionality to allow providers and health systems using its software to readily exchange data amongst themselves, calling the network Care Everywhere. Care Everywhere was followed in 2013 by the development of the CommonWell Health Alliance, another vendor-led initiative to allow the exchange of data between users of several EHR vendor systems. The proliferation of several additional private health information networks to address market needs followed.

With network proliferation, a clear need emerged for a trust framework to facilitate exchange across and between evolving networks. Trust frameworks, developed in other industries, such as financial services and telecommunications, support cross-network data sharing and workflows.

The first such framework, started in 2011, was DirectTrust, which governed numerous interoperable Direct Networks or HISPs pushing Direct Secure Messages.

2014 brought the Carequality Interoperability Framework, a trusted exchange framework that governs Carequality Networks (Carequality Implementers). The Carequality Framework consists of a common trust agreement, policy requirements, technical specifications and governance processes. Frameworks like these enable healthcare to replicate other industries' success in breaking down barriers between many networks, programs, and platforms.

Frameworks (DirectTrust, Carequality, and TEFCA) provide Networks with specific governance, guidelines and accreditation to exchange electronic protected health information (ePHI).

Frameworks share certain characteristics:

1. A standard set of data-sharing policies and legal terms participants must agree to
2. Technical standards by which exchange happens (Implementation Guides / SOPs)
3. Technical means of identifying trusted endpoints (directory)
4. A process for onboarding and monitoring to ensure participants adhere to technical standards
5. Governance to regularly review and update all the above

Trust Frameworks utilize agreements to define an Entity that acts as an intermediary (the Network) and clearly distinguish those Entities from the "connections/participants" who typically do not contract directly with the Trust Framework, but contract with their chosen Network. The component Networks often provide technology hubs that connect participants and provide access to the other Networks within the specific Trust Framework. ePHI can be readily exchanged across the Networks operating under their given specific Framework; however, networks operating under different Frameworks cannot exchange ePHI. For Example, eHealth Exchange and CommonWell, independent Networks with their own subscribers, cannot exchange data outside their subscriber base. Both of these independent networks, however, are also networks under the Carequality Framework, therefore if their participants additionally subscribe to use these networks under the Carequality Framework, they can exchange information.

TEFCA, the federally supported Nationwide interoperability Framework called for by the Cures Act Final Rule, has been modeled on the existing industry-driven Carequality Framework.

Table 1. Networks and Frameworks

Network	Push/Pull	Consent	Trust Framework	Directory	Record Locator Service	Documents	Use Cases

QHINs Five Designated QHINs as of 12/2023: eHealth Exchange, Epic Nexus, Health Gorilla, Konza and MedAllies	Currently Pull Query only Push Future	Yes	TEFCA	QHIN Directory (Organization Level) FHIR Directory Future	All QHIN Networks need to have	IHE based C-CDA, Aggregated Record FHIR Resources Future	Initial Required IAS and Treatment Future: operationalize additional purposes of use in short order, including Public Health, Payment, and Healthcare Operations
Carequality^{TM} Multiple Networks called “Carequality Implementers”	Currently only Pull Query Push future	Yes	Carequality Trust Principles Agreement and Carequality Connected Agreement	Carequality Directory (Organization Level) FHIR Directory in Development	Yes	IHE based C-CDA, Aggregated Record FHIR Resources Future	Finding available patient data. Treatment Required with Live. Future: IAS, OBO, operationalize additional purposes of use in short order, including Public Health, Payment, and healthcare Operations, On Behalf Of (OBO)
CommonWell^{TM} (*Also, a Carequality Implementer) Data Privacy and Security Policy and CommonWell Member Services Agreement	Query based Pull	Yes	***Not a Framework***	CommonWell Directory	Yes	IHE based C-CDA, Aggregated Record FHIR Resources Future	Finding available patient data. Treatment Required with Live. Future: IAS, OBO, operationalize additional purposes of use in short order, including Public Health, Payment, and healthcare Operations, On Behalf Of (OBO)
Direct	Push	Not required for Provider	Registration Authority,	Direct Directory (Individual Level)	No, not required as Point to Point Push	IHE based C-CDA, Aggregated Record	Transition of Care, ADT Alerts, Any

Multiple Vendor Networks called HISPS		to Provider,	Certificate Authority, HISP Trust Framework, Federated Services Agreement			FHIR Resources Future Also, Sent Information May be Curated from Sender to Receiver	Push Document Exchange
Regional/State HIE Multiple Via Participation Agreement (Business associates or their covered entities) HIE can produce an audit log	Pull Data received by Direct Networks or Queried via National Networks	Yes	***Not a Framework***	No	No RLS, Each HIE maintains own MPI and data clean up algorithms maintained by many HIEs	Aggregated Record for specified region	Finding available patient data and may have cleaning (e.g. Deduplication), sharing as needed with their membership ADT Panel Based Push Notification
eHealthExchange (*Also a Carequality Implementer) DURSA Trust agreement	Pull	Yes	***Not a Framework***	EHE Network Directory	No RLS	IHE based C-CDA, Aggregated Record, FHIR Resources Future	Same as Carequality

The following chapters are about the frameworks and networks mentioned in this introductory chapter and written by these organizations' current leaders and staff. Finally, we’ll look ahead and anticipate what the near future might bring in this realm.

References:

[1] [JAMIA 2018 Sept; 25(9): 1259-1265]
[2] [Health Affairs 2019 Feb; 38(2)]

Push Interoperability: Direct Secure Messaging and DirectTrust®

History

DirectTrust was born out of The Direct Project, which began as a next step to HITECH in 2010 as a grass-roots public/private partnership focused on creating a simple and low-cost mechanism for healthcare interoperability. The goal was to enable secure health data exchange and reliable communication among EHRs and other systems. This effort resulted in the Direct Standard for exchange. The Office of the National Coordinator later included the Direct Standard in the “Meaningful Use” government incentive program.

As a result of the development and early deployment activities of the Direct Standard in 2011, a consensus developed that an organization would be required to establish and grow a “trust community” that could establish “Rules of the Road” for the new technology to scale. By the end of 2011, the first meeting of DirectTrust was held with the mission of providing policy and governance for the new trust framework. In April of 2012, the organization was incorporated as a 501(c)(6) non-profit trade association to develop, promote, and enforce the rules and practices needed to maintain security and promote confidence in a federated, national-scale healthcare information exchange community.

In 2013 and 2014, DirectTrust received support through an ONC Cooperative Agreement to advance the work of the trust framework. As a part of Stage 2 Meaningful Use and the ONC Certification Program, every certified EHR technology (CEHRT) system incorporated Direct Secure Messaging into their products.

In 2019, DirectTrust reached the landmark milestone of one billion messages exchanged because of the technical investments made by the healthcare industry and the trust fabric established by DirectTrust. The organization became recognized as an American National Standards Institute (ANSI) Standards Development Organization, promptly convening several Standards Consensus Bodies, including the Direct Standard and Trusted Instant Messaging Plus.

DirectTrust began to grow further and emphasize the trust components needed for a trusted health information exchange environment. This included convening new consensus bodies, like Event Notifications via Direct, an answer for Admission/Discharge/Transfer notifications sent via Direct, as well as Information Exchange for Human Services and Privacy-Enhancing Health Record Locator Services (PEHRLS) Ecosystem Consensus Bodies. The global pandemic in 2020 placed additional emphasis on the prime opportunity for Direct Secure Messaging to replace fax, including in public health use cases.

Noting the criticality of certificates and trusted identities to exchange, DirectTrust acquired the assets of SAFE Identity in 2021, expanding identity services.

In 2022, DirectTrust celebrated its 10-year anniversary, including a decade of growth and evolution, but an everlasting commitment to trusted health information exchange, trust-in-identity, and community.

In January 2023, the Electronic Healthcare Network Accreditation Commission (EHNAC) and its more than 20 accreditations and HITRUST consulting services merged with and into DirectTrust, with the

Commission overseeing accreditations. Founded in 1995 with an origin related to HIPAA, EHNAC has its own unique and storied history.

Today, DirectTrust operates as an organization focused on instilling trust in healthcare data exchange. While the origins of DirectTrust are Direct Secure Messaging, with more than four billion messages exchanged as of September 2023, Direct Secure Messaging is only possible because of DirectTrust's foundation of trust. The organization has expanded this trust emphasis into four primary focus areas: community and membership, standards development, accreditation, and other trust services.

Advantages

Direct Secure Messaging, commonly referred to as Direct, is an easy-to-use and secure method of sending information over the internet. Because a user initiates sending information to another, it's often referred to as "push" interoperability for the analogy of "pushing" information to another person or organization who may need it. Where query-based information exchange operates as a "pull" for all available information, push interoperability represents an opportunity for the sender to curate the information they believe would be of value to the receiver.

Direct has multiple advantages, including its ease of use, the prevalence in CEHRT and technologies, low cost, security and encryption, identity verification, Aggregated Directory, content agnosticism, message delivery notifications, and scalability.

Direct is often integrated directly into healthcare technologies like EHRs. The incorporation into the workflow makes it so easy to use that sometimes users are unaware they are using Direct Secure Messaging. Overall, sending a Direct message is as easy as sending an electronic fax or an email. Additionally, Direct mirrors the practice of medicine - clinicians often send information to other clinicians who may benefit, which is an advantage for using this type of interoperability.

A key requirement of the Direct Standard was for it to be inexpensive to deploy. Health Information Service Providers (HISPs), who are DirectTrust network operators, are prohibited from charging other HISP networks for exchange. HISP networks generally charge their participants for exchange; it is an open and competitive market with many different business models. Some scale on the number of Direct addresses, while others charge based on the transaction volume. Direct remains a cost-effective means of exchange.

Direct is known for its security, as only the intended recipient of a message can decrypt it. The Direct Standard uses email as a base protocol but provides additional security and utility by using digital certificates and standards for integrating with technical systems, particularly EHRs, HISPs, and other technology providers. A user or organization must be identity-proofed to obtain a Direct address and communicate via Direct. Regular email addresses cannot communicate to Direct addresses, nor vice versa. One role of a HISP is to host and manage the servers and certificates that allow the Direct protocol to function, making it very easy and cost-effective to take advantage of the security elements of the model.

DirectTrust provides an Aggregated Directory of published Direct addresses. The ability to search this "white pages"-type address book and find the user or organization desired for information exchange offers an advantage over other communication methods.

The Direct Standard is content-agnostic and does not limit the types of payloads a message may carry. Direct is commonly used for structured data exchange via CCDAs, notifications, PDFs, and images, but many other payloads can be carried too, including FHIR. EHRs and technologies may impose content constraints on what they accept inbound.

Upon delivery of a Direct message, the sender receives a Message Delivery Notification. This notification provides reassurance that the message made it to the intended destination.

Direct Secure Messaging is scalable because of DirectTrust. DirectTrust arose as an organization to create an accreditation program and a single Federated Services Agreement, meaning HISPs wouldn't need to create "pairwise" agreements, and a network could scale. Today (in 2023), about 30 Accredited HISPs are exchanging over 200 million Direct Secure Messages a quarter between about 300,000 organizations.

Limitations

Direct Secure Messaging is push interoperability based on the Direct Standard - Direct doesn't support query. Limitations of Direct often come from differing implementations of the standard rather than issues with the standard itself. For instance, different EHR vendors have implemented Direct differently into their technologies and workflows. Additionally, as Direct was launching at the time of Meaningful Use, many EHR vendors took the opportunity to "white label" their Direct Secure Messaging products. This has led to confusion in the marketplace about the ability to communicate with users of other EHRs and technologies. While clinicians on different platforms can use Direct, they may not realize they can communicate with each other in this way because each technology named the Direct capability something different, leading to confusion regarding the ability to communicate. DirectTrust has published a Direct Secure Messaging Aliases crosswalk to help eliminate confusion over the white labeling of Direct tools.

Additionally, Direct Secure Messaging today is enhanced when paired with context, a description of what the message is or contains. Some EHR and technology vendors use context today, which allows for routing and additional parsing or routing of messages. Those who don't implement context may not reap the full benefits of the standard. The Direct Standard Consensus Body will address the Context Implementation Guide in the near future. Currently, the standard does not specify a minimum file size to support for exchange. The group may also address and enforce a specific minimum supported file size. For most EHRs to accept messages, the context in the form of minimal metadata with patient-matching attributes is required. Messages that don't contain context must at least include a Consolidated CDA (C-CDA) document to be accepted by many EHR systems.

Finally, the Aggregated Directory is a clear advantage of Direct but also has opportunities for improvement. One clear opportunity is the additional publication of Direct addresses. At the time of implementation of Direct, many did not understand the implications of the Directory. For Direct to be used to its full potential, additional enhancement and publication of addresses in the Aggregated Directory is needed. DirectTrust’s Directory Improvement Initiative is specifically addressing these issues and seeing progress. One benefit of recent Directory enhancements are the new fields that expose what use cases and capabilities a given Direct address supports, such as 360X Closed Loop Referrals. This way, addresses requiring specific content standards or accepting general messages with arbitrary payloads can be identified before sending a message.

Consent

Direct Secure Messaging is the ideal interoperability method for exchange regarding consent. Because the disclosing party initiates the exchange, the initiator needs to know their obligations regarding consent before disclosure. Direct is the perfect way to send sensitive data and connect community-based organizations to the healthcare ecosystem without risking inadvertent disclosures. Even so, it is important to note that restrictions on redisclosure exist, like the confidentiality of substance use disorder records covered under 42 CFR Part 2. If a provider who receives such data has a clear indication that the data is protected by Part 2, they will be able to safeguard it appropriately. In general, Part 2 information is more challenging with query interoperability.

Much of the exchange via Direct is related to Treatment and is covered by the HIPAA's Treatment/Payment/Operations provision. This means a clinician can send information to another clinician (or for payment or operations purposes) on a mutual patient without obtaining additional consent from the patient. Since someone who knows where the information needs to go triggers the “push” of Direct, Direct is ideal for patient privacy and compliance with HIPAA.

Use Cases

Direct Secure Messaging is the perfect interoperable transport mechanism for any time there is a need to send or “push” information from one entity to another, as it mirrors the standard way clinicians communicate with each other. For use cases where there needs to be communication and exchange from person to person, person to organization, organization to person, and organization to organization, Direct Secure Messaging is the flexible choice.

Referrals, Transfers of Care (including EMS transfers to hospitals), and Event Notifications (Admission/Discharge/Transfer alerts) are the most common provider-to-provider use cases. Additionally, Direct is frequently used for Public Health Reporting, including Electronic Case Reporting (eCR). Because of its ease of deployment and prevalence, Direct was frequently used as a communication mechanism to connect public health and clinicians during the global pandemic. For the same reasons, Direct is increasingly becoming the communication method to connect community-based organizations like food pantries to the healthcare system.

There are many other use cases – HIEs sometimes use Direct to receive information as an alternative to VPNs or other dedicated connections. Some states use Direct to support cases where information exchange is sensitive and needs to happen expeditiously, like sharing information related to foster care and child protective services cases.

One use case with traction is 360x Closed-Loop Referrals, an IHE profile, and a workflow using Direct for its transport. It’s vital that when a clinician refers a patient to another clinician, the referred-to clinician has the critical information to efficiently and effectively care for the patient and that the referring clinician receives information back. 360x describes how an EHR or other technology can track that referral and ensure the specialist receives the information and gets back to the referring clinician, following the consultation, thereby “closing the loop” of the referral. 360X is also working to have IHE approvals for multiple other transitions of care use cases, including referral to Skilled Nursing Facilities (SNFs), the transition from SNF to ED, referral to Home Health, referral to community-based organizations (CBOs) for SDOH needs, etc. Because 360x uses ubiquitously adopted standards like Direct, the development bar for EHRs and other technologies is low. Due to the value that 360x provides, several EHRs and technologies offer 360x in their production environment today, with many others in development.

New use cases for Direct are continuously emerging. As more organizations look for an electronic and structured data alternative to exchange via fax, Direct is increasingly used, and the number of Direct use cases grows.

Future

DirectTrust is eager to see Direct Secure Messaging grow and other services that instill trust in exchange in and beyond healthcare. As a forum for a consensus-driven community focused on health communication, we expect to see dialogue and use cases around Direct Secure Messaging grow in conjunction with the growth of interoperability.

Second, as an American National Standards Institute (ANSI) standards development organization, DirectTrust will further develop Standards that support trust in healthcare. For instance, the Direct Standard Consensus Body will continue to address needs that enhance the ability for all to use Direct Secure Messaging, like the Context Implementation Guide.

Third, as the need for trust grows in the healthcare ecosystem, so does the need for independent accreditation. DirectTrust operates an accreditation and certification body through EHNAC (the Electronic Healthcare Network Accreditation Commission). The accreditation and certification programs DirectTrust offers include Privacy and Security aligned with HIPAA, as well as accreditations for Direct Secure Messaging network operator HISPs, Certificate Authorities, Registration Authorities, and then programs beyond Direct specifically like ePrescribing for Controlled Substances, healthcare networks related to payers, and many more.

Finally, DirectTrust continues to expand its trust services, including trust frameworks and supportive services such as credential and certificate issuance and directories for secure information exchange. While certificate issuance programs began to support Direct Secure Messaging, in recent years, this has expanded to support the query environment and other types of information exchange as well. As trusted, interoperable exchange expands, so will the need to know and trust the parties in exchange, meaning identity-proofing and digital certificate services will also grow.

Overall, DirectTrust is proud to be the initial framework to facilitate interoperability and looks forward to providing and supporting trusted exchange and other trust services well into the future.

Carequality

History

Carequality was the first organization to tackle the process of establishing the nationwide, technology-agnostic framework necessary to make health data interoperability a reality across the country. Launched as an interoperability initiative of The Sequoia Project in 2014, Carequality published the first set of legal terms, policy requirements, technical specifications, and governance processes designed to underpin the exchange of healthcare information and data nationwide.

The Carequality Interoperability Framework, published in 2015, was quickly adopted by 13 pioneering health organizations, including our nation's largest ambulatory EHR vendors, leading e-prescribing and clinical information networks, and 30 percent of the inpatient market.

The organization began by creating the Carequality Principles of Trust, which enumerate legal terms, policy requirements, technical specifications, and governance processes. The Principles of Trust encourage industry interoperability efforts to remain scalable, implementable, and flexible.

Carequality operationalized the principles with its Interoperability Framework. The Framework, which is available to all health information exchange networks, payers, and others in the healthcare industry, established standards, common rules, technical specifications, processes, and directories for connecting the many disparate systems used by electronic medical records (EMRs), health information networks (HINs), payers, and providers, ultimately allowing for the seamless exchange of health data between and among existing Carequality networks, called Carequality Implementers.

Within weeks of its release, the Carequality Interoperability Framework enabled the first exchange of clinical documents between an Epic client, and an athenahealth client. Less than three months later, athenahealth, eClinicalWorks, Epic, HIETexas, NextGen Healthcare and Surescripts had connected more than 3,000 clinics and 200 hospitals to share electronic health information.

By 2018, Carequality had established itself as the clear leader in facilitating healthcare data exchange, with more than 50 percent of all providers engaged. Recognizing this success, The Sequoia Project updated its corporate structure to spin off Carequality as an independent non-profit organization.

Since then, Carequality leaders have continued its mission to ensure safe and reliable exchange of clinical documents throughout the U.S. healthcare system.

Why Carequality

With the exception of the Direct Framework, before the launch of Carequality, each provider, payer, EMR, and network used proprietary software and technology, making it challenging to share data with other healthcare organizations and across technology platforms. Carequality was launched to build a solution.

To do this, the framework designers considered use cases, from which they developed guides to support the implementation of key aspects of interoperable exchange:

- Query-based document exchange
- Imaging data
- Electronic case reporting
- Fast Healthcare Interoperability Resources (FHIR)-based exchange
- Push notifications

The Query-Based Document Exchange guide addressed the need for relevant healthcare information to be available to the appropriate parties when requested. For example, a hospital may need information from a primary care physician, or a payer may need information from an emergency department. Workgroups comprised of Carequality implementers and subject matter experts considered these challenges and developed a guide to clarify how those in need of information receive it. Workgroups continue to update this guide as needed.

The Imaging Data Exchange Supplemental Implementation Guide extends the Query-Based Document Exchange guide. It was jointly developed with the Radiological Society of North America (RSNA) to address technical standards specific to medical images.

The Electronic Case Reporting (eCR) Guide provides healthcare organizations connected to Carequality implementers with the ability to notify public health agencies of cases of reportable illnesses. This was crafted in response to the COVID-19 pandemic but is relevant for any reportable infectious disease.

Perhaps the most notable achievement is the FHIR-based exchange, which enables EMRs, HINs, and others to use FHIR resources/bundles to quickly and safely transmit health data across the healthcare ecosystem. Workgroups composed of Carequality's implementer community and other subject matter experts determined this was needed to enhance flexibility and access in data exchange.

Push Notifications are the next step in advanced personalized medicine. This Carequality feature allows providers to subscribe to specific patients and be alerted any time those patients are admitted to a hospital or medical facility. This helps them to best coordinate patients' care plans for recovery.

Notable Achievements

Since the first exchange of health data in 2016, thousands of EHRs, HINs, payers, providers, and others have adopted the Carequality Interoperability Framework to exchange health data.

As of 2024, Carequality's efforts have facilitated the exchange of billions of healthcare records. Throughout the journey, the organization has marked numerous milestone achievements:

- December 2016: CommonWell Health Alliance announced its intention to adopt the Carequality Interoperability Framework and become a Carequality Implementer. This combination brought more than 90 percent of the acute electronic health record (EHR) market and nearly 60 percent of the ambulatory EHR market together.
- July 2017: By the first anniversary of the first Carequality exchange of health data, more than 23,000 clinics, 850 hospitals, and 260,000 physicians were regularly sharing more than 1.5 million documents monthly via Carequality Implementers.

- December 2017: Carequality participation had grown to more than 1,000 hospitals, 25,000 clinics, and 580,000 healthcare providers, representing more than half of all U.S. healthcare providers.
- March 2018: Carequality announced at HIMSS that 2.4 million clinical documents were being exchanged per month.
- December 2018: Carequality was spun off from Sequoia as an independent, nonprofit organization.
- January 2020: More than 50,000 clinics and 4,200 hospitals had connected to Carequality Implementers.
- March 2020: Carequality updated polices to address the COVID-19 pandemic to better support public health use cases, including creation of an Electronic Case Reporting Implementation Guide.
- April 2020: Carequality celebrated the exchange of its 1 billionth clinical document. By the end of the year, more than 2 billion clinical documents had been exchanged.
- March 2021: Carequality, in coordination with the Radiological Society of North America (RSNA), adopted the Image Exchange Implementation Guide.
- August 2021: Carequality approved the Push Notifications Use Case for production exchange. Current and future Implementers may now adopt the new Use Case as a standalone Use Case, or in conjunction with any of Carequality's other Use Cases.
- March 2022: Carequality published version 2.0 of its guidance document "Concise Consolidated CDA: Deploying Encounter Summary and Patient Summary Documents with Clinical Notes" detailing constraints for improved use of CDA document exchange.
- March 2022: Carequality published the Carequality Framework Policies, consolidating policies from multiple Implementation Guides into a single document to ease future updates spanning multiple use cases.
- August 2022: Carequality published updates to the Carequality Connected Agreement, in coordinating with the Social Security Administration, Department of Defense, and Department of Veterans Affairs, to better enable federal government agency participation.
- December 2022: More than 4 billion clinical documents were exchanged in the 2022 calendar year.
- June 2023: Carequality published the final version of its FHIR R4 Directory Implementation Guide.
- August 2023: Carequality's Steering Committee and Implementer community approved the first major updates to the Carequality Framework Policies document, improving patient access, enabling payer-based Care Coordination, and allowing new provider apps to easily connect furthering improved patient care.
- December 2023: More than 6 billion clinical documents were exchanged in the 2023 calendar year.

Future

The Office of the National Coordinator for Health IT recently began implementing the Trusted Exchange Framework and Common Agreement (TEFCA), which builds on the foundation created by Carequality's

Interoperability Framework. Carequality continues to work with ONC as part of The Sequoia Project's Recognized Coordinating Entity (RCE) team to enhance and inform TEFCA as it is rolled out.

In addition to playing a critical role in TEFCA, Carequality will continue to innovate and create new use cases and better interoperability approaches to continue making the nationwide framework even more inclusive and effective.

TEFCA

The Trusted Exchange Framework and Common Agreement (TEFCA) represents a significant stride towards achieving nationwide health information interoperability, addressing longstanding challenges in seamless healthcare data exchange. Developed to create a unified landscape for health data exchange, TEFCA aims to address the complexity of negotiating multiple individual agreements between healthcare entities, thereby simplifying the legal and technical aspects of data sharing. It sets forth a common set of rules and standards, fostering a more consistent and efficient flow of information across different healthcare constituents and jurisdictions.

To operationalize these objectives, TEFCA introduces Qualified Health Information Networks (QHINs), which serve as the onramp for the TEFCA Framework, enabling nationwide secure and efficient health information exchange across diverse authorized healthcare stakeholders. The creation of QHINs marks a critical step towards establishing a nationwide, interoperable health information Network of Networks for sharing data seamlessly and securely. The components of TEFCA include:

- The Common Agreement is the legal contract that the RCE will sign with each QHIN defining legal and technical requirements for secure information exchange on a national scale, and in turn each QHIN will sign with their Participants and the Participants will sign with their Subparticipants.
- The Trusted Exchange Framework are the principles to establish trust across the Framework's QHINs, Participants and Subparticipants.
- The QHIN Technical Framework delineates the technical components for exchange among QHINs.

Healthcare constituent organizations may contract directly with a QHIN to access the nationwide TEFCA interoperability. In this case they are a QHIN Participant. Alternatively constituent organizations may contract with a Participant to access TEFCA, in which case they are a Subparticipant. For example, an EHR vendor may contract directly with a QHIN and be the QHIN's Participant. As the organizations that have implemented that EHR are on-boarded to the QHIN, they become the QHIN's Subparticapants. All QHINs, Participants, and Subparticipants must sign the Common Agreement to utilize TEFCA and must participate in the TEFCA national interoperability health information exchange. Therefore, once a healthcare constituent organization has access this Network of Networks through a QHIN, or a Participant, they have access to share and receive information from all the healthcare constituent organizations that are participating as long as the request is appropriate to the exchange purpose of use of the query.

TEFCA also delineates specific exchange purposes. At the time of publication, the exchange purposes supported by TEFCA are Treatment, Payment, Health Care Operations, Public Health, Government Benefits Determination and Individual Access Services (IAS). These specified exchange purposes standardize the context and scope of data exchange within the healthcare ecosystem. This clarity in exchange purposes aims to facilitate more meaningful and purpose-driven sharing of health information, aligning it with the needs of patients, providers, insurers, public health organizations and payers while adhering to legal requirements. Moreover, by promoting greater access to and control over their health data for patients, TEFCA empowers individuals to be more engaged in their healthcare decisions, fostering a patient-centric healthcare environment.

The Sequoia Project, selected by the ONC as the Recognized Coordinating Entity (RCE), plays a pivotal role in this transformation, overseeing the development, implementation, and maintenance of the TEFCA's Common Agreement, and administering the QHIN designation and monitoring processes. Through its leadership, the Sequoia Project ensures the successful integration of QHINs into the healthcare system, moving the nation closer to a unified and interoperable health information ecosystem.

The Sequoia Project

The Sequoia Project is an independent, nonprofit organization working to advance nationwide health information exchange. For more than a decade, its experts have worked with partners across government, healthcare, and health information technology to improve the health and wellbeing of all people in the U.S. by making health information more readily accessible electronically.

The organization is a recognized thought leader in developing, implementing, and operationalizing the policies, governance, standards, and infrastructure needed to enable nationwide interoperability. The Sequoia Project organizes its work under independent initiatives – each with its own mission, governance, membership, and structure. By convening diverse stakeholders, it is uniquely able to identify practical solutions to persistent and emerging challenges facing nationwide health information exchange.

History

The Sequoia Project is a nonprofit founded in April 2012 to foster close collaboration on interoperability among the health IT private sector and government. Its first major project was assuming temporary stewardship of the eHealth Exchange, a nationwide health information exchange created by the Office of the National Coordinator for Health Information Technology (ONC). In less than a year, The Sequoia Project grew the network from nine founding members to 40 participants.

In 2014, The Sequoia Project announced its second initiative, Carequality, an interoperability framework used by health information networks to interconnect throughout the country. As an incubator for an idea born out of the health IT sector, Sequoia Project leaders brought together a dozen organizations with a stake in health information sharing. Facilitated by The Sequoia Project, organizations large and small – including fierce competitors – worked together to build the interoperability framework that remains the industry standard for data sharing today.

Other early initiatives included:

- Image Share Validation, a program in collaboration with the Radiological Society of North America (RSNA) to promote the adoption of image-sharing capabilities and expanded access to medical images and reports.
- The Patient Identity Matching Workgroup, which established standards for accurately identifying patient information within and across health systems.

By 2018, the long-term viability of nationwide health data sharing had improved. In that year, recognizing the maturity and sustainability of eHealth Exchange and Carequality, both initiatives relaunched as independent, standalone nonprofits – a clear demonstration of The Sequoia Project's commitment to incubating big ideas, fostering collaboration, and letting industry lead implementation.

Interoperability Matters

Today, The Sequoia Project continues to push into new territories to shape the national dialogue on health IT interoperability. Its focus extends beyond health data sharing for medical care to include public health, provider/payer communication, patient access, and other use cases.

In 2018, The Sequoia Project announced a public-private cooperative, Interoperability Matters, which invites subject matter experts from the private sector and government to identify and collaborate on the most pressing challenges facing nationwide health information sharing.

Interoperability Matters prioritizes issues that demand or benefit from national-level, public-private collaboration. This cooperative effort engages diverse groups to identify needs and priorities and develop work products and implementation resources. There are multiple workgroups included under the Interoperability Matters umbrella.

The Information Sharing Workgroup focuses on the practical implications of ONC's information blocking rules and on-the-ground approaches to facilitate information sharing. The workgroup provides inputs and comments on proposed rules and helps clarify policies and considerations for implementation and compliance with final rules. In 2020, The Sequoia Project published implementation guidance and hosted its first information blocking boot camp – a 13-week, intensive session to help healthcare IT communities prepare to comply with ONC's information blocking rules. In 2022, the workgroup published good practice recommendations and policy considerations as the information blocking rules took effect. The group will continue to review new regulatory proposals and provide implementation guidance.

Launched in 2020, The Data Usability Workgroup targets improvements necessary to ensure the usability of data received interoperably by end users within their workflows. With more than 260 participating organizations, the workgroup develops pragmatic guidance to help vendors, providers, public health, payers, implementers, networks, governance frameworks, and testing programs implement the data usability guide. In 2023, The Sequoia Project spearheaded a joint initiative with the American Health Information Management Association (AHIMA) to create a community of practice committed to implementing guidance developed by the Data Usability Workgroup. Dubbed Data

Usability Taking Root, the initiative provides technical assistance and a testing platform to help implementers improve the quality and usability to make health information more comprehensive and actionable.

The Public Health Workgroup provides a forum to learn about lessons learned and opportunities to improve public health agency access to health information. By connecting federal, state, and other jurisdictional public health authorities, federal agencies, and health information networks, the workgroup serves as a community of practice to address policy, regulatory, and programmatic challenges to the interoperability of public health data. Its initial focus was to identify lessons learned from the response to the COVID pandemic and recommendations to help local, state, and federal stakeholders better coordinate their response to future public health emergencies. In 2022, The Sequoia Project published the workgroup's recommendations as a free resource.

The Consumer Voices and Consumer Engagement Strategy Workgroups bring the voice of patients, caregivers, advocates, and other consumers into the conversation. These workgroups solicit feedback from individuals to understand their experiences with accessing, using, and sharing their health records. Initial efforts have already revealed meaningful insights into consumer experiences and priorities and have informed recommendations to help providers and others better serve consumer needs.

The Privacy & Consent Workgroup works to further propel the healthcare community toward information exchange that appropriately protects patient privacy. Key questions include:

- What level of exchange is permitted?
- When is consent required?
- What is the proper standard to obtain and electronically share consent?

This workgroup also addresses data segmentation and privacy issues, including evaluating the existing landscape for tools that might allow individuals and data holders to identify particularly sensitive information when sharing records.

TEFCA Recognized Coordinating Entity®

The Sequoia Project has consistently leveraged its industry knowledge and years of experience as it has worked with ONC to develop and implement the Trusted Exchange Framework and Common Agreement℠ (TEFCA℠), which establishes the standard set of principles, terms, and conditions for facilitating nationwide health information exchange.

In 2019, ONC selected The Sequoia Project as the Recognized Coordinating Entity® (RCE™) for TEFCA under a cooperative agreement, and in 2023, awarded the nonprofit a contract to continue in this critical role. As the RCE, The Sequoia Project is responsible for developing, implementing, and maintaining TEFCA and monitoring compliance with the framework. The Sequoia Project also manages the application and designation process for TEFCA Qualified Health Information Networks™ (QHINs™) that form the backbone of TEFCA. As the RCE, The Sequoia Project has also undertaken significant efforts to engage and educate stakeholders and promote participation in TEFCA by providers, payers, public health agencies, and others.

Annual Engagement for Real Impact

Each year, The Sequoia Project hosts a meeting for its members and other key stakeholders – including federal agencies, health systems, health IT developers, physicians, interoperability service providers, and regional and state HIEs. The annual meeting fosters continued engagement, understanding, education, and networking – with dozens of presentations, seminars, and discussion sessions on critical topics in interoperability. It also provides a formal opportunity for the health IT community to coalesce around the shared goal of comprehensive nationwide interoperability.

The Path Ahead

In the near term, The Sequoia Project anticipates launching a new workgroup under Interoperability Matters focused on understanding best practices and approaches for supporting payer-to-payer application programming interfaces (APIs) as required in CMS' rules. The other workgroups under Interoperability Matters will continue to advance solutions to key roadblocks for information sharing. In its role as the RCE, the organization will continue to work with ONC to maintain and advance the TEFCA framework and support TEFCA-based exchange.

Networks

Independent HIEs

Background and History

There are approximately 89 independent Health Information Exchanges (HIE) in the United States, at least one in every state, and several states have multiple regional or local HIEs. Pennsylvania has 5 HIEs, and California has 15 regional HIEs (https://www.ca-hie.org/initiatives/hie-in-ca).

There is a long history of organizations and initiatives aiming to establish data exchange between healthcare providers. In the 1990's, these were called "Community Health Information Networks" (CHIN). In the early 2000s, the term became "Regional Health Information Organizations" (RHIO). CHINs and RHIOs were unsuccessful, primarily because there were not enough participating health systems and physician offices with the necessary EHRs for electronic data sharing[1]. That changed with the HITECH Act of 2009, which provided incentives for hospitals and practices to install EHRs, which digitized clinical data and created the necessary infrastructure to send and receive data. The HITECH Act also included requirements and incentives for data sharing between organizations. After 2010, with EHRs in place in most hospitals and physician practices, health information sharing needs resulted in what we now call "Health Information Exchanges" (HIE) or "Health Information Organizations" (HIO).

While some HIEs are wholly funded from public funding sources (for example, fully state-sponsored), many HIEs receive a mix of funding from participating organizations and members, supplemented with public or state funding in the form of grants and annual funding. Millstein et al. report that half of HIEs struggle with sustainable funding.[2]

The most common participating organizations in HIEs are hospitals, health systems, and physician practices. Healthcare provider organizations are the primary participants in HIEs as both senders and recipients of clinical data. To provide continuity of care to patients, the healthcare provider organizations share the clinical records with other clinicians outside of their organization who are also on the patient's care team.

Many HIEs also have other members who connect to the HIE and participate in the data exchange:

- Health plans, health insurance companies, and payers. Health plans need to receive clinical information about patients (with the patient's consent) to help coordinate the care for the patient and address quality measures and care gaps. Health plans can also be a strong source of funding for the HIE.
- Public Health organizations – such as county or city departments of health.

Public Health departments play an important role in caring for residents in their jurisdictions, particularly in managing infectious diseases, drug and alcohol abuse, and maternal health care. They are important participants in HIEs as data contributors and recipients.

- Post-Acute Care Organizations – such as nursing homes, home healthcare, rehabilitation facilities and others. Often a patient transitions from a hospital or acute care setting to a post-acute care organization, and these transitions require transmitting the patients' clinical records, discharge instructions, and medication lists. To make sure that care transitions are smooth and without errors, the HIE plays an important role in ensuring that the Post-Acute Care organization receives complete and accurate clinical data.
- Community-Based Organizations (CBO) – for example housing agencies, food pantries, religious community organizations, homeless shelters. Patients who need support from CBOs will benefit if the CBO has access to certain clinical and demographic information. As we will see in the "future" section, there is a growing trend to include CBOs as participants in the HIE.

HIE Services and Use Cases

Regional HIEs provide data exchange between healthcare providers in a variety of ways. The most common services provided by HIEs are Clinical Data Exchange, Encounter Notification, and support for Direct Messaging as Health Information Service Providers (HISP). In addition, independent HIEs can store clinical data into a regional Clinical Data Repository, called a Non-Federated Model, which can support regional healthcare initiatives for research, population health and public health programs. In an HIE Federated model the patient information stays in the originating organization's database.

Clinical Data Exchange

The primary purpose for most HIEs is exchanging clinical data between healthcare providers and other HIE participants. The most common vehicle for clinical data exchange is the Continuity of Care Document (CCD) or any document following the Consolidated Clinical Document Architecture (C-CDA) standard. The HIE can pass the CCD from one provider to another. Some HIEs parse and store the data in the CCD in a Clinical Data Repository which allows clinicians in participating member organizations to view the data via a web-portal.

Some HIEs receive clinical data from participating providers via HL7 interfaces. This can be patient demographics and ADT data (Admission, Discharge, Transfer), Lab results, radiology reports or clinical documents. These HL7 interfaces feed into the HIE's Clinical Data Repository where clinicians can access and view the data.

Many EHRs allow clinicians to see documents from other organizations within the EHR. HIEs can push clinical data and clinical documents into the organization's EHR, typically in CCD or C-CDA format, so that clinicians can view the patient's data without having to leave the EHR or log into another system. An example is Epic's Care Everywhere, where clinicians can see records from other Epic organizations but also documents and records coming from the HIE.

Encounter Notification

While Encounter Notification is one of the simpler and technically straightforward services, it is often also one of the more valuable and heavily used services. Encounter Notification is a real-time or near-real-time notification if one of the organization's patients or members has an encounter at one of the participating hospitals. The most common Encounter Notifications are for Emergency Department (ED) visits, hospital admissions, and hospital discharges.

A crucial concept for Encounter Notification is the “panel” – the group of patients or members for which a practice will receive Encounter Notifications. For a health plan, the panel will be its members. For an ACO, the panel will be the patients who are enrolled as a member in any of the ACO’s plans. For a practice, the panel is typically the patients associated with the practice, and specifically the patients where the practice has a Value-Based Care (VBC) contract with an ACO or health plan. The panel determines for which patients or members the organization will receive notifications.

The Encounter Notification system receives real-time ADT interfaces (typically HL7 format) from all participating hospitals and health systems. The ADT interfaces include ED admissions, hospital admissions and hospital discharges. They may also include ambulatory encounter registrations. In many settings, Post-Acute Care admissions and discharges are also included in the Encounter Notification system. The Encounter Notification system sends an alert to any party who has a patient in their “panel”.

Direct Messaging and HISP services

Independent HIEs are often the Health Information Service Provider (HISP) to their participating health systems and practices. This means that the HIE can be the provider for transmission services for Direct Messages, which are HIPAA compliant, encrypted and secure messages from one provider to another, from one EHR to another. Direct Messages can include CCD or other C-CDA documents.

Patient Consent

Independent HIEs need to comply with HIPAA patient privacy regulations. Depending on the state(s) in which the HIE operates, patients can either opt out of data sharing, or need to actively opt in before any of their data can be shared. Patients can indicate their decision to opt in or out of data sharing at any of the participating member organizations, or directly at the HIE, typically through a web form or phone call. HIEs track a patient’s opt-in or opt-out elections and use this information to determine whether a patient’s data should be shared with other providers or not.

Future Opportunities and Challenges for Independent and Regional HIEs

HIEs face a constantly changing landscape, with both challenges and opportunities in how healthcare organizations will exchange data in the future.

Challenges

One of the major trends facing HIEs is the emergence of TEFCA, the national data sharing Framework and the TEFCA designated Qualified Health Information Networks (QHINs). If healthcare organizations can query any other healthcare system in the nation via a query through their QHIN, the need for regional health data sharing would be superseded by national data sharing. The major EHR firms are becoming QHINs themselves or associating with one of the QHINs, meaning that their clients will have a connection to the other QHINs and their connected organizations.

Another parallel threat to HIEs is data exchange via the EHR vendor, Epic. for example. Epic clients exchange data with other Epic clients through the Care Everywhere Network. Some other EHRs also connect into Epic's Care Everywhere network via the Carequality Implementer they have contracted with within the Carequality Framework. This level of clinical data exchange fits very well into the workflow for clinical users, and in many cases can supersede the data exchange via the regional HIE.

If a critical mass of healthcare organizations shifts their clinical data exchange to the National Networks (QHINs) under the TEFCA Framework, it would remove one of the main business use cases for the HIEs. But, as always, as one door closes, other doors may open, and new opportunities emerge for regional HIEs.

TEFCA QHIN and Carequality Implementer interoperability may threaten HIEs financially as HIE participants joining TEFCA for nationwide interoperability may not wish to pay duplicate fees to their HIE. With the attrition of healthcare constituent organizations away from HIEs, maintaining paying customers may become quite difficult, particularly as the Federal, and even some State funding, support for HIEs is drying up.

Opportunities

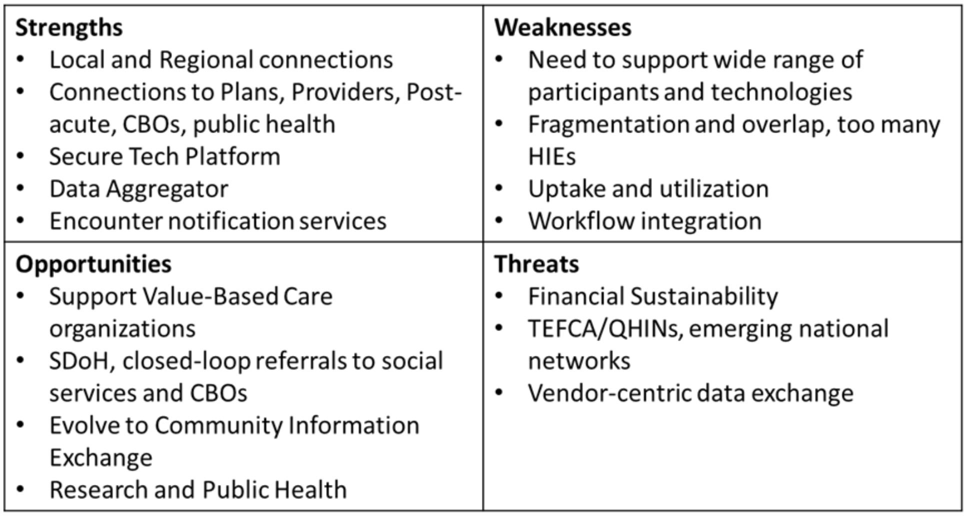
If and when clinical data exchange moves from HIEs to national networks or EHR private networks, HIEs still have ample opportunities to serve their healthcare organizations as data hubs. HIEs can focus on one or more of the following use cases to serve their communities and connected member organizations

Social Determinants of Health, and connections to Community-Based Organizations (CBOs). Healthcare organizations want to partner with local Community-Based Organizations to provide services to patients in need of housing, nutrition support, social services, transportation, or any other need that falls outside a typical healthcare facility. HIEs can provide the closed-loop referral system from the provider via a Resource Directory Service (such as FindHelp or UniteUS), to an appropriate CBO, and receive notification and updates from the CBO when a patient registers and receives services. This type of data exchange typically involves many very local organizations, which provides the HIE with an essential missing-link opportunity. An example of data exchange between healthcare providers and CBOs is the Pennsylvania state-sponsored PA Navigate project.[3]

HIEs and CIEs also have an opportunity as healthcare delivery and payment models increasingly shift to Value-Based Care (VBC) models – for example ACOs, practices participating in Medicare Shared Savings Plans, practices with risk-based contracts and per-member-per-month payments from health plans, and ACO-Reach practices. These physician groups and ACOs need to keep track of the healthcare quality and utilization for a population assigned to the practice. HIEs and CIEs are tools for effective population health management, in particular the user of Encounter Notification to track and reduce avoidable acute care utilization, and the connectivity to CBOs to provide appropriate social services to patients in need.

This expansion from strictly healthcare data exchange into social services and related services can shift the concept of “Health Information Exchange” to “Community Information Exchange”, which expands the scope of data exchange services for the regional HIE.[4,5] As we saw in the beginning of this chapter, health information exchange organizations evolved from CHINs and RHIOs to HIEs, and the shift to CIEs seems to be the next phase. CIEs are essential to providing healthcare and social services for patients in the region.

Table 2. Independent HIE SWOT Analysis



Strengths	**Weaknesses**
• Local and Regional connections • Connections to Plans, Providers, Post-acute, CBOs, public health • Secure Tech Platform • Data Aggregator • Encounter notification services	• Need to support wide range of participants and technologies • Fragmentation and overlap, too many HIEs • Uptake and utilization • Workflow integration
Opportunities • Support Value-Based Care organizations • SDoH, closed-loop referrals to social services and CBOs • Evolve to Community Information Exchange • Research and Public Health	**Threats** • Financial Sustainability • TEFCA/QHINs, emerging national networks • Vendor-centric data exchange

References:
[1] https://geekdoctor.blogspot.com/2007/11/are-regional-health-information.html
[2] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2020.01497
[3] https://pa-navigate.org/
[4] https://nhchc.org/wp-content/uploads/2020/04/NHCHC_Community-Information-Exchange2.pdf
[5] https://www.communitycommons.org

Civitas Networks for Health

History

At the heart of Civitas Networks for Health is community. Its vision – communities are thriving and healthy, realizing the full potential of data-driven, multi-stakeholder, and cross-sector approaches to health improvement and information exchange – prompted its creation. In October of 2021, Civitas Networks for Health was created through a formal affiliation of two national membership organizations.

The Network for Regional Healthcare Improvement (NRHI) and the Strategic Health Information Exchange Collaborative (SHIEC) entered a formal partnership process in 2021 to explore the potential of bringing organizations that exchange and move data closer to entities that were meaningfully using data to drive health improvement efforts in communities throughout the country. Leaders determined that the partnership would increase the impact, visibility, and effectiveness of advocacy, broaden reach and opportunities across both public and private sectors, and accelerate influence while simultaneously growing overall sustainability.

Civitas describes itself and its members as the bridge between “data” and “doing”. Almost two years later, the network has 170 organizational members across the country working to use health information exchange (HIE), health data, and multi-stakeholder, cross-sector approaches to improve health. Civitas educates the private sector and policy makers on matters of interoperability, quality, care coordination, health equity, and cost-effectiveness of health care. The 501(c)(3) nonprofit organization leads multi-site grant-funded programs and projects. Civitas supports local health innovators by amplifying their voices at the national level and increasing the exchange of valuable resources, tools, and ideas.

Civitas' predecessor organizations

NRHI, a national nonprofit member organization of Regional Healthcare Improvement Collaboratives (RHICs), during its existence represented more than 30 RHICs and state-affiliated partner organizations across the United States. RHICs are non-profit organizations governed by multi-stakeholder boards that include consumers, health care providers, payers, and purchasers of health care. They are trusted, neutral conveners that help local stakeholders identify opportunities for improving the health and health care of their communities while facilitating planning and implementation of strategies to achieve improvements.

SHIEC, the national trade association for HIE organizations and strategic business and technology partners, represented 76 state and regional HIEs for an overall total of 113 members working to manage and provide for the secure digital exchange of health data for hospitals, health care providers, and other participants. Its members worked to improve care coordination and care management across health care systems and communities, enable more informed clinical decisions, and reduce hospital readmissions and other preventable expenditures such as unnecessary or duplicative tests and procedures.

Civitas related Federal Advocacy and Policy Milestones that Prompted Health Information Exchange, Quality Improvement Efforts, and Advancement of Health Equity.

2021

- Civitas Networks for Health is established as a nonprofit multi-stakeholder national collaborative. HITECH match funding ends for state HIE services.

2022

- Civitas publishes the to clarify the role and function of HDUs.
- Maryland's Chesapeake Regional Information System for our Patients (CRISP) becomes the first state designated HDU in the nation with the enactment of a new state law upgrading its official HIE status to that of an HDU, with additional health data sharing functions.

2023

- Civitas, in partnership with the Maryland Health Commission, publishes the Consortium for State and Regional Interoperability publishes the HDU Maturity Model.

Advantages

There is benefit in bringing HDUs, HIEs, RHICs, QIOs, All-Payer Claims Databases (APCDs), and other data-led health collaboratives closer together. This bridge between data and doing provides necessary infrastructure in communities throughout the country working to improve health and advance health equity.

One way to articulate this advantage is by looking at the HDU Model. HDUs are equity infrastructure. They are statewide entities that combine, enhance, and exchange electronic health data across care and service settings for treatment, care coordination, quality improvement, and public and community health purposes. They have specific, defined use cases in accordance with applicable state and federal laws protecting patient privacy. HDUs require deep commitment to community multi-stakeholder governance and are best led by nonprofit entities working collaboratively and serving as a neutral convenor. The evolution of HIEs and emergence of HDUs is the result of significantly expanded health data use cases, moving far beyond clinical data exchange to meet the needs of public health, community health, health data research, and more. Examples of how HDUs are providing essential services can be found in the use cases section of this chapter.

In the coming year, the industry will see the promise of partnerships among HIEs, HDUs, and QIOs as these entities work to address tasks under CMS' 13th Statement of Work. The emphasis of this next phase of quality improvement work is on advancing health care through technology. The goal is to make sure providers and clinicians in underserved areas are using modernized IT systems for data collection and advanced analytics to improve quality and outcomes. It will be beneficial for QIOs to use existing infrastructure established by HIEs to extract necessary data and to continue to increase connectivity with rural providers.

Limitations

Some important limitations specific to nonprofit, community serving organizations, and in some cases specific to HIEs, are market consolidation, business and technology models that cannot be replicated elsewhere, and sustainability. Increased consolidation can be a threat to regional HIEs. In certain states, regional HIEs are working collaboratively to meet state needs, but increasingly state-designation and coordination of services results in merging regional and community entities. Additionally, for-profit vendors and private HIEs are also a threat to nonprofit HIEs. Though potentially attractive, for-profit service providers do not always ensure careful data governance, community involvement, and deep understanding of state and local laws. However, there are many highly productive partnerships between nonprofit HIEs and technology solutions partners and private HIEs.

While it is necessary for HIEs to meet unique community needs, the approach, technology, and services offered do not need to be so vastly different, HIE to HIE, that it inhibits connectivity and/or causes confusion in the market about the structure and services rendered. This is a benefit of the HDU model in that there are clear replicable characteristics and a base set of use cases needed to establish that an entity is an HDU.

Nonprofit data-led health organizations – HDUs, HIEs, RHICs, QIOs, APCDs – need to have diversified revenue, and be careful to not lean too heavily on federal grant funds. Sustainability requires careful attention and dedicated effort to stack, braid, and blend participant fees, local, state, federal, and private grants and/or services rendered.

As Civitas works to bring its diverse membership base closer together, there is a challenge in finding the right balance between areas of focus, advocacy attention, business development opportunities, and programming. Civitas is concentrating on how to bridge data and doing, and where there are additional opportunities for collaboration across member organization types. Maintaining a common thread among members has its challenges, but pursuing the organizational vision and national network is a worthy cause.

Consent Management

The need for protocols and increased management of patient consent are ever present in 2024. With expanded use cases for health data exchange – behavioral health, SDOH, substance use disorder, and reproductive health – honing these processes is necessary. HIEs have typically been Business Associates of HIPAA Covered Entities, so exchange of patient data among providers and HIEs has been allowed by HIPAA. Extending data sharing to include Community Based Organizations and public health agencies requires new acquisition and management of client consent.

In 2023, Civitas hosted a three-part member roundtable series focused on management of sensitive health data. A clear outcome was the potential of adopting and furthering the use of Data Segmentation For Privacy (DS4P), a method that is making inroads in tagging sensitive health data, streamlining processes, and ensuring the right level of privacy. This will be an important area of focus for HIEs and HDUs in 2024 and in the years to come.

Future

Comprehensive health data exchange is a significant step in improving health outcomes. Equally, if not more important, is taking the data and driving meaningful action. Civitas believes its national network will expand work in the areas of care coordination, community engagement, emergency preparedness, Medicaid partnerships, public health data modernization, the evolution of TEFCA, and adoption of value-based care over the next year and in the years to come.

Care Coordination and Community Engagement

Improving the flow of health information sharing across the care continuum is allowing for care teams – providers, clinical teams, CHWs, social service providers, and community partners – to provide person-centered care extending well beyond clinical settings. This level of information sharing not only requires robust data exchange, but also acquisition and management of client consent, trusted relationships, multi-stakeholder and cross-sector engagement, and a commitment to inclusive governance and practices. Civitas members are working across the full spectrum from implementing SDOH data standards to building community capacity through workforce initiatives.

Emergency Preparedness

The challenge of collecting health data on a national level was demonstrated during the COVID-19 pandemic as health care providers and federal agencies alike struggled to access and aggregate data in real time. While efforts to rapidly scale new capabilities were confronted with challenges, many existing parts of the health care infrastructure, like HIEs and HDUs, were able to stretch and adapt to meet new demands. State-based HIEs and HDUs, including many Civitas members, addressed the data challenges of the COVID-19 pandemic by maintaining detailed COVID-19 tracking databases, building vaccine reporting interfaces, and helping small providers automate data entry to meet new reporting demands.

By serving as neutral and trusted hubs of information, HIEs and HDUs offer a foundational infrastructure in existing data aggregation, quality, governance procedures, and technology that help to ensure a nimble response to many emergent situations.

Public Health Data Modernization

Launched in 2020, and perhaps the most widely recognized public health data modernization effort of the CDC is the DMI. This multi-year, billion-plus dollar effort is aimed at modernizing core data and surveillance infrastructure across the federal and state public health landscape.

Currently, many Civitas members are seen as a vital partner to their respective state's public health department in data collection and aggregation needs. Civitas members can play an important role in large, national public health data modernization efforts, such as the CDC's DMI, as they have the flexibility to adapt and compensate for any needs and challenges at the state and local level, while also providing the infrastructure to report appropriate information to the federal government.

Additionally, many HIEs and HDUs are experts in the privacy laws of their states and maintain the trust of their local communities. These factors can help increase the likelihood of success in public health data modernization efforts.

TEFCA

There is increased collaboration across operators of health data infrastructure as HIEs and other health data collaboratives engage in new initiatives like the TEFCA for Interoperability. This trend is a clear indication of Civitas members striving to broaden their reach and interoperability capabilities. By participating in these national initiatives, HIEs and other health data collaboratives are not only expanding their geographical coverage but also enhancing their ability to exchange health information more efficiently and securely across different regions and health systems.

These partnerships are vital to achieve a level of interoperability that transcends local or state boundaries, which is essential in today's health care landscape where patient mobility and cross-state health care delivery are commonplace. Civitas provides a platform to share best practices, learn from others within the health data sharing ecosystem, and collectively address common challenges.

Medicaid Partnerships

Civitas members are increasingly aligning their strategies with Medicaid reforms and initiatives, tapping into new funding opportunities that support the advancement of health equity and the transition towards value-based care models. This alignment is critical for health data collaboratives to stay relevant and effective in a health care system that is steadily moving away from fee-for-service models and better meeting the needs of underserved communities.

Value-Based Care

Beyond offering comprehensive data that supports whole person care, Civitas members also provide technical assistance for delivery and payment reform. Central to this is the commitment to regional and local learning forums that encourage multi-stakeholder and cross-sector collaboration. Serving as neutral convenors and presenting aggregate public data and quality measures requires careful skill and deep understanding of divergent perspectives and community interests.

eHealth Exchange ™

The eHealth Exchange was born out of federal efforts to develop a foundation for interoperable data exchange nationwide. Continuing work started by the Obama administration's Executive Order 13410￼ issued in 2007, The Office of the National Coordinator for Health IT (ONC) established the Nationwide Health Information Network (NwHIN). In 2009, its first data exchange connected the Social Security Administration and MedVirginia, and within two years, the network had grown to 23 participants, including five federal agencies.

In 2012, the ONC transferred stewardship of NwHIN to The Sequoia Project to prepare the network to stand alone as an independent entity in the private sector. While under The Sequoia Project, the network was renamed as the eHealth Exchange and continued its rapid growth. Six years later in 2018, eHealth Exchange became a fully independent nonprofit organization. In December 2023, the eHealthExchange became one of the first five QHINS to serve under ONC's TEFCA.

Connectivity, Governance, and Data Security

Over its nearly 20-year history, eHealth Exchange has evolved to become the largest HIN in the country. It facilitates roughly 20 billion data exchanges annually, providing connectivity for 60 regional and state HIEs, 75 percent of U.S. hospitals, 70,000 medical groups, 5,800 dialysis centers, and many urgent care centers, surgery centers, and clinical laboratories. Notably, the eHealth Exchange Network connects to five federal agencies:

- Department of Defense (DoD)
- Food and Drug Administration (FDA)
- Indian Health Service (IHS)
- Social Security Administration (SSA)
- Veterans Administration (VA)

As a technology-agnostic network, eHealth Exchange can connect to any electronic health record system (EHR) that either is on eHealth Exchange or on another Carequality Implementer Network or QHIN.

Because of its commitment to data privacy and security, the eHealth Exchange limits its functional role to data transfer and like some of the other Networks operates a Federated Network Model. Federated Networks do not store, track, use, or sell any data transmitted by participants, there is no central database or repository of data to attract cyber criminals. Rather, participants retain control over their patient data and fidelity to patient consent. While the advantages of this approach are clear and significant, it also means that eHealth Exchange offers no Master Patient Index to support medical history searches. Participating federal agencies, providers, and HIEs connect to the eHealth Exchange Hub to access and share medical records.

The eHealth Exchange supports the latest and most secure technology systems and standards, including all HL7 International's Faster Healthcare Interoperability Resources (FHIR) data standards. Nationwide Trust

Participants in the eHealth Exchange voluntarily agree to comply with a standard set of technical and policy requirements. All exchange partners sign a DURSA trust agreement. A group of federal agencies and private sector organizations developed the DURSA through a collaborative process, and it serves as the foundation for trusted data sharing at a national level.

Signing the DURSA without modifications, participants forego the need to negotiate and execute point-to-point legal contracts with each exchange partner. Instead, the eHealth Exchange is responsible for developing the legal infrastructure to support health information exchange for its participants by establishing technical and policy requirements, providing network exchange oversight, enforcing testing obligations, managing digital security certificates, maintaining a broader network security framework, maintaining a network directory of exchange partners, and deploy a hub-and-spoke network technology platform to automate connectivity. eHealth Exchange is HITRUST and NIST certified.

Designed for Enterprise Participants

eHealth Exchange relies heavily on its participants and partners to manage their own integration, technical readiness, data standards, and consent compliance. As a result, the ideal participants are large healthcare systems or provider networks with robust and knowledgeable IT teams. For small physician practices and care facilities, eHealth Exchange encourages connection via their regional or state HIE. eHealth Exchange expects providers to follow applicable consent laws and provide patients with the necessary forms to opt out of the data exchange process.

Driving Public Health Use Cases

While eHealth Exchange has proven to be a reliable network for supporting treatment use cases, it is increasingly proving value in driving exchange in public health. For example, eHealth Exchange transmits roughly 95% of public health electronic case reporting today. The exchange even allows nonparticipants to share public health data through the network at no cost. It also provides the network for PULSE – the Patient Unified Lookup System for Emergencies – an electronic health information system that helps people manage their healthcare during and after a disaster. Powered by the eHealth Exchange, PULSE allows authorized first responders and other healthcare volunteers to query and view evacuees' medical records from all connected healthcare organizations using nationally recognized standards. Ongoing efforts to extend public health use cases include collaborating with the FDA to track adverse events among immunization patients. Using FHIR standards, 12 large health systems and the Veterans Health Administration (VHA) have begun exchanging adverse event data with the FDA.

By spotlighting the effect of FHIR-based exchange on data transactions, this pilot project informed the development of a usable FHIR app and optimized APIs. Lessons learned will help further expand use cases to include electronic prior authorization and other automations that will reduce burdens on patients, providers, and payers.

As the COVID pandemic showed, providers and public health agencies must be able to accurately and effectively share data to allow for effective responses to infectious disease outbreaks. The eHealth Exchange is committed to working with public health agencies nationwide – including state, tribal, local, and territorial agencies – to enhance reporting capabilities and increase the volume and quality of available public health data.

Looking Ahead

eHealth Exchange is actively encouraging participants to transition from traditional fax technology and begin FHIR-based exchanges with payers and public health agencies to reduce the burden on clinicians and increase care quality. eHealth Exchange is actively engaging payers and others to help prepare for the 2026 implementation of new standards for processing electronic prior authorization requests.

In the longer term, eHealth Exchange anticipates skyrocketing volumes of data exchange as its participants expand their use cases beyond clinical treatment. In addition to public health, the prior authorization and payment, future use case, the network expects to enable risk adjustment, healthcare operations, individual access, government benefits determination, and more.

As a designated QHIN in December 2023, the network will actively encourage participants to opt into the TEFCA value framework to scale exchange nationwide effectively.

eHealth Exchange has proven its ability to evolve over the past two decades as the industry and technology shifts. As a member-driven organization, it will continue to shift in line with the market to ensure that data can reach its potential and become the true enabler for better care and medical breakthroughs.

To learn more about eHealth Exchange, visit www.ehealthexchange.org.

CommonWell

Early History

Recognizing the Meaningful Use program begun in 2009 could only go so far on its own, in 2012 at a meeting of the Bipartisan Policy Committee, Dr. Farzad Mostashari, (then the Director of the ONC) challenged Health IT leaders in the room to build connections across patient records.

The health IT industry heard the challenge. Recognizing the need for health interoperability to be a coordinated effort across many vendors, the five founding Members of CommonWell introduced CommonWell to the world on March 4th, 2013, in New Orleans at HIMSS. Later in 2013, the Alliance was officially incorporated as a 501c6 non-profit Trade Association, and the first round of providers went live on the CommonWell network in January 2014.

Technical Underpinnings

The right patient data - <u>ALL</u> the patient's data – at the right place at the right time.

This is a simple premise with a complicated history. This desire for a comprehensive picture of a patient's clinical history is the key driver of how CommonWell was set up. Other drivers included:

- Enabling access to ALL the Data
- Not reinventing what works.
- Creating and maintaining trust.

To start, the founding members knew CommonWell would need to be a centrally coordinated query-based system not a push-based environment. Assuming you know where the data is you ensure the opportunity to get all the data. If you push, you either need to know where to send data based on referral patterns or you need a centralized warehouse to which all the data is pushed. On a massive national scale, hundreds of thousands of data sources expected over time being pushed to a centralized warehouse is costly and a potential security concern. Warehousing data has benefits for some health information networks, but using the guiding principles above, the choice was easy – keep the federated data within the source systems and pull the data out when it is needed, where it is needed.

On demand query-based access

The security risks associated with all the data for all patients nationwide are obvious. Lesser so is the support implications. Leaving data where it is stored is fundamentally easier and enables data to be accessed on demand. This is not just about the expense related to duplicating data, it is about data integrity and support. If data is warehoused, the centralized system needs to be made aware of new data types. To keep up, many interfaces need to be rebuilt or refactored regularly to process new data types. At a national scale, with tens of thousands of sources, this becomes an infinite resource support problem. We have to look no further than the evolution of United States Core Data for Interoperability (USCDI) (https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi) to see this. As this data standard from the ONC is revised annually, new data types are made available for storage and exchange between systems. If pushed, the interfaces to the central entity would need to be maintained. If kept where they are, as the edge upgrades so does data availability from that edge.

Additionally, data changes at the record level over time. As orders are processed and data is generated records change. Discharge summaries are generated and signed off. Images are reviewed with a preliminary result that may be revised and signed as final later. Labs go from preliminary to final with many steps in between including but not limited to fulfilled, preliminary, revised, etc. In a federated, query-based world, when one side makes a request, it gets whatever data is available at that moment in time and as it revises new data can be queried. In addition, to create trust the data is not transformed as it moves from the source to the requestor. This enables trust beyond security and privacy. The querying party can trust the data they get is the other entity’s data without modification.

The CommonWell Record Locator Service

Health care in the United Stated is a complex industry made up of hundreds of thousands of providers and payers, large geographic coverage, and complex and sometimes conflicting state and federal policies. Finding data across this vast array of systems and data nodes is not a small task, but this is where a record locator service helps. A record locator keeps track of where the data is stored so when an entity asks for data, it can assist with where to go. Without a record locator, each entity would need to query each other directly to ask if the potential responder has data for a particular patient. If every visit or encounter (about 1.15 B per year) yielded one query across all clinical practices (over 200,000), the amount of searches per day would be almost 2 factors higher than the number of web searches serviced by Google every day.

- Approximate Number of Clinical Events per Year: 1.15B

    - Ambulatory visits: 1B
    - ED Visits: 136M
    - Hospitals Admissions: 34M
- Clinical sites: 200,000
    - Ambulatory: 200,000 and Hospitals: 5,000

Table 3: Query Volume Analysis

	Point to Point Patient Discovery Volume Analysis	Record Location Based Query Volume Analysis
Entities to Query	200000	1
Clinical Events per Year	1,150,000,000	1,150,000,000
Queries for a comprehensive search	230,000,000,000,000	1,150,000,000
Queries per Week	4,423,076,923,077	22,115,385
Queries per day with a 6 days clinical week	737,179,487,179	3,685,897
Google searches every day	9,000,000,000	9,000,000,000
Ratio of Patient Discovery Searches to Google Searches Daily	81.90883191	0.000409544

Obtaining a comprehensive view of a patient's clinical history using point to point queries is incredibly different than a coordinated approach. With a record locator, the math and computational power required to manage it is dramatically different – querying one entity is clearly more efficient than having to query all 200,000. Knowing this, CommonWell built itself around a central record locator and then sought to get as much of the healthcare ecosystem to connect to it as possible to create scale. As of the writing of this chapter, CommonWell has approximately **34,000 clinical sites** serviced via 3 dozen connected technology members. While individual providers could join the Alliance and connect individually, the primary method of connection is through technology vendors who had providers as their customers. This is how 3 dozen connections balloons to 34,000 and counting.

Record location itself was not enough to get the job done. In order for the record locator to know an individual, e.g., John Smith, was in nodes A, H and Z it needed some way to match patients across the nodes. Unfortunately, the United States is lacking a national health identifier to uniquely identify each patient and help with matching. To solve this problem, the RLS is driven by a Master Patient Index (MPI). An MPI is a system designed to analyze individuals' demographics across sites and determine which patient record is for the same person. All the sites connected through CommonWell members send real-time demographic feeds to CommonWell to enable this to work. Example: John Smith, Male, Aug 1st, 1956, 123 Main St, Los Angeles, CA, 90210, etc. In the early days of CommonWell, the MPI evaluated potential matches and the providers connected to CommonWell manually reviewed computationally identified probable matches. As CommonWell matured, this manual confirmation process became more automated. As of November 2023, CommonWell has 220M unique individuals matched in its RLS.

Governance

The CommonWell Health Alliance is a Membership organization incorporated as a 501c6 Trade Association. Membership is open to any person or entity and is primarily made up of health information technology vendors. The Members participate in committees that inform the Alliance's Board of Directors on direction with the primary product of the committees and the Board being the CommonWell Specification. The specification is a publicly available specification located here https://specification.commonwellalliance.org. The current committees include:

- STIG – Standards Technology and Implementation Group
- Use Case
- Privacy and Security
- Deployment and Utilization
- Government Affairs
- Marketing
- Operating

External Frameworks

From the beginning, CommonWell network was open to vendor participation across all care settings. While the Alliance believes in its model, it also recognized there are other approaches to interoperability. As such, over time it extended its connectivity to frameworks. First, it joined the Carequality Framework in 2018 and went live in 2019 as a Carequality Implementer network. Connecting to the framework created a spike in usage both for CommonWell and the existing Implementers within Carequality. Next, CommonWell has applied to be a Qualified Health Information Network (QHIN) under TEFCA. The Alliance submitted its QHIN application February 2023 and had its application approved to continue on with the process.

Use Cases

1.0 Treatment

CommonWell was founded to address transitions of care between health care providers. Under HIPAA this exchange between covered entities is considered **treatment**. For the first three years, CommonWell only did **treatment**-based exchange. But, as the network evolved, CommonWell's Members recognized the same network could be used for other use cases. In 2016, the Alliance launched individual access and allowed consumer applications to make queries on behalf of patients. This allowed one click access to a patient's data across all participating Providers. Today, over **6,000 sites** in CommonWell respond to patient access queries and this is growing by the day.

2.0 Payments and Operations

In 2021 CommonWell moved into the next phase of support for HIPAA covered exchange with the launch of data exchange for **payment and operations**. Initial use thus far has been for payment, but operations was piloted and while adoption is small today, the Alliance continues to grow support for the new use case.

The Specification

CommonWell built on the success of others and made things better. The specification is a mix of standards and proprietary technology coming together. When it launched in 2013, CommonWell was primarily based on Integrating the Healthcare Enterprise (IHE) standards with proprietary APIs for management of the central record locator and its associated MPI. In 2017, CommonWell became the first national network to use the Argonaut Project's FHIR Specifications to create a broker that enabled FHIR documents to be exchanged but also converted FHIR to IHE and vice versa enabling many new Members to join the Alliance.

In addition to query-based exchange the Alliance also supports an event notification service (ENS). The network's first use of ENS was the sharing of ADTs for TREATMENT.

Future Goals

The Alliance continues to grow and thrive under our goal of interoperability done right! Low-cost, nationally scaled exchange that is super charged by a standards-based driven specification and a record locator. While connecting to other frameworks and adopting FHIR were significant steps for CommonWell, the Alliance continues to look ahead to what is next. For example, the Alliance started to explore an extension to its specification to enable the exchange of discrete data under FHIR. The Alliance started this FHIR journey in 2021 and continued on to do public demonstrations at HIMSS 2022 and HIMSS 2023. Also in spring 2022, it hosted a successful, Member-wide connectathon. The Alliance is completing its FHIR Implementation Guide (FHIR IG) and provided preliminary drafts of its FHIR IG to the ONC to help in its design of TEFCA and its FHIR roadmap.

We collectively have more work to do to get more of the health ecosystem connected. While the future is uncertain, the Alliance embraces change and continues to update and improve its specification to meet new needs. We look forward to connecting our members and their customers to the CommonWell network and to the TEFCA, once we have achieved designation, while we collectively advance interoperability at scale.

ONC on the Future of Interoperability

Per Steve Posnack, the Deputy National Coordinator for Health Information Technology of the ONC, as we look to the future of interoperability part of the answer will be aligning the market drivers of business interests, market incentives and Government Policy. Aligning these three, we have a greater ability to bridge gaps in information sharing between healthcare and non-healthcare settings.

He specified that having healthcare traditionally connect to non-healthcare has not been widespread there is, however, a growing interest in this now with shifts from Fee for Service payment to alternative payment models with shared risk and savings such as value-based care. These alternative payment models rely on ongoing information about participating patients across the spectrum of care and orchestrated care coordination and care management across the care team. This requirement for patient information for care coordination and management is a key driver of interoperability. Success additionally requires supportive policies and other structures to be in place from a business and Market dynamic. Information sharing must go beyond just the right thing to do for optimal efficient effective care but also to drive changes in healthcare delivery and savings.

The Future of Interoperability for Resolving Care Gaps and Closing Care Loops

To resolve care gaps, we need to ensure that the individual’s information flows to the individual and to the care team members to whom that individual has given access rights. For example, if a patient has a vaccination at a pharmacy, the patient’s PCP should have interoperable access to this information, given that the patient has consented for the PCP to have right of access. The PCP office can then focus efforts on ensuring vaccine care gaps are closed for their patient roster who do not have any contraindication and have not received vaccines.

Closing referral or transfer loops means that the receiving organization has the patient information prior to the referral or transfer event. Such that the referring clinician receives the consultation report following a consultation or the transferring clinician/organization receives information that the patient has been admitted at the time of admission and the discharge report at the time of discharge. The entire Healthcare industry is working with networks governed by national frameworks, enabling data exchange and supporting a ‘plug and play’ process for interoperability to continue the expansion of the accessibility and reach of data to inform care and reduce duplicative services and redundant testing. CMS incentive programs include new shared risk and reward payment models with financial incentives for care coordination and information sharing. These practices/standards and innovations continue to move healthcare interoperability in the right direction, positively impacting patient-centric care.

While celebrating the strides made, we remain mindful of the prevailing challenges. Barriers to electronic health data sharing, fragmented health information exchanges, and the evident gaps in health IT incentives underscore the work ahead. A collective approach is pivotal, accentuated by our ambition to prioritize information dissemination, uphold technology standards, and ardently support health equity.

Together, we stand at the precipice of creating a robust, interconnected health IT infrastructure for future generations. The ONC-supported TEFCA Framework with its designated QHIN Networks will indeed be the “on-ramp” for the next phase of national interoperability, simplifying the process for patients, providers, and authorized healthcare constituents to share health information securely and efficiently, while respecting consumers’ privacy. This framework represents our ambition to achieve a single nationally interconnected health system.