PUBLIC HEALTH DATA MODERNIZATION

Listening Session on Real-World Testing of 21st Century Cures Act Requirements

EXECUTIVE SUMMARY

Session Held on July 16, 2020

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Listening Session on Real-World Testing of 21st Century Cures Act Requirements

Background and Goals

The universal health data application programming interfaces (APIs) called for in the 21st Century Cures Act present an opportunity for public health to access valuable information on cohorts and populations. Real world testing is needed to demonstrate how this emerging *lingua franca* can help public health—at all levels from local to national—to obtain timely, accurate, and actionable data from electronic health records.

Building on the momentum of its Data Modernization Initiative, CDC hosted a listening session on July 16, 2020, to discuss ways emerging standards—including but not limited to standardized APIs for population level data, often referred to as bulk data—could benefit public health. This meeting brought together key stakeholders from across public health and healthcare, including the Deputy Director for Public Health Science and Surveillance at the US Centers for Disease Control and Prevention (CDC); representatives from state and local public health agencies; the Director of the Office of the National Coordinator for Health Information Technology (ONC) and other members of the ONC staff; as well as representatives from health systems and technology innovators.

The goals of the meeting were to:

> Understand how recent changes in the regulatory environment may benefit public health, including but not limited to the US Core Data Elements for Interoperability and best practices for accessing bulk data;

> Identify the technical aspects that need to be addressed to conduct real-world testing of electronic health record interoperability standards newly regulated by ONC; and

> Outline policy and socio-regulatory considerations pertaining to patient privacy and accessing data from electronic health records at scale.

Meeting Highlights

What is already known about the topic?

All levels of public health, from the local level to the national level, struggle to obtain timely, accurate, and actionable information from electronic health records. The current data environment too often relies on cumbersome, non-electronic methods for data exchange that can pull frontline public health officials and clinicians away from essential work and result in data omission and errors. Although methods for electronic data collection are available, several still cannot be implemented at scale without significant effort.

What is added by this report?

Important progress has been made over the last decade to standardize the exchange of health data. Modern data standards and technologies are evolving at faster rates and are designed to promote data liquidity as called for in the 21st Century Cures Act. To fulfill the requirements of this Act, federal regulators have established a common and consistent set of expectations regarding what data elements will be structured and made widely available. The policy and technical specifications are now being solidified to simplify the process of requesting and exchanging data across organizational and jurisdictional boundaries. This will result in an enhanced data environment that is set to become a reality by the end of 2022.

What are the implications for public health practice?

The standardization and baseline capabilities that are coming into play over the next two years present an opportunity for public health to access richer data to drive decision making and inform the public more quickly and with greater precision. If architected appropriately, data modernization efforts supported by CDC could reuse and extend capabilities that already exist (such as health information exchanges) and that will soon exist (such as core data elements and standard application programming interfaces for accessing health data nationwide) instead of operating and maintaining a set of one-off, niche-specific systems used to report data to public health.

This more unified and modern approach could help to provide state and local public health departments access to well-processed and up-to-date information, which could be de-identified and rolled up to national-level data requestors more seamlessly to drive federal policy making. These scalable, non-proprietary tools and approaches to interoperability could help provide useful and actionable data to accommodate various levels of information sharing while addressing long-standing, cross-cutting public health data challenges in a sustainable manner.

Opening Remarks
Chesley Richards (CDC)

Overview

All levels of public health, from the local level to the national level, struggle to obtain timely, accurate, and actionable information from electronic health records. The current data environment too often relies on cumbersome, non-electronic methods for data exchange that can pull frontline public health officials and clinicians away from essential work and result in data omission and errors. Although methods for electronic data collection are available, several still cannot be implemented at scale without significant effort.

Key Takeaways

SIGNIFICANT TRANSFORMATION IS NEEDED TO ENSURE PUBLIC HEALTH CAN ACCESS DATA TO HELP PROTECT COMMUNITIES

Currently, health systems provide data to public health through multiple channels. Too often, the burden of implementing these solutions is so high that frontline public health professionals are forced to fall back on phone calls, paper forms, and faxes. As a result, clinicians are unduly burdened with filling out paper forms instead of delivering needed care, or they simply do not report what is needed to public health.

Although there have been pockets of innovation regarding electronic data exchange, public health traditionally hasn't had the resources or the will to scale new approaches broadly. Without significant transformation, public health reporting will continue to be beset by delays, incomplete information, and missed opportunities.

UNPRECEDENTED RESOURCES ARE NOW AVAILABLE TO ADDRESS LONG- STANDING ISSUES WITH DATA AND TO CREATE MODERNIZED SYSTEMS

Thanks to funding for data modernization and through supplemental appropriations, public health is getting resources that are truly unprecedented to address data issues and to create the kinds of data systems required to meet longstanding needs.

INPUT IS BEING SOUGHT FROM INNOVATORS TO HELP DEFINE AND BUILD THE FUTURE OF PUBLIC HEALTH DATA INTEROPERABILITY

Input from innovators can help bring about long overdue transformation in public health reporting. This is the first of many listening sessions that will bring together experts from state, local, and federal governments and the private sector to hypothesize how data collection efforts supported by CDC can be more modern, adaptable, scalable, and sustainable.

What's Coming in 2022 and What Opportunities Does This Present for Public Health?

Ken Mandl (Boston Children's Hospital & Harvard Medical School)
Introduced by Steven Posnack (ONC)

Overview

Important progress has been made over the last decade to standardize the exchange of health data. The 21st Century Cures Act, passed in 2016, includes a focus on application programming interfaces (APIs) and sets the expectation that those APIs will allow information from medical records and other certified IT products to be accessed without special effort.

The Health Level Seven(HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard has matured and is now used across the globe. In recent regulations, the Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare & Medicaid Services (CMS) named FHIR Release 4 as the standard required to fulfill the requirements of the 21st Century Cures Act. Additionally, ONC's regulation established a common and consistent set of expectations regarding what data elements will be structured and made available to fulfill multiple purposes. ONC's rule also requires certified health IT vendors to support the bulk FHIR API to enable access to data on groups, cohorts, and populations.

This enhanced data environment will roll out nationwide and is set to become a reality by 2022. Collectively, the standardization that is coming into play could help make it easier for public health to access data, drive decision making, and inform the public more quickly and with greater precision.

Key Takeaways

MUCH RICHER, STANDARDIZED ELECTRONIC HEALTH DATA WILL SOON BE AVAILABLE NATIONWIDE TO MEET MULTIPLE NEEDS

Regulations recently finalized by ONC and CMS establish a set of common and consistent data expectations that certified health IT vendors (e.g., electronic health record vendors such as Epic, Cerner, and Allscripts) are required to support. These upgrades will focus initially on a common set of data elements known as the US Core Data for Interoperability (USCDI). USCDI data elements will be available and consistently formatted to the FHIR Release 4 standard, which will aid in the interoperability of that data. ONC's regulation also mandates that large, population-level data in USCDI be made available via a mechanism known as a bulk FHIR API.

Developers of certified health IT products now have approximately two years to update their software and roll that software out to their customers.

PUBLIC HEALTH CAN LEVERAGE FEDERALLY REQUIRED STANDARDS AND OTHER BROADLY ADOPTED CAPABILITIES

In effect, these federal requirements a) set expectations around data liquidity, and b) create a baseline for what data will be readily available and what functionality will be supported nationwide. This functionality includes both access to fine-grained data on one patient at a time as well as access to data on entire groups, cohorts, or populations. By leveraging FHIR-based approaches, the standards are open, freely available, and agnostic to the underlying systems where the data are stored. This provides public health an opportunity to reuse and extend what is already being built instead of operating and maintaining a separate, niche-specific infrastructure.

MODERN TECHNOLOGIES ARE AVAILABLE TO SUPPORT PUBLIC HEALTH PRIORITIES FROM THE LOCAL TO THE NATIONAL LEVEL

Widespread adoption of FHIR-based standards will provide additional capacity to support modern computing interactions that could help bring advanced data science capabilities to public health. These capabilities may include, but are not limited to:

> **Predictive Analytics:** Advanced analytics on data from notes, medication orders, lab results, procedure codes, and other data commonly captured in EHRs as well as additional data elements making their way into EHRs, such as social determinants of health

> **Enhanced Surveillance:**

» Refining and seamlessly deploying case definitions as they evolve without burdensome and time-consuming integrations at each site

» Spatial clustering and enhanced temporal predictions powered by machine learning and artificial intelligence that can link and process data from multiple sources

» Up-to-date information on populations with chronic diseases and behavioral health needs

> **Personalized Communications:** Personalized (even two-way) public health communications with care providers and patients

> **Streamlined Data Sharing While Preserving Patient Privacy:** Ensure users at multiple levels (federal, state, local) can only access the data they need and are authorized to access

Modern, cloud-based technologies make it possible for public health to leverage and contribute to a distributed system (i.e., a broad, federated network) that makes data accessible in analytics-ready environments to address multiple needs. These needs range from treatment, payment, healthcare operations, requests from patients, post-market surveillance, research, public health, and other authorized uses of the data. Public health has the opportunity to re-use this emerging, regulated set of capabilities to address federal, state, and local needs in a way that is satisfactory and mutually beneficial to users at multiple levels of the ecosystem, without relying on a single vendor or a single technology company.

Overview HL7 FHIR and Bulk FHIR
Dan Gottlieb (Boston Children's Hospital & Harvard Medical School)

Overview

FHIR is emerging as the rally point for data standards—and for good reason. It offers data building blocks that can be combined to ensure health data can be more easily analyzed, interpreted, and put to use. Release 2 is being used in production today, and release 4 is increasingly moving toward adoption. Bulk FHIR allows data to flow in batches at a population level, and it is already supported by entities like CMS, Microsoft, and IBM. Increased adoption of FHIR-based approaches could help public health to access and share information more broadly and seamlessly.

Key Takeaways

▌ FHIR IS EMERGING AS A *LINGUA FRANCA* TO PROMOTE INTEROPERABILITY

FHIR provides a set of data models—called resources—that can be queried in different ways and linked together. It's helpful to think of these resources as chunks of health information clumped together into building blocks, such as patient demographics, medications, immunizations, or claims, that can be combined to answer both simple and complex questions about healthcare.

FHIR resources mature at different rates, depending on testing and adoption. At set points in time, the standard "stands still" and is versioned. FHIR release 2 is the main version that is in production now and is being used by Apple among many other implementers. In building toward the future, EHR vendors are required to support FHIR release 4 to fulfill regulatory requirements for health IT certification.

▌ BULK FHIR MAKES IT EASIER TO ACCESS DATA ON GROUPS, COHORTS, AND POPULATIONS

Bulk FHIR is designed to exchange large analytical datasets. It is a batch API, wherein data may be queried nightly or on another regular basis to pull data (in a streaming way) into a platform that will be used for analytics. It allows data requestors to access data from multiple EHRs in a standardized and secure way without manual processes and without having to customize routines for every vendor or every site. Bulk FHIR also supports updates so if, for example, you do a nightly data pull, you can request only data that have changed since your last pull.

Microsoft, IBM, and other technology vendors support the bulk FHIR API already. CMS is using it to send beneficiaries' claims data to healthcare providers and accountable care organizations to help improve health outcomes and lower costs. Additionally, EHR vendors are starting to prepare to support this capability in anticipation of the federal regulations going into full effect in 2022.

CORE DATA ELEMENTS FOR INTEROPERABILITY WILL BE MAPPED TO THE FHIR STANDARD AND SUPPORTED NATIONWIDE

Today, the common clinical data set provides a baseline for what health information can be easily exchanged. Moving forward, USCDI will become the new baseline. It includes clinical notes and additional data elements, such as lab results, problems, procedures, vital signs, data provenance, and more detailed demographics. USCDI will grow and evolve over time based on a process defined by ONC. Public health officials are encouraged to recommend changes and additions to USCDI following the ONC-defined process. A draft of the next version of USCDI will be presented to the public for review and comment before it is finalized.

MODERN TECHNOLOGIES THAT UNDERPIN FHIR ARE NOT SPECIFIC TO HEALTHCARE, MAKING FHIR A POWERFUL ENGINE FOR GROWTH AND INNOVATION

FHIR is an open standard, licensed under creative commons. You don't have to subscribe or pay any fees to access or use it, unlike other standards where you have to become a member before you can even read the documentation. The standard uses the same underlying set of web-based protocols modern developers use at companies such as Amazon, Twitter, and other tech companies. This makes FHIR-based solutions compatible with modern technologies and advanced analytical approaches.

Federated EHR Data for Public Health Surveillance, Including Cloud and Open APIs

Dan Gottlieb and Ken Mandl (Boston Children's Hospital & Harvard Medical School); Josh Mandel (Microsoft Healthcare, Boston Children's Hospital & Harvard Medical School)

Overview

Modern standards and technologies are evolving at faster rates and are designed to promote data liquidity. If architected appropriately, new approaches to interoperability built on top of these standards can help address longstanding public health data challenges, resulting in well-processed data that are useful and actionable. These approaches can also help preserve patient privacy and address multi-layered data access needs without requiring public health to shoulder all of the burden of operating and maintaining a separate infrastructure.

Key Takeaways

FEDERATED MODELS FOR ACCESSING DATA, SUPPORTED BY CLOUD-BASED INFRASTRUCTURE, OPEN NEW OPPORTUNITIES FOR PUBLIC HEALTH DATA MODERNIZATION

Data must be processed to be useful. The data pipeline starts with getting the data out of the source system and applying standard transformations, such as mapping to standard formats or indexing the data, applying terminologies or other coding systems, and filtering out sensitive information such as identifiers.

The simplest way to process data and run analytics can be to use a **centralized** model. Under this model, users querying the data have a straightforward path because their applications only need to connect to one place and access data in the centralized datastore. Centralized models are not often used because there are a number of disadvantages and risks associated with them. There are significant privacy and security risks, especially if the system is hacked. There are reliability and uptime risks; if the datastore goes down you lose access. A centralized model may also lead to duplication of data and increased costs, especially when a data user wants to run a different type of analytics and may not have the opportunity to create their own infrastructure on top of the centrally stored data.

In contrast, under **federated** data sharing systems, data are stored locally at multiple nodes across a network. Each node runs software to map data to a common model, and nodes across the network are queried for intelligence. One advantage is that data control is local, and data breaches or system failures on a single node may not impact the entire platform. Also, the local node can be designed to be useful for local analyses and processes. However, federated data models currently in production—such as the ones funded by the National Institutes of Health or the Patient Center Outcomes Research Institute—require tremendous local expertise to get the data out of EHRs, they tend to be driven by principal investigators and not institutions, and they're not supported by regulations. Furthermore, maintaining and updating node specific infrastructure can be costly and complex.

Combining a **federated model with cloud-based capabilities** provides advantages of both centralized and federated approaches. Organizations can control their own data and allow others to use the data for multiple purposes. Users have the advantage of accessing the data at multiple sites through a secure firewall without having to customize their requests at every site. This multi-scale approach helps to address sometimes divergent needs of federal, state, and local data users, while generating well-processed data that are useful and actionable across the public health ecosystem.

Organizations at each node of the network maintain control of their data and can use it for local objectives as well. Technology vendors may provide services to help run the infrastructure at scale and support more advanced analyzes of the data, but each site of care retains ownership and control. It is a very important aspect of the design. Building on top of the cloud can help standardize the infrastructure used at each node, resulting in better maintainability of the network.

THERE ARE SIGNIFICANT ADVANTAGES TO ADOPTING STANDARDS THAT ARE REGULATED AND WELL-SUPPORTED BY MULTISECTOR, MULTISTAKEHOLDER ALLIANCES

In practice, every installation of every brand of EHR generally stores data in a unique, proprietary format, and those data need to be extracted from the EHR for meaningful analysis in another software system. The standards required by federal regulators will dictate what data elements will be captured and made available, in a standard format, nationwide. Because these same FHIR standards will be used to support payment, it is more likely that the data flowing through the regulated APIs will be high-quality and available in near real-time.

As the standards become more broadly adopted, public health can leverage FHIR APIs to harvest USCDI data elements (including clinical notes) from EHRs across the country without having to operate and maintain siloed reporting systems or one-off protocols for requesting data. This can help drive down costs and make it easier to build out a common set of data tools that scale and can be used at multiple levels of the public health ecosystem.

For example, the standard APIs will make it easier for provider institutions to use data from their EHRs to measure quality, track outcomes, conduct research, make resource allocation decisions, and offer clinical decision support. Through the same APIs, a state or local public health department could access up-to-date data and roll up the data to the level needed to fulfil their missions. Multiple users could explore the data through dashboards, dynamic visualizations, and more advanced analytics. Similarly, federal data users could use the same APIs to access de-identified data needed to drive policymaking.

The distributed model, in which each institution's data are maintained separately, not only affords local control over data and participation in studies but also enables member institutions to develop important local applications that use their own data plus networked-derived intelligence. Subject to regulatory requirements, data holders at each level of the ecosystem could explicitly decide what queries can be run, and after the queries are run, they can also decide where and how to allow the results of those queries bubble back up. This functionality offers local control as it allows each local institution or public health department the ability to ask the same kinds of questions users at the national level might decide to ask.

In short, the standard APIs required by federal regulators coupled with cloud storage and elastic computing capabilities offer opportunities for co-development of public health data science that happens at scale at multiple sites across the country.

STANDARDS AND TECHNOLOGY PRODUCTS EMERGE AND EVOLVE TOMEET REAL-WORLD NEEDS OF THE COMMUNITIES WHO ENGAGE IN THEIR DEVELOPMENT, TESTING, AND ADOPTION

FHIR focuses on addressing real-world challenges. For example, SMART on FHIR is a protocol that helps individuals to access their own data or clinicians to plug apps into their EHRs. Bulk FHIR offers access to population-level data inside EHRs, and CDS Hooks provides in-depth clinical decision support tools that can integrate into EHRs in standard and scalable ways.

Community interest in building and maintaining interoperability standards needs to be driven from the top down, with policies and priorities, but also from the bottom up, with grassroots implementations. The standards development process brings a broad set of viewpoints that help stakeholders go from a set of needs, to a set of detailed prototypes, and ultimately to a set of standards that feed into regulations. Public health can build on this community process to extend and accelerate the adoption of standards others have committed to implement instead of building a one-off, public-health-specific approach.

The technology giants and the EHR vendors have an important role in the development of such a system. However, the regulated APIs dramatically reduce dependence on EHR vendors for building a system. A standards-based, interoperable surveillance backbone can be built and managed as a multi-stakeholder public utility, with the opportunity for innovation and contribution by government, academia, and business.

Needs of State and Local Public Health Partners

Letitia Dzirasa (Baltimore City Health Commissioner), Gillian Haney (Massachusetts Department of Public Health), & Jen Layden (Chicago Department of Public Health)

Overview

State and local health departments need information very quickly, typically within 24 hours, so they can act on it. Federal stakeholders, in contrast, need data at more aggregated levels. The COVID-19 pandemic has proven that a general investment in modernizing public health IT infrastructure is needed, particularly at the state and local level. Without investing in scalable approaches, based on modern web standards, public health will continue to suffer from lags and incomplete data. Additional resources and manpower will be needed to use data robustly in real-time.

Key Takeaways

THE NEEDS OF PUBLIC HEALTH ORGANIZATIONS AT THE STATE AND LOCAL LEVEL ARE DISTINCT FROM THE NEEDS AT THE NATIONAL LEVEL

Across public health, there are multiple levels of information sharing from the state and local level up to the federal level. At the state and local level, there is a particular interest in understanding the social determinants of health and how they can be linked to both individual and population health outcomes for the residents served. These data can help make the case for why the health department is performing a particular intervention for a particular population and also help ensure that the health department is not providing duplicative services. During infectious disease and other time-sensitive outbreaks, state and local health departments need information very quickly, typically within 24 hours, so they can act on it promptly. They need detailed, patient-level data so they can better understand the populations affected and the burden of disease so that they can conduct case investigations and implement proper prevention and control measures. Federal stakeholders, in contrast, typically need data at more aggregate levels.

One panelist added that sometimes public health gets stuck in the "disease du jour" versus thinking through more generic capabilities that could help provide enough information to point decisionmakers in one direction or another. She added, "helping us know what we don't have to pursue would allow us to prioritize the information that's coming in."

During COVID-19, detailed laboratory data are a common need at the state and local level. The initial case notifications are very lab-based; however, basic demographic information doesn't typically flow from the ordering EHR to the laboratory information system. Consequently, necessary data elements needed to help initiate a case investigation are missing when the labs report their results to public health. This hinders public health's ability to respond in real time.

PUBLIC HEALTH NEEDS MODERN DATA CAPABILITIES THAT ARE FLEXIBLE, DYNAMIC, AND CAN WORK SEAMLESSLY WITH SYSTEMS USED IN HEALTHCARE SETTINGS

It has been a challenge for state and local public health partners to balance their needs with the needs of national requestors, such as CDC. The systems that are currently in place at the state and local level could not easily extract the information that is requested to be reported up the chain, especially information contained in clinical text. It is extremely time consuming for state and local public health departments to manage the massive amounts of laboratory data that are being reported to them during the COVID-19 pandemic. It is not easy to ingest the line-level data, and it has been burdensome for state and local partners to report the line-level data to the federal level.

The panelists agreed that a flexible mechanism is needed whereby multiple organizations can submit various types of data to accommodate various levels of information sharing. They also agreed that standardization could help, especially in terms of exchanging data more seamlessly with one another and with both federal as well as health system partners. Ideally, this data exchange mechanism would scale up and scale down nimbly, particularly when it is no longer prudent to collect certain data elements and send them up the chain.

INTELLIGENCE DERIVED FROM PUBLIC HEALTH DATA CAN BE USEFUL TO CLINICAL CARE

The panelists agreed that bi-directional information exchange between public health and healthcare is important, particularly for data elements that directly impact clinical care, such as vaccination history or key laboratory data. Additionally, linking to data held in public health registries or deriving intelligence from data captured in public health surveillance systems can help provide necessary context to help inform immediate decisions in clinical care settings. These types of bidirectional information exchanges would benefit from more user-friendly ways (such as CDS Hooks) to alert the clinician at the right time and in an effective manner to help support any immediate interventions that could be taken.

One panelist cited an example where a single patient presented at 10 emergency departments within a matter of 48 hours and was tested for COVID at least four times during that time period. Fortunately, the individual did not have COVID, but recognizing this pattern early on and altering health systems to take certain safety precautions could help to reduce costs, protect the public, and save lives.

Policy Considerations to Help Protect Patient Privacy

Kathryn Marchesini & Elisabeth Myers (ONC), Deven McGraw (Ciitizen)

Overview

Federal and state laws establish both permissions and restrictions around data sharing. Generally, under federal law, disclosures of data to public health are allowed without authorizations from individuals. It is important for regulators and public health authorities to be as detailed as possible when providing guidance around permitted disclosures and data element/information reporting requirements. The 21st Century Cures Act introduces a paradigm shift wherein data blocking is a restricted activity and where a broader baseline of data will be more readily available to be shared via standard mechanisms.

Key Takeaways

HIPAA ALLOWS DISCLOSURE OF "MINIMUM NECESSARY" DATA TO PUBLIC HEALTH AUTHORITIES FOR PUBLIC HEALTH PURPOSES

Federal privacy requirements, such as those mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), are agnostic to the underlying technologies being used. The HIPAA Privacy Rule permits covered entities to disclose protected health information directly to public health authorities who are legally authorized to receive such information for the purpose of preventing or controlling disease, injury, or disability (including to an organization that has a contractual relationship or some other grant of public health authority, such as a health information exchange, with the public health authority) without an individual's authorization. Under HIPAA, covered entities include healthcare providers, health plans, and clearinghouses whereas business associates are persons or entities acting on behalf of covered entities (e.g., healthcare providers) such as a health information exchange or an EHR vendor. The HHS Office for Civil Rights has announced enforcement discretion allowing business associates to share information with public health authorities (or their contractors) notwithstanding terms in their contracts (business associate agreements) with covered entities for the duration of the COVID-19 national public health emergency.

When covered entities and business associates disclose protected health information for public health purposes, the HIPAA Privacy Rule includes a "minimum necessary" requirement, meaning that protected health information must not be used or disclosed when it is not necessary to satisfy a particular purpose or carry out a specific function. The Privacy Rule generally requires covered entities to take reasonable steps to limit the use or disclosure of, and requests for, protected health information to the minimum necessary to accomplish the intended purpose. Covered entities and business associates can rely on the public health authorities' request for such information as the minimum amount of information that is needed, without the entity having to make its own determinations or decisions about the minimum amount of information that is needed. Such reliance must be reasonable under the particular circumstances of the request.

It is important for regulators and public health authorities to be as detailed as possible when providing guidance around permitted disclosures and (data elements/information) reporting requirements to public health. Covered entities are risk averse and may fear being out of compliance with the law. Public health authorities or their associations can help assuage this fear by making explicit determinations about the minimum data elements necessary and being clear about how the protected health information will be handled once received by public health.

THE 21ST CENTURY CURES ACT INTRODUCES A PARADIGM SHIFT WHEREIN HEALTH INFORMATION WILL BE MORE READILY AVAILABLE TO SUPPORT MULTIPLE NEEDS

In general, under the 21st Century Cures Act, information blocking is a practice by a health IT developer of certified health IT, health information network, health information exchange, or healthcare provider that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information (EHI).

In the ONC Cures Act final rule, ONC identified eight categories of such reasonable and necessary activities that do not constitute information blocking, provided certain conditions are met—these are referred to as "exceptions." The exceptions support seamless and secure access, exchange, and use of EHI and offer actors certainty that practices that meet the conditions of an exception will not be considered information blocking. The exceptions are divided into two classes: exceptions that involve not fulfilling requests to access, exchange, or use EHI; and exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI. An example of the first class of exception is the "Privacy Exception" that states that an actor should not be required to use or disclose EHI in a way that is prohibited under state or federal privacy laws. One such exception in the latter class is the "Content and Manner" exception that relates to the data classes and types that must be included as well as outlining a technical framework for the manner of the response.

In section 4003 of the Cures Act, Congress directed ONC to "develop or support a trusted exchange framework, including a common agreement among health information networks (HINs) nationally." In developing a Trusted Exchange Framework (TEF) and a Common Agreement that meets the industry's needs, ONC has focused on three high-level goals: provide a single "on-ramp" to nationwide connectivity, enable EHI to securely flow when and where it is needed, and support nationwide scalability. The TEF describes a common set of principles that facilitate trust between HINs for nationwide electronic health information exchange, and the Common Agreement will provide the governance necessary to scale a functioning system of connected HINs to meet multiple use cases, including public health.

The ONC Cures Act final rule also operationalizes the manner in which, under HIPAA, patients can invoke their right to access their own health information and share that information however and with whomever they choose by implementing requirements for certified health IT related to standardized application programming interfaces (APIs). Standardized APIs broaden the possibility for public health authorities to receive and share data directly with patients or consumer-facing technologies as directed by patients. These consumer-facing technologies are not covered by a comprehensive privacy law, however the commitments these technology vendors make about how they handle sensitive data are enforceable by the Federal Trade Commission.

FILTERS CAN BE APPLIED AT MULTIPLE POINTS IN THE DATA FLOW TO ENSURE ONLY NECESSARY DATA ARE SHARED

Technology offers opportunities to develop and apply filters to help ensure that only data that should be shared are shared. These filters could be applied at multiple points in the data flow to support both covered entities and public health authorities in sharing or disclosing only what is needed for the use case or purpose, and appropriately disposing of information that may not be minimally necessary. Data segmentation and filtering technologies that would not rely on manual support are largely still under development; however, there are efforts throughout the industry to address and develop new tools for high priority use cases. Examples of evolving standards that could facilitate the development of these filters include the provenance resource in FHIR; the development of National Library of Medicine value sets for specific purposes, patient sets, or reportable cases for use in querying via a FHIR-based API; and the continued evolution of security labelling standards like the HL7 Data Segmentation for Privacy standard.

Overview of ONC's Standards Version Advancement Process

Steven Posnack (ONC)

Overview

The 21st Century Cures Act offers flexibility for technology developers to adopt new standards that meet evolving needs. ONC is currently establishing processes through which particular federally adopted standards can evolve in a more streamlined manner based on evidence gathered during real world testing.

Key Takeaways

ONC HAS FLEXIBILITY TO APPROVE NEW STANDARDS ON A VOLUNTARY BASIS WITHOUT LENGTHY RULEMAKING

As technology evolves, standards named in regulation can quickly become obsolete. The "Real World Testing" provision of the 21st Century Cures Act authorizes ONC to establish a process wherein certified health IT developers can adopt more advanced versions of standards voluntarily. More details regarding the Standards Version Advancement Process are available at https://www.healthit.gov/isa/standards-version-advancement-process.

Only specific standards and implementation specifications (and their versions) will be considered for advancement through this process. USCDI is one example. Other examples include syndromic surveillance, reporting to immunization registries, electronic lab reporting, cancer reporting, reporting of healthcare associated infections, and healthcare surveys

USCDI WILL EXPAND OVER TIME AND NEW DATA ELEMENTS CAN BE ADDED BASED ON INPUT FROM THE PUBLIC

As part of the Standards Version Advancement Process, ONC has prepared a process for engaging the public that includes a data elements submission system to identify potential data elements to be promoted into the next version of USCDI. Evidence of implementation is an important factor in determining what data elements will be added to the core. Public health partners are encouraged to get involved to help shape future iterations of USCDI and other standards eligible for advancement through the ONC defined processes. This will help to ensure that federally adopted interoperability standards evolve in a way that meets the needs of public health stakeholders.

Overview

Public health is entering a new era. Federal regulators have set a baseline for what data will be readily available and what functionality will be supported nationwide. This is helping to unleash a vast amount of data that could be very valuable to public health. A new type of public-private partnership, based on a coalition of the willing, could help public health to architect modern data capabilities that are agnostic to the underlying systems where the data are stored.

Key Takeaways

NOT MAPPING TO NATIONWIDE STANDARDS COULD RESULT IN INCOMPATIBLE SYSTEMS, DECREASING INTEROPERABILITY RATHER THAN INCREASING IT

Across public health, there are multiple levels of information sharing from the state and local level. Public health data requests vary significantly in content and format. This results in duplication of effort and incomplete reporting. Standards help to ensure the sending and receiving systems speak the same language, promote seamless data exchange to local, state, regional, and federal public health data requestors while preserving the original meaning of the underlying data.

The realities of COVID have exposed an underlying need for very real-time information, or at least information that is as up to date as possible. During periods of public health response, there is often a need to scale up surveillance activities very quickly. It is easier to meet these demands if the data already flow more fluidly on an ongoing basis.

Additionally, public health stands to benefit from federal efforts around establishing trust mechanisms. The 21st Century Cures Act includes provisions for a Trusted Exchange Framework to enable widespread data exchange across organizational boundaries. The Trusted Exchange Framework includes a set of policies, procedures, and technical standards necessary to advance a single on-ramp to interoperability.

As ONC-required data standards begin to rollout nationwide and as the Trusted Exchange Framework is put into operation, public health can shift from a "reporting" mindset to the possibility of "harvesting" vast amounts of data that are broadly available. To take advantage of this opportunity, public health could architect applications in ways that are scalable and that plug into the infrastructure being created. A marketplace could emerge for open-source FHIR applications designed by one or more states to access USCDI data elements via ONC certified APIs without any sort of vendor control in the process. These applications could help handle routine processing of the data so that the public health workforce can focus on analytics that drive action instead of trying to build and maintain non-standardized IT tools.

HEALTH SYSTEMS ARE BECOMING MORE WELL-VERSED IN FHIR AND API-BASED WAYS OF EXCHANGING DATA

For several years, HCA Healthcare (a provider of healthcare services comprised of 185 hospitals and approximately 2,000 care sites) has been using FHIR internally to exchange data outside of its EHR. In this context, FHIR has proven to be scalable and more amenable to change than other standards and approaches. HCA is excited about the prospect of moving to bulk FHIR, and the organization supports a federated + cloud model for data exchange more broadly. This model is appealing to HCA because it offers local benefit and maintains local control while supporting multiple levels of information sharing.

HEALTH INFORMATION EXCHANGES CAN PLAY AN IMPORTANT ROLE

Health information exchanges (HIEs) can provide an important complement to other methods of public health data acquisition. Under current public health reporting protocols, there is significant overlap. Multiple agencies request duplicate reports that result in significant processing expenses. HIEs already receive much of the same data and are in the business of normalizing, cleaning, and linking the data across multiple sources and removing duplicates. Also, since HIEs operate within states, they are well-versed in the state-specific privacy provisions and other state laws around health data.

HIEs are particularly well-positioned to assist state and local public health agencies in accessing identifiable, patient level-data, particularly social determinants of health and longitudinal data needed to evaluate health outcomes. Since HIEs capture vast amounts of operational data, they can provide mechanisms through which public health can explore answers to both simple and complex questions in privacy-preserving ways. This could be particularly helpful during situations like the current COVID-19 pandemic where public health needs to ask new questions of the data as time goes on, such as: How much time does it take between a COVID positive and a negative test, and then between a negative test a marker of serology? How useful is the serology marker? What's the rate of reinfection? HIEs can help provide the computational environment and access to the data needed to answer these types of questions on an ongoing basis.

A COALITION OF THE WILLING COULD HELP PUBLIC HEALTH JUMPSTART NEW APPROACHES TO INTEROPERABILITY

Recruiting and retaining people well-versed in these modern approaches to interoperability has been an ongoing challenge for public health. Public-private partnerships provide an opportunity to address longstanding data and interoperability challenges and to upskill the current public health workforce. "If we work with each other," said Dr. Chesley Richards, "our combined competencies can truly transform public health data systems."

In the spirit of collaboration, there are opportunities for a coalition of the willing to jumpstart the development of a federated data exchange model, supported by cloud-based technologies. This coalition of the willing could include committed visionaries from across public health, health information exchanges, technology companies, and experts in interoperability. An initial focus could be on how public health might leverage the bulk FHIR specification that will be implemented across the nation once certified health IT providers are in full compliance with the 21st Century Cures Act. Cloud IT providers have already started some of this work; having a dialogue about what's possible could help ensure that public health needs are prioritized and accelerated.

A similar coalition of the willing formed around scalable, FHIR-based approaches for supporting consumer access to data. This coalition helped to get us to the point where we are now, where patients can access their health data on their iPhones and Android devices, where the VA and CMS make the health and payment data they collect available to patients and beneficiaries using the same standards, and where a robust market place has emerged to innovate at a pace that previously would have been unimaginable. We're entering a new era where the vision shared in this listening session can soon become a reality for public health. There's no time to waste.

Appendix A: Questions and Answers

The listening session included opportunities for participants to ask questions of the speakers.

Q1: How can the public health workforce learn more about FHIR?

FHIR is an open, web-based standard that aligns with the libraries and software tools developers commonly use today. The entire specification is available online for free at http://hl7.org/fhir/, and anyone can join the conversation at https://chat.fhir.org/.

The open licensing and active community around FHIR make it easier to learn and apply FHIR than older healthcare-specific standards. Tutorials are freely available on the web. On the EHR vendor side, Epic and Cerner have detailed tutorials and on the cloud side Google, IBM, Microsoft, and Amazon all have detailed tutorials. In addition, the community gathers on an ongoing basis through conferences, Connect-a-thon events, and workgroups to learn and share what they know.

Q2: How might federated, cloud-based systems reduce burden on state health departments in terms of data collection, cleaning, and analysis?

One main benefit of adopting a common, web-based standard across a federated system is that you can leverage the power of the cloud to build tools and services on top of a common foundation. Once the data are mapped to FHIR, then basic data wrangling processes, such as transformations, data quality checks, and initial data explorations, can run on data from across multiple health systems in the same way.

In the way federated networks are often built now, there's usually an intense data wrangling process at every healthcare institution where they develop their own mappings into a proprietary schema or a schema that is specific to that network, resulting in a significant duplication of effort. Mapping data into a common standard that can be used to support multiple purposes can help streamline the data cleaning process and make it easier to build tools that public health departments can use to access, analyze, and act on cleaned and processed data.

Q3: How might bulk FHIR help to improve electronic case reporting?

Bulk FHIR is a common way of accessing USCDI data elements across the country. This includes both the structured data elements from EHRs and laboratory results as well as detailed clinical notes. Imagine an example where there is a case of probable COVID, and no laboratory results are available. Parsing clinical notes using high throughput computing can help to detect these cases. This can help automate not only the collection of the initial case report but also more detailed follow-up that currently happens in case reporting. Additional work would need to be done to assess the sensitivity and the specificity of these classifiers.

Q4: Can bulk FHIR implementation timelines be accelerated in the face of the current pandemic?

It is something that can be done if there is a will and an interest. Some systems have put bulk FHIR capabilities into production already. The rest have a two-year timeline to meet the regulatory requirements.

Q5: What are state and local public health obligations with respect to patient access to data via FHIR, and what is the timeline for enforcement of those provisions?

Developers of Certified Health IT, Health Information Exchanges and Health Information Networks, and Providers are subject to the information blocking provisions of ONC's final rule. Public health agencies, particularly those who provide health services, may be considered healthcare providers as defined for information blocking provisions. Similarly, some public health program networks and exchanges may be considered health information networks and exchanges as defined for information blocking provisions. Compliance is required by November 2, 2020, which is 6 months after ONC Final Rule publication.

The Office of the Inspector General at the Department of Health and Human Services issued a rule on how it will oversee enforcement of the information blocking provision in the 21st Century Cures Act.

Q6: How can public health provide input into USCDI?

As part of the Standards Version Advancement Process, ONC has prepared a process for engaging the public that includes a data elements submission system to identify potential data elements to be promoted into the next version of USCDI. Evidence of implementation is an important factor in determining what data elements will be added to the core. Public health partners are encouraged to get involved to help shape future iterations of USCDI and other standards eligible for advancement through the ONC defined processes.

Q7: How can public health learn more about ONC's Cures Act Final Rule, The Standards Version advancement process, and interoperability standards?

Interested parties can follow along at:

> Cures Act Final Rule webinars: https://www.healthit.gov/curesrule/resources/webinars

> Cures Act Final Rule fact sheets: https://www.healthit.gov/curesrule/resources/fact-sheets

> Standards Version Advancement Process (SVAP): https://www.healthit.gov/isa/standards-version-advancement-process

> Interoperability Standards Advisory (ISA): https://www.healthit.gov/isa/

> USCDI fact sheet: https://www.healthit.gov/cures/sites/default/files/cures/2020-03/USCDI.pdf

Appendix B: Biographies

Paula Braun, Entrepreneur-in-Residence, CDC (Co-Moderator)

Paula Braun is an Entrepreneur-in-Residence at the US Centers for Disease Control and Prevention. She tracks evolving tech trends and helps to communicate why they matter to public health. In 2019, she was named one of the top 50 Influencers in the Federal Government on artificial intelligence. She engages stakeholder groups from across government, academia, and industry to help improve public and population health. She is an internationally recognized expert on interoperability and innovation, and she collaborates with colleagues from across CDC to use design thinking and advances in technology to help address real world health challenges.

Aneesh Chopra, MPP, President, CareJourney

Aneesh Chopra is the President of CareJourney, an open data membership service building a trusted, transparent rating system for physicians, networks, facilities, and markets on the move to value. He served as the first US Chief Technology Officer under President Obama ('09-'12) and in 2014, authored, "Innovative State: How New Technologies Can Transform Government." He serves on the Board of the Health Care Cost Institute and the New Jersey Innovation Institute. He earned his MPP from Harvard Kennedy School and BA from The Johns Hopkins University.

Letitia Dzirasa, MD, Commissioner of Health, City of Baltimore

Dr. Letitia Dzirasa joined Baltimore City government as the Commissioner of Health in March 2019. Dr. Dzirasa, a Hopkins-trained pediatrician, believes that equitable care is basic right for all and will tirelessly advocate for programs that support the overall health and wellbeing of all Baltimore city residents. Dr. Dzirasa's special interests include obesity management and prevention, trauma-informed care in children and adolescents, and expanded use of technology to improve health outcomes.

Prior to joining the Health Department, Dr. Dzirasa worked at Fearless Solutions (Fearless), a Baltimore-based digital services firm that builds custom software solutions for local and federal government clients. In her role at Fearless as Health Innovation Officer, Dr. Dzirasa was responsible for managing the Healthcare IT portfolio for the company and provided clinical subject matter expertise to HIT projects. Dr. Dzirasa also has close clinical ties to the Baltimore community, having trained at the Johns Hopkins Hospital in pediatrics and having worked as medical director for school-based health and quality at Baltimore Medical System from 2013-2016.

In addition to holding a BS from University of Maryland, Baltimore County, in biological sciences, Dr. Dzirasa graduated from Meharry Medical College, *summa cum laude*, in 2007. She lives in downtown Baltimore with her husband and son.

Dan Gottlieb, MPA, Clinical Informaticist and Software Consultant, Boston Children's Hospital and Harvard Medical School

Dan Gottlieb, MPA, is a clinical informaticist and software consultant working with the Harvard Medical School Department of Biomedical Informatics, the Boston Children's Hospital Computational Health Informatics Program, and other organizations to create healthcare standards and open source tools that empower patients, care providers, and researchers.

William Gregg, MD, MPH, Chief Clinical Transformation Officer & Vice President, Clinical Informatics, HCA

William (Bill) Gregg, MD, MS, MPH, joined HCA Healthcare in 2014 as Chief Clinical Transformation Officer and Vice President, Clinical Informatics. In addition to his medical degree, Dr. Gregg holds an undergraduate degree in Electrical Engineering from the Georgia Institute of Technology. He earned his master's degrees in Clinical Informatics and Public Health at Vanderbilt University and was a VA Quality Scholars Fellow. He is board certified in Internal Medicine and Clinical Informatics. Prior to joining HCA, Dr. Gregg served as an Assistant Professor of Informatics and Medicine at Vanderbilt University and was the Director of Population Health Informatics. He helped develop successful clinical programs and led software development in population health and clinical decision support. As a part of HCA's Clinical Operations Group, Dr. Gregg is responsible for programs in Health Information Exchange/Interoperability and Enterprise Clinical Decision Support. His primary focus is on system level integration of technology, interoperability, and processes to support transformation of clinical care in our rapidly changing healthcare landscape.

Gillian Haney, MPH, Director of Office of Integrated Surveillance and Informatics Services, Bureau of Infectious Disease and Laboratory Sciences, Massachusetts Department of Public Health

Gillian has been an epidemiologist with the Bureau of Infectious Disease and Laboratory Sciences at the Massachusetts Department of Public Health for 20 years, and is currently the Director of the Office of Integrated Surveillance and Informatics Services. In this capacity, she implemented and oversees the state's integrated infectious disease surveillance and case management system "MAVEN", electronic laboratory and health record reporting, syndromic surveillance, and other aspects of infectious disease reporting and surveillance. Ms. Haney is also the chair of the Council of State and Territorial Epidemiologists (CSTE) Surveillance Practice and Implementation Subcommittee that covers topic areas such as surveillance methods, data standards, electronic health records, and the Reportable Conditions Knowledge Management System (RCKMS).

Jennifer Layden, MD, PhD, Deputy Commissioner and Chief Medical Officer at Chicago Department of Public Health

Dr. Jen Layden serves as the Deputy Commissioner and Chief Medical Officer for the Chicago Department of Public Health. Prior to joining CDPH, she served as the State Epidemiologist and Chief Medical Officer for the Illinois Department of Public Health from 2016-2020. Additionally, she currently holds a faculty appointment at the University of Illinois at Chicago's Department of Medicine. Prior to joining public health practice, she was on faculty at Loyola University Chicago, in both the Departments of Public Health and Medicine from 2011-2016.

Currently, she leads the COVID-19 response for CDPH, and is integrally involved in efforts to enhance data integration from health systems and public health to optimize COVID disease surveillance. She has led numerous prior public health responses, including the 2019 EVALI outbreak while at IDPH. She has served on CSTE and other national task forces during large public health responses and has presented at national and international conferences. Dr. Layden has published extensively, with over 70 peer reviewed publications, including scientific work produced while in public health practice and in academia.

Dr. Layden earned her BS from the University of Notre Dame, and her MD and PhD in Public Health from the University of Illinois at Chicago. Dr. Layden is clinically trained in internal medicine and infectious diseases.

Kathryn Marchesini, JD, Chief Privacy Officer, ONC

Kathryn Marchesini serves as the chief privacy officer (CPO) at ONC where she advises the national coordinator on matters related to health information privacy, security, and data stewardship, especially as these issues impact IT development and implementation. Ms. Marchesini works closely with other HHS divisions and federal agencies to assure a coordinated, nationwide approach to maintaining the privacy and security of electronic health information.

Prior to serving as CPO, Ms. Marchesini served as a senior advisor at ONC where she advised stakeholders about the privacy and security implications surrounding electronic health information, technology, and healthcare. She worked with OCR, National Institutes of Health (NIH), and other federal agencies, to provide strategic direction and substantive expertise at the intersection of privacy and cybersecurity law, technology, and health research. In her seven years at HHS, Ms. Marchesini also served as deputy director for privacy, where she led ONC's privacy team and helped with federal, state, and international policy guidance and education initiatives addressing emerging health IT privacy, data protection, and security-related issues. In 2014, she served as acting CPO.

Before joining HHS, Ms. Marchesini was a strategy and technology consultant at two international management consulting firms. She led IT modernization and business transformation efforts to help organizations bridge the gap between business requirements, technology, and law. Ms. Marchesini also worked in state government and at a multinational clinical research organization.

Ms. Marchesini earned her JD from the University of North Carolina School of Law, where she was executive editor of the North Carolina Journal of Law and Technology (JOLT). She earned a professional certificate in strategic decision and risk management in healthcare from Stanford University and BS in international economics and finance with a management information systems minor from Catholic University. Ms. Marchesini also maintains a Project Management Professional (PMP) and Certified Information Systems Security Professional (CISSP) certificate.

Josh Mandel, MD, Chief Architect, Microsoft Healthcare

Josh C. Mandel, MD, is a physician and software developer working to fuel an ecosystem of health apps with access to clinical and research data. As Chief Architect for Microsoft Healthcare, Chief Architect for SMART Health IT, and Lecturer at the Harvard Medical School Department of Biomedical Informatics, Josh works closely with the standards development community to lay groundwork for frictionless data access, authorization, analytics, and app integration. He led development of the SMART specification and launched the Clinical Decision Support Hooks project. As a member of the national Health IT Standards Committee, Josh showed a special interest in tools and interfaces that support software developers who are new to the health domain.

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program (CHIP);
Donald A.B. Lindberg Professor of Pediatrics and Professor of Biomedical Informatics,
Boston Children's Hospital and Harvard Medical School (Co-Moderator)

Dr. Kenneth Mandl directs the Computational Health Informatics Program at Boston Children's Hospital and is the Donald A.B. Lindberg Professor of Pediatrics and Biomedical Informatics at Harvard Medical School. He is trained as a pediatrician and pediatric emergency physician. His work at the intersection of population and individual health has had a unique, sustained influence on the developing field of biomedical informatics. Mandl's Presidential Early Career Award for Scientists and Engineers was for pioneering real time biosurveillance, tracking infections and detecting outbreaks with diverse data. He has long advocated for patient participation in producing and accessing data and was a pioneer of the first personal health systems, using crowdsourced knowledge from online patient networks, and advancing participatory medicine and engagement in clinical trials.

Cognizant of the limitations of extant electronic health record systems, Mandl developed a widely-adopted, highly influential approach (SMART)—substitutable apps that run universally on health IT systems. SMART lets innovators reach market scale and patients and doctors access an "app store for health." Through the 21st Century Cures Act, SMART is now regulated as the standard interface by which patients, providers, and apps access data from electronic health records. He applies open source inventions to lead EHR research networks. He is a leader of the Genomics Research and Innovation Network across three leading children's hospitals. He directs the Boston Children's Hospital Precision Link Biobank for Health Discovery.

Dr. Mandl was on the Advisory Committee to two Directors of the CDC. He has been elected to membership in the American Society for Clinical Investigation, the American College of Medical Informatics, the Society for Pediatric Research, and the American Pediatric Society.

Deven McGraw, JD, MPH, LLM, Chief Regulatory Officer, Ciitizen

Deven McGraw is Chief Regulatory Officer for Ciitizen, a consumer health technology start-up. Previously she directed US health privacy and security as Deputy Director, Health Information Privacy at the HHS Office for Civil Rights and Chief Privacy Officer (Acting) of the Office of the National Coordinator for Health IT. Widely recognized for her expertise in health privacy, she directed the Health Privacy Project at the Center for Democracy & Technology for six years and led the privacy and security policy work for the HITECH Health IT Policy Committee. She also served as the Chief Operating Officer of the National Partnership for Women and Families. She advised health industry clients on HIPAA compliance and data governance while a partner at Manatt, Phelps & Phillips, LLP. Deven graduated magna cum laude from Georgetown University Law Center and has a MPH from Johns Hopkins University.

Elisabeth Myers, MBA, Deputy Director, Office of Policy, ONC

Elisabeth Myers has worked on health IT policy at HHS since 2012, working on CMS quality programs, the CMS eHealth Initiative, and the EHR Incentive Programs before moving to the Office of the National Coordinator for Health IT. Prior to her work at HHS, Elisabeth worked on healthcare initiatives in the non-profit and private sector, and at the state level in the Governor's Office of Health Care Reform in Pennsylvania. In her role at ONC, Elisabeth is helping to lead the team implementing the 21st Century Cures Act that addresses a wide range of health IT provisions, from interoperable standards development to health IT for specialty settings and sites of service including pediatric care. Elisabeth also leads ONC policy efforts related to the health IT provisions within the Support for Patients and Families Act that was signed into law in December of 2018 to drive policy initiatives in support of OUD prevention and treatment.

Steven Posnack, MS, MHS, Deputy National Coordinator for Health Information Technology, ONC

Steven Posnack serves as the Deputy National Coordinator for Health Information Technology. In this role, he advises the national coordinator, leads the execution of ONC's mission, and represents ONC's interests at national and international levels. In conjunction with the national coordinator, Steve oversees ONC's federal coordination, regulatory policy, public-private initiatives, and the overall implementation of statutory authorities and requirements, such as those from the 21st Century Cures Act and HITECH Act.

Chesley Richards, MD, MPH, FACP, Deputy Director for Public Health
Science and Surveillance, CDC

Chesley Richards, MD, MPH, FACP, is the Deputy Director for Public Health Science and Surveillance at the Centers for Disease Control and Prevention. In this position, he is responsible for strengthening CDC's scientific foundation by working across the Office of Science, the Office of Laboratory Science and Safety, the Center for Surveillance, Epidemiology, and Laboratory Services, and the National Center for Health Statistics. A primary focus of his role is to advance an agency-wide public health data strategy and serve as an advisor to the CDC Director.

Prior to this position, Dr. Richards served as CDC Deputy Director for Public Health Scientific Services and Director of the Office of Public Health Scientific Services, where he oversaw a broad range of epidemiology, public health surveillance, laboratory services, and health statistics initiatives aimed at improving population health. During his tenure, he developed and implemented CDC's Surveillance Strategy to improve the agency's public health data surveillance capabilities from 2014-2018.

Dr. Richards works at the intersection of public health, healthcare, and health IT. He began his public health career as a CDC Epidemic Intelligence Service Officer in the Hospital Infections Program. Since then, he has held a range of positions, serving as the Director of the Immunization Services Division; the Director of the Office of Prevention through Healthcare; and as the Deputy Director for the Division of Healthcare Quality Promotion, where he led the expansion of the National Healthcare Safety Network—the nation's most widely used healthcare-associated infection tracking system.

Dr. Richards earned his MD from the Medical University of South Carolina, and his MPH in Health Policy and Administration from the University of North Carolina at Chapel Hill. He is board certified in Internal Medicine (Medical College of Georgia), Geriatric Medicine (Emory University), and General Preventive Medicine and Public Health (UNC Chapel Hill). He completed the Cancer Control Education Fellowship at UNC Lineberger Cancer Center and the Program on Clinical Effectiveness at Harvard School of Public Health.

Don Rucker, MD, National Coordinator for Health Information Technology, ONC

Dr. Don Rucker is the National Coordinator for Health Information Technology at the US Department of Health and Human Services, where he leads the formulation of the federal health IT strategy and coordinates federal health IT policies, standards, programs, and investments.

Dr. Rucker has three decades of clinical and informatics experience. He started his informatics career at Datamedic Corporation, where he co-developed the world's first Microsoft Windows-based electronic medical record. He then spent over a decade serving as Chief Medical Officer at Siemens Healthcare USA.

Dr. Rucker has also practiced emergency medicine for a variety of organizations including at Kaiser in California; at Beth Israel Deaconess Medical Center; at the University of Pennsylvania's Penn Presbyterian and Pennsylvania Hospitals; and, most recently, at Ohio State University's Wexner Medical Center.

Dr. Rucker is a graduate of Harvard College and the University of Pennsylvania School of Medicine, with board certifications in Emergency Medicine, Internal Medicine and Clinical Informatics. He holds an MS in Medical Computer Science and an MBA, both from Stanford.