Meeting to Advance Push Button Population Health: SMART/HL7 Bulk Data Export/FLAT FHIR

EXECUTIVE SUMMARIES

November 6, 2019

Meeting funded by the Office of the National Coordinator for Health Information Technology and hosted by the Computational Health Informatics Program (www.chip.org) and www.smarthealthit.org at Boston Children's Hospital

MEETING INTRODUCTION

The universal health data application programming interfaces called for in the 21st Century Cures Act present an opportunity to create the learning healthcare system that has been long envisioned. A learning healthcare system must be able to do more than conduct individual queries on one patient; it requires the ability to aggregate and analyze data at a population level. Activities such as managing population health, delivering value-based care, and conducting discovery science requires access to large population data sets. Population level data combined with new technologies such as machine learning and AI has extraordinary potential to improve the health and lives of Americans.

 To address this need, the SMART team and HL7 have jointly developed the SMART/HL7 Bulk Data/Flat FHIR standard and associated tools.

Building on the momentum of our 2017 Population Level Data Export/FLAT FHIR Meeting, the Office of the National Coordinator for Health Information Technology asked the Computational Health Informatics Program (CHIP) and SMART Health IT team to host a second meeting to measure interval progress on use and uptake of the SMART/HL7 Bulk Data/Flat FHIR standard and tools, understand where the rough edges are, explore federal use cases, and drive toward effective regulation.

The Meeting to Advance Push Button Population Health: SMART/HL7 Bulk Data Export/FLAT FHIR was held on November 6th at the Harvard Medical School Countway Library. Sixty stakeholders from across the healthcare ecosystem gathered to talk about bulk data use cases and experience, and plan next steps for the standard and its use.

Ken Mandl, MD, MPH

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ONC Introduction, Perspective, and Goals

Don Rucker, MD, National Coordinator for Health Information Technology
Steven Posnack, MS, MHS, Deputy National Coordinator at Office of the National Coordinator for Health Information Technology

OVERVIEW

Don Rucker and Steve Posnack welcomed attendees, summarized the goals of this meeting, and described the environment and challenges for health information technology.

Since an initial meeting on bulk data in late 2017, there has been tremendous progress in developing specifications for FHIR, implementing it, and gaining real-world experience. This meeting aims to provide a progress update and to identify future needs and direction.

KEY TAKEAWAYS

THIS MEETING TAKES PLACE AT AN IMPORTANT TIME.

This meeting is about moving large data sets around the healthcare system in a principled and reproduceable way, and developing tools around those data sets. It takes place about two years after an initial meeting.

At that initial meeting, a conceptual understanding was developed about transmitting and using bulk data and a direction was established related to FHIR. During the past two years, specifications have been developed, CMS has implemented the FHIR Bulk Data API, and a number of payers and EHR vendors have started exploring opportunities for Bulk Data API implementations.

In a short period of time there has been extraordinary work, which represents a tremendously effective expenditure of taxpayer dollars.

> "There's a lot of change that we've seen in the past few years."
>
> — STEVEN POSNACK

The intent of this meeting is to measure interval progress on use and uptake of the SMART/HL7 Bulk Data/Flat FHIR standard and tools, understand where the rough edges are, explore federal use cases, and drive toward effective regulation.

IT IS ALSO AN IMPORTANT TIME IN THE EVOLUTION OF HEALTHCARE IN THE UNITED STATES.

This is a tremendously interesting moment, with a confluence of events:

- The emergence of extraordinary computing power
- The emergence of a national vision of what data can do
- A deep public unhappiness with the state of American healthcare
- Rising interest in greater accountability of all participants in healthcare, particularly providers and payers

With this as the overall context for healthcare in the United States, ONC is looking at integrating financial and clinical data with other healthcare data. That's because as efforts increase to link purchasing to value, it is essential to have greater transparency. With this in mind, the President issued an executive order on price transparency, which takes into account price and clinical data.

> "It's going to be a complicated battle, but one way or the other, however it plays out, there's going to be data transparency."
>
> — DON RUCKER

SMART Overview and LEAP Goals

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program (CHIP); Donald A.B. Lindberg Professor of Pediatrics, Professor of Biomedical Informatics, Harvard Medical School

OVERVIEW

Ken Mandl reviewed the specification that led to the creation and adoption of the WWW and asked if a similar process could solve problems in healthcare. He discussed the idea of federated EHR networks, posed questions about bulk data uses cases, and laid out an agenda for the meeting.

The success and rapid growth of the World Wide Web can be attributed to initially focusing on one use case and having a clear, simple set of specifications. Can this be an analogy for healthcare?

In the past two years, tremendous progress has been made developing specifications for extracting and sharing bulk data, and organizations are beginning to get experience in this area. But several important problems remain. Now is a time to identify specific use cases and develop plans to get to the next level.

KEY TAKEAWAYS

THE CREATION OF THE WORLD WIDE WEB PROVIDES AN ANALOGY FOR SOLVING HEALTHCARE PROBLEMS.

In creating the Web, Tim Berners-Lee had one focused use case. He didn't try to build a platform for commerce or do multiple things. He wanted to develop a way to make his scientific articles look as if a journal had printed them and wanted to be able to share preprints of these articles.

In creating the Web, which was built over the existing TCP and IP protocols, Berners-Lee had four basic building blocks, which ultimately resulted in tremendous impact. He needed:

- Textual format to represent hypertext documents – Hypertext Markup Language (HTML)
- Simple protocol to exchange documents – Hypertext Transfer Protocol (HTTP)
- Client to display these documents – first Web browser called WorldWideWeb

- Server to give access to the documents – an early version of httpd

With those few specifications Berners-Lee created a pre-print sharing service. Then, he created an organization that enforced the specification so everyone marked up the same way, had browsers that met certain standards, and had compatible servers. Suddenly there was an incredible scaffolding that could be applied to other use cases.

Can healthcare learn from this experience and do something similar?

WITH STANDARDS FOR INTEROPERABILITY, WHAT HEALTHCARE PROBLEMS COULD BE SOLVED?

Mandl laid out four healthcare problems and solutions that could arise from interoperability standards.

Problem #1	Solution
Apps don't connect to health systems data	Substitutable apps

In the past, apps have not been able to easily connect to health system data. This problem was addressed through the SMART project, which using the iPhone as a model, suggested an API layer that allows apps to connect.

It was 10 years from when this suggestion appeared in the *New England Journal of Medicine* to when the SMART on FHIR API was named the standardized way to connect apps to EHRs. The proposed rule that follows from the 21st Century Cures Act put this specification—which is simple, open, and free—into wide-scale public adoption.

Problem #2	Solution
Can't launch apps at just the right moment	Trigger-able decision support (CDS Hooks)

It is hard to launch apps at the right moment in the physician's workflow and physicians can't be expected to remember which app to launch at which time. CDS Hooks specifies a way to move decision making into third-party services, to be able to call those services, or to be able to launch SMART apps at the right moment, such as when a physician opens the chart, orders a lab, or prescribes a medication.

Problem #3	Solution
Patient-generated data are non-standardized and in separate silos	SMART Markers (coming soon)

The 21st Century Cures Act directs the use of patient-reported outcomes. But how do we integrate patient-generated data into the healthcare system? It is difficult because data are non-standardized and tend to be in separate silos. Can patients report in a reliable, standardized, valid way?

Or, consider new consumer devices that generate health data, such as the Fitbit or the Apple watch. There are five products that measure atrial fibrillation, but they are all different. How do we marshal the data that comes out of these devices in a standardized way? One idea being worked on (using ONC funding), which extends the SMART framework, is SMART Markers.

Problem #4	Solution
Getting data out of EHRs into analytic platforms tends to require specialized teams	Pushbutton population health

Getting data out of the EHR into analytic platforms tends to require specialized teams. Yet only the most advanced academic or private for-profit medical centers have these teams; smaller medical centers and practices rarely do. And these individuals are hard to find and train. This means the bulk

data that exists today is from a very specific slice of the healthcare system. And, when bulk data is pulled from EHRs, it doesn't exist in standardized way.

The question is how to extract and share bulk data in a standardized way.

One idea is federated EHR networks where data resides at the site but there are principled ways to bring datasets together. This could be done through a community effort to advance FHIR to achieve these goals.

> "The current SMART on FHIR API is designed for one patient at a time . . . so for population health, the bulk data (Flat FHIR) API is a an essential advance."
>
> — KEN MANDL

THE IDEA OF FEDERATED NETWORKS HAS POTENTIAL BUT REQUIRES GETTING HEALTH SYSTEMS TO PARTICIPATE.

Mandl's 2015 co-written article in *Nature Biotechnology*, Federalist Principles for Federated Healthcare Networks, looked at getting health system data to be shared and used at scale. It raised the question of how to put software into health systems that is maintained beyond the life of a particular grant. The article suggested that if there is a federated network, health systems need to be engaged as fully participatory members. But getting health systems to participate is challenging.

When National Coordinator Don Rucker read this article, he had an epiphany. He said, "If the health system is going to care about data, they should be about payment." Rucker suggested looking at SMART as a model in getting data out of EHRs in a principled, reproducible way.

This discussion led to an initial meeting in December 2017 about population-level data exports to support population health and value.

What has happened since 2017 has been astounding. While the SMART project took 10 years to go from the first *New England Journal* piece to the proposed rule, CMS was using the initial draft bulk data standard to provision data to ACOs in pilot within months. The pace of adoption has been 10 times faster.
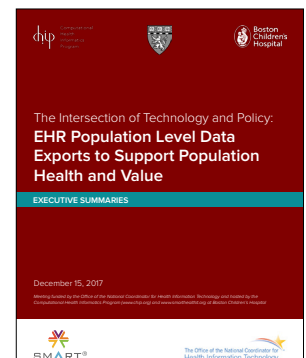
AN IMPORTANT USE OF POPULATION DATA IS TO IMPROVE THE VALUE-BASED PAYMENT PROCESS.

Currently, value-based payments are based on hospital-generated metrics that show performance. Reports are produced by an ACO or risk organization at the end of the year. These reports are sent to the payer to show the level of performance, and are used for remediation or for next year's contracts. But these reports are manually generated, customized, and typically a year behind. Then, everyone typically argues over exactly what the (dated) data means.

To address this situation, Mandl, under an ONC Leading Edge Acceleration Projects (LEAP) funding award, has been working on a population health app that would enable a payer and a health system to share claims and electronic health record data. The intent is to improve data sharing and payment processes.

This app provides a principled way to look at the data between the two organizations. The data is as current as the frequency of the ETLs. It allows stakeholders to look at data based on the contract and the service level agreements. It provides the opportunity to think about line-level data or aggregate metrics, whatever is agreed upon. Importantly, it moves data sharing to a near real-time mode.

But, to reiterate, a critical caveat is that the current FHIR API is designed for one patient at a time. Current FHIR APIs are not (yet) well suited to cohort creation. This means it's important to look at bulk data APIs.

OTHER KEY USE CASES

If FHIR becomes a lingua franca of sorts, which looks like a very good bet, and if a Flat FHIR dataset exists at each site of care to facilitate payment, what are additional use cases? Known use cases include research, surveillance, drug development, and clinical care. And, there is momentum at the federal level with ONC, CMS, the NIH, AHRQ, and the FDA. Still, other essential use cases need to be identified and agreed on.

Questions include what does the 21st-century real-time, real-world health information economy look like? How do we get to the next level? Is there more we can do around standardization to make what we're doing into a fundamental property of the healthcare system?

> "How do we get to the next level? . . . We must work quickly to standardize and regulate so that pushbutton export becomes a fundamental property of the healthcare system."
>
> — KEN MANDL

Important organizations have cropped up around this. Two are Da Vinci, on the payer side, and Argonaut, on the EHR vendor side.

Meeting Objectives

Objectives for this meeting are to:

- Obtain feedback on the FHIR bulk data API. What's not there? What needs to happen?
- Understand the next steps for payers and EHR vendors.
- Explore additional federal agency use cases.
- Discuss how to structure the regulatory environment to promote the implementation and adoption of bulk data APIs.

LEAP Funding: Pop Health App
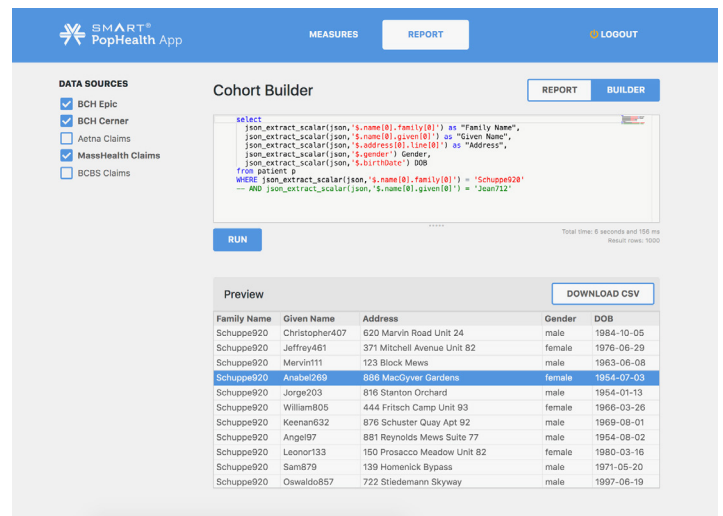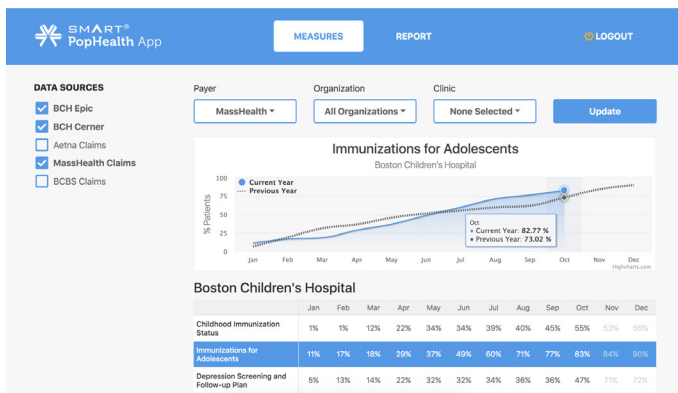
Bulk Data Overview: Extending FHIR to Population Level Datasets

Dan Gottlieb, MPA, Clinical Informaticist and Software Consultant

OVERVIEW

Dan Gottlieb reviewed existing challenges around working with bulk data, and described how the FHIR bulk data specification has evolved and is being implemented to address these challenges.

Being able to exchange large amounts of clinical and payment data in healthcare is important, and to date it is often a cumbersome and manual process. Leveraging work done on the FHIR API can help accelerate efforts to support population level data access. In a short period of time, tremendous progress has been made, tools have been developed, and server implementations have been initiated. At this moment, additional implementations and pilots are needed to identify gaps and move forward.

KEY TAKEAWAYS

SHARING POPULATION LEVEL DATA IS CUMBERSOME.

Three examples showing how cumbersome it is to share population level data are described below.

- A large academic medical center was running a study where some care was provided in a third-party clinic. The AMC wanted to pull data from the clinic into its primary EHR. To do this required custom mapping and a nightly export from the third-party EHR. This worked, but these mappings are time consuming and brittle.

- A healthcare institution bought a care management product from a vendor. They wanted to backload EHR data into this system. The vendor had to build a custom import script for this institution's EHR to do the upload, which was time consuming and is brittle if either system changes.

- A machine learning startup was doing a pilot of its algorithm with a physician group. For the startup to tune its model, the company needed historical data for all of their patients. The group had FHIR access to the data as it was using a cloud EHR that supported FHIR, but obtaining this data required hundreds of thousands of individual FHIR API requests. This process worked, but the company was terrified of updating its model, because it would have to repeat this complex and time-consuming process.

Other common uses cases for transferring population level data include:

- Payers get clinical data to assess care quality, which often happens by emailing spreadsheets around. This is a time-consuming, manual process.

- Providers want to access claims data to see care patients are receiving outside the network. To bring that data into the EHR, it would be beneficial to be able to pull in bulk data from claims.

- Many healthcare institutions have a data warehouse that pulls in data from clinical systems to support analytics use cases like finding research cohorts for studies. Frequently, this process uses custom scripts that are brittle and must be updated as the systems they interface with change.

- A great deal of work goes on in healthcare institutions around reformatting data to send it to different disease registries.

> "There are a lot of use cases where we need to share population level data. And what it comes down to today is that it's pretty cumbersome."
>
> — DAN GOTTLIEB

EXISTING WORK ON FHIR CAN BE LEVERAGED FOR POPULATION LEVEL DATA.

The FHIR API is great for obtaining data on single patients or small populations but is inefficient for large populations. At the same time, over the last few years a huge amount of work has gone into the FHIR standard. Can that work be leveraged to simplify bulk data exports? For example, can FHIR data models (termed "resources") be used as a standard format to move data between systems?

- We leverage the FHIR operation API structure in developing a bulk data API.

- We build on standard formats to enable use of existing FHIR validation infrastructure, existing FHIR parsers, and other tooling.

- The SMART authorization protocol has seen a lot of work and has had a lot of adoption. We leverage it to have a standard way to authorize client applications against the bulk data export API.

By using standard APIs, it is possible to plug components together. This means it isn't necessary to build every export scenario into a single API. Instead, modules like deidentification and transforming clinical code systems that support this API can be combined to create pipelines with these mix and match pieces to support many types of export scenarios.

Pipelines can support many scenarios

In working on FHIR for bulk data, the focus has been on technical standards. For now, several areas are important but not in scope at this time, including a legal framework for sharing data, real-time data sharing, data transformation, and patient matching.

AN INITIAL FHIR SPEC FOR BULK DATA HAS BEEN DEVELOPED.

The FHIR spec is now draft standard for trial use. It was validated through HL7 in September and is available on the HL7 website. Types of requests being supported with version 1.0 of the FHIR bulk data API are:

All data on ALL patients [FHIR Server Base]/Patient/$export

This is saying to a FHIR server (such as an EHR or data warehouse or claim system)—give me all the data on all patients in your system. This might be moving data into a research data warehouse or for analytics. "All data" means whatever the system has mapped into FHIR and is willing to give to this user.

For EHRs and clinical systems, we assume they will use the Common Clinical Dataset, which many systems have already mapped into FHIR for single patient access. They will just expose that by a bulk data API. For claim systems it will be financial data like the Claim and Explanation of Benefit FHIR resources.

All data on a GROUP of patients [FHIR Server Base]/Group/ [group id]/$export

This is exporting data on just a group of patients, such as a research cohort for a study or a set of subscribers for a particular payer. This leverages the existing FHIR groups API.

FHIR has a mechanism to define groups of patients. A user would define groups using the regular FHIR APIs. But you can also say you want to reuse that group to export all of their data using this export FHIR bulk operation. And some of the EHRs may even have ways in the UI to create a group of patients that can then be exposed through this mechanism.

All data on the server [FHIR Server Base]/$export

This is doing an export of all data on the server. This came out of the idea that some people want to be able to back up their FHIR servers or move servers between different vendors without missing small pieces of data. When you export data on patients, things like defined FHIR value sets won't come along, nor will practitioner data that is not tied to specific patients. Exporting at the FHIR server level provides all the FHIR data in the server, whether or not it's tied to a specific patient.

In contrast to other FHIR operations, the bulk data API is an asynchronous operation. A user has the option to submit a request, which could take several hours. The user is then notified when the data is ready and can download it. This is a mechanism to meet health systems where they are and make it easy to implement on existing infrastructure.

NDJSON format

The format that servers have to support under the specification is ndjson. What matters with ndjson is that you don't have to read the entire file into memory to start generating or parsing it. This makes ndjson conducive to working with large amounts of data where you can read and write it in a streaming way without having to wait for the entire file to be read.

> "We wanted to have a simple, text-based, highly compressible format as a baseline so that anytime you hit a bulk data server you know you can get data in a format that your system can read."
>
> — DAN GOTTLIEB

Contrast to SMART on FHIR Authorization

In the normal SMART on FHIR flow, when your app wants to connect into a clinical system, you get redirected to a login page to enter your login credentials. That works great for an app, for example, embedded in an EHR or running off of a data warehouse.

But with bulk data, we want to have services that run nightly and pull down data. We don't want someone to have to log in each time they request data. So, for the bulk data spec, we're using the SMART Back End Services Authorization spec. This is a public key encryption-based system where a user pre-registers their public key with the bulk data server they want to retrieve data from. Subsequently, the data consumer can use their private key to sign tokens to request data. It is a machine-to-machine authorization format that doesn't require intervention once it is set up.

Tools and Resources

Over the past two years the SMART team and other folks in the community have developed some great tools. A few of the tools include:

- **SMART Reference Server Implementation.** This is a FHIR bulk data server designed for testing SMART clients. It provides the ability to inject an error into the testing process, such as an authentication error, and allows setting different server speeds. This enables a user to test a variety of scenarios.
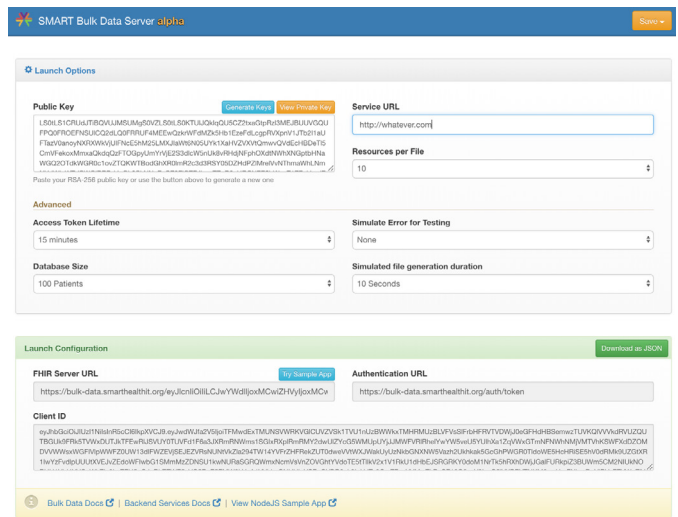
- **SMART Sample Command Line Client.** This sample sucks down data from the server.

- **SMART Bulk Data Testing Tool.** This tool verifies server compliance with the spec and and provides a detailed report.

THERE ARE SEVERAL IMPLEMENTATIONS STARTING OUT AROUND BULK DATA.

Some of the implementations include:

- **CMS ACO Beneficiary Claims Data pilot.** This is a bulk data service for ACOs to retrieve claims data about their members. There is huge enthusiasm about being able to get the data in a standard format and use standard FHIR tools.

- **CMS Data at the Point of Care pilot.** This uses Medicare's Blue Button to expose claims data to create a 360-degree view of Medicare patients for providers at the point of care.

- **Boston Children's Hospital Payer Analytics.** This will eventually be open source, using the bulk data mechanism to retrieve data and do quality measures and other types of analytics.

There are also several open source servers that have now implemented the bulk data specification. These include:

- Microsoft FHIR Server and a service that runs on Azure

- HAPI FHIR server, which is a building block of systems that want to provide a FHIR interface into existing data; it supports part of the bulk data spec

- IBM FHIR server that has support for bulk data

- Google Cloud, which is working on support for FHIR bulk data

▪ Epic and Cerner both participated in development of the standard and created pilot implementations to help refine the spec and make sure it could work with EHRs. EHRs will probably have a different interface from their existing FHIR APIs, which are running at the transactional system. For bulk data it probably makes sense to run against data warehouse or population health systems to create data exports. But vendors can use knowledge they gained in doing this initial mapping for FHIR to do the mapping for FHIR bulk data.

> "I think we can't have enough open source bulk data FHIR servers that cover different use cases and different optimizations."
>
> — DAN GOTTLIEB

AN EARLY DRAFT PROPOSAL HAS BEEN DEVELOPED ON IMPORT OPERATION.

Import operation is all about getting data into systems. Initially, export is probably more critical than import. Once people have the data, they can usually figure out a way to import it. But the community can benefit from import standardization.

The community has just started work on standardizing approaches to importing data, with a draft standard on GitHub and much discussion in the community about which import use cases to support. Those use cases will dictate how the import spec evolves. This is very early-stage work.

HL7 Standard

Wayne Kubick, Chief Technology Officer, Health Level Seven International

OVERVIEW

Wayne Kubick provided an update about what has happened with bulk data from HL7's perspective and discussed future plans.

HL7 is a well-established, credible ANSI-accredited healthcare standards development organization. HL7's vision is a world where everyone can securely access and use the right health data when and where they need it. FHIR is a key part of realizing that vision.

Creation by HL7 of a FHIR bulk data implementation guide has moved at warp speed. Bulk data was officially approved as a project by HL7 in January of 2019, bulk data was balloted in April 2019, and an HL7 standard for trial use was published on August 26, 2019. This is incredibly fast compared to most other HL7 projects.

HL7 is currently working on the next release for FHIR, which will be FHIR R5, planned for late 2020. Now is the time to answer important questions—such as necessary modifications to the bulk data spec to be incorporated into R5 and additional use cases to be explored. HL7 wants input, but it needs to be provided quickly.

KEY TAKEAWAYS

HL7 IS A FAMILIAR, ACCREDITED HEALTHCARE STANDARDS DEVELOPMENT ORGANIZATION.

Familiarity with HL7 was high among meeting participants. Important facts to know about HL7 include:

- It is an **ANSI-accredited healthcare standards development organization**. The ANSI accreditation means that HL7 supplies rigor and due process in how it operates to make sure the standard has been accepted by a broad community.

- It is an **international organization**. Most perspective about the FHIR bulk data specification has been oriented toward the United States. This is appropriate since ONC has provided such significant funding support. But it is important to keep in mind that HL7 is international, and the specification could apply to other countries.

- The **HL7 vision**: A world in which everyone can securely access and use the right health data when and where they need it.

> "This is what HL7 is trying to do, and FHIR's the way to get us there."
> — WAYNE KUBICK

- **HL7 Mission**: To provide standards that empower global health data interoperability.

HL7'S BULK DATA STANDARD HAS MOVED AT WARP SPEED.

Bulk data was officially approved as an HL7 project in January of 2019. Prior to this, work related to bulk data had been taking place within the FHIR community for some time, including at Boston Children's Hospital.

After being officially triggered as an official project in January 2019, bulk data was balloted in April 2019 and an HL7 standard for trial use was published on August 26, 2019. This is warp speed for HL7; it is amazing that it has been pulled together so fast, proving the potential for the community to move quickly.

TO INCORPORATE BULK DATA INTO FHIR R5, SEVERAL IMPORTANT QUESTIONS MUST BE ANSWERED.

FHIR is on an 18- to 24-month release cycle, which means the expectation is that FHIR R5 is likely to be released around the end of 2020. This in turn means going to a ballot in March or April 2020. Listed below are goals for FHIR R5.

Goals for FHIR R5 (late 2020)

- Moving additional resource content to formal normative status

- Improving tools and processes for publishing implementation guides (for discrete business needs and international requirements)

- Expanding content for newly developing domains (genomics, public health, research) and to provide access to the complete medical record

- Improving support for applications using multiple FHIR releases, and also multi-language support and federated servers

- Adding new facilities for migrating data to and from HL7 v2 messages and CDA documents

- Continuing to develop frameworks and adjunct specifications—SMART App Launch, CDS Hooks, FHIRCast, CQL, Bulk Data, and others—that build out a complete API-based ecosystem for the exchange of healthcare data

- Developing and exploring many new FHIR implementation guides at FHIR Connectathons and other forums.

The content pieces will be one of the top priorities of R5. Knowing about this upcoming release, important questions include:

- What changes, enhancements, or modifications to the FHIR core spec supporting the bulk data process should be incorporated into the R5 specification?

- What additional use cases should be explored?

- Should we be considering international use cases? (Greater acceptance on an international basis gives the standard more traction.)

- Is there a role for FHIR Accelerators?

- Should we explore changes to the IG for other formats? Other authentication methods? Streaming?

- Should we plan for updates to the STU spec?

- Should we plan to move the IG—with some additional modifications and improvements—to normative status?

While efforts are under way to develop the ballot and the plans for R5, there is still room to add things (though there's also a case to hold back on modifications until more implementation experience has been gathered). This requires input from the community on where R5 should go.

> "The question is, from a prioritization standpoint, what do we want to do with the spec? . . . We'll try to get some input that will help us drive our planning process for the next version."
>
> — WAYNE KUBICK

THE HL7 FHIR ACCELERATOR PROGRAM AIMS TO ENGAGE OTHER COMMUNITIES TO ACCELERATE PROGRESS.

The HL7 FHIR Accelerator Program is designed to assist communities and collaborative groups across the global health care spectrum in the creation and adoption of high-quality FHIR implementation guides or other standard artifacts to move toward the realization of global health data interoperability.

In some ways, this program gives a formal name to things that were already happening. Argonaut was the first accelerator. Da Vinci was an accelerator after that. And those two communities have had direct involvement with bulk data.

This accelerator program is a way to engage other communities to work with the HL7 environment to get going quickly and help remove roadblocks and stumbling blocks that slow down implementation.

Payer Use Cases & Experience

Aneesh Chopra, MPP, President, CareJourney (Moderator)

Amy Gleason, Digital Services Expert, United States Digital Service, HHS/CMS

Kirk Anderson, VP/CTO, Regence

Lenel James, Business Lead – Health Information Exchange, Blue Cross Blue Shield Association

Patrick Haren, Architecture Director, Cigna's IT Architecture for Health Engagement and Clinical Interoperability

Kathe Fox, PhD, Informatics Consultant

Jamie Colbert, MD, Senior Medical Director, Delivery System Innovation & Analytics, Blue Cross Blue Shield of Massachusetts

OVERVIEW

After Aneesh Chopra provided some background information to set the stage, Amy Gleason provided a deep dive of CMS's experience with bulk data and Kirk Anderson did the same for Cambia. Then, representatives from major payers—BCBS, CIGNA, BCBSMA, and Aetna—provided their perspectives.

As representatives from CMS and major payers shared, there are many situations when payers want to be able to share data with providers. While data sharing may happen today, it is complex, cumbersome, slow, and inefficient. There is significant enthusiasm for the FHIR bulk data spec, with multiple payers, providers, and organizations such as Da Vinci engaging in reference implementations and pilots.

To maintain the momentum for bulk data standards, there are still areas that require additional work, such as finishing the defining and mapping of CPCDS and creating a list of all possible data elements.

KEY TAKEAWAYS

Background

CMS has embraced FHIR APIs. Blue Button 2.0 went into production in August and dozens of apps have been approved. In the absence of payer consensus, CMS went on its own. This has moved quickly from concept to production. At the White House Blue Button developer conference in July, more than 20 health systems and health plans committed to move the HL7 balloted standard into real-world testing.

CMS

Three FHIR-based projects CMS is working on are:

- **Blue Button.** This allows individual Medicare beneficiaries to share their data with an app or health system.

- **Beneficiary Claims Data API.** This API came out earlier this year. It takes attributed and attributable patients for an ACO and provides the ACO with all claims data using bulk FHIR. This allows a machine-to-machine transaction and takes away the burden of having a person doing a transaction over and over.

- **Data at the Point of Care (DPC).** This allows any provider, including fee-for-service providers, to access patient data using bulk data calls. It uses a roster and an attribution model.

The data for all three of these projects, for all stakeholders, is stored in and served up from the Beneficiary FHIR Database (BFD). Data from 837 claims comes in on a daily basis, goes into the common working file, and goes through a quality process to remove duplicates and perform edits. On a weekly basis it is pushed out to the national claims history. From there it gets copied over to the chronic care condition warehouse (CCW). It is dropped in an S3 bucket for the BFD to pick up and process. When put into the BFD database, it is already pre-mapped to FHIR, making it easy to pull out in FHIR. Sometime in 2020, CMS will evolve the BFD server into R4 mapping.
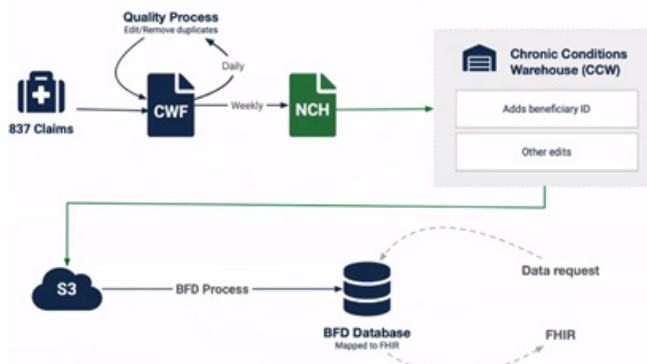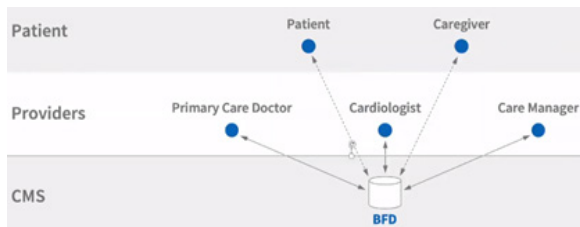
Figure 1: BFD Process

Figure 2: Same Data out of BFD for All Use Cases

At the Blue Button developers conference in July, CMS invited providers to participate in the Data at the Point of Care pilot. Thus far, about 105,000 providers have requested access, showing that demand is extremely high. CMS is working through this list to get providers connected.

Challenges

Among CMS's challenges are:

- A lot of extra context needing to be added.
- Ensuring compliance.
- Knowing who the provider is for each patient, which can be difficult to determine.
- Getting data from the EMR, such as the appointment date.

Contributions

CMS's contributions to the FHIR ecosystem include:

- Trying to push forward interoperability on a broader basis.
- As an open source implementation, showing how to solve a problem within FHIR.
- Testing bulk FHIR with large groups and health systems. This testing involves significant volume.
- Testing delegated access and giving providers some control.

- Mandating that providers add their FHIR endpoints to NPPES in order to receive data.
- Creating a record locater service by returning the FHIR endpoint for each provider in the claims history.
- Testing FFS attribution logic through rosters (provider asking for data on patients instead of CMS saying 'this is your data on patients").
- Exploring other ways that payers can help with authorization.

> "The biggest thing with this project is not so much the actual bulk FHIR spec, because that's a fairly simple part. It's more of this roster and attribution and who should have access to the data and doing some different workflows. Bulk FHIR is just the format we're using."
>
> — AMY GLEASON, CMS

Cambia

Cambia has multiple companies active in the FHIR ecosystem, including companies with consumer-focused solutions that have third-party apps that pull data from CMS and an insurance business through which Cambia has been active in Da Vinci.

Cambia realized that certain use cases require the movement of population-level health data, which is important for ACOs. Cambia concluded that standard RESTful APIs and other manual processes are not optimized for retrieving data in bulk and are a major pain point for both payers and providers. Cambia needed bulk data capability and saw benefits in the FHIR bulk API approach. Upon learning about the FHIR bulk data spec, Cambia saw two opportunities:

1. Work on the foundational problem of understanding who the individuals are that payers and providers want data on

2. Test the bulk FHIR spec

The problem of identifying *who* is termed by Cambia as "risk-based contract member identification." Cambia's goal is to enable payers and providers to exchange information that identifies members of a patient population associated with a particular risk-based contract or any other meaningful group. Identifying who is in a group is also known as a "member roster."

To gain experience, Cambia is working on a reference implementation with MultiCare, a large provider system in Washington State. In this implementation, the scenario Cambia is working on is sharing the member attribution list. Doing so will be foundational in that the member roster will be able to be used for other use cases.

In scope for this implementation are requests, notification, and delivery of member rosters in support of but not limited to risk-based programs. Cambia is well aligned with the FHIR bulk API spec but is diverging a bit on the data resources that are used.

> "Our use case is going in the direction of payer to provider . . . we're the server in this."
>
> — KIRK ANDERSON

The type of data that Cambia is sending in the bulk exchange includes:

- Patient demographic data
- Attributed provider data
- Health plan data, including details like subscriber ID, member ID, Medicare/Medicaid ID, plan name, and plan type
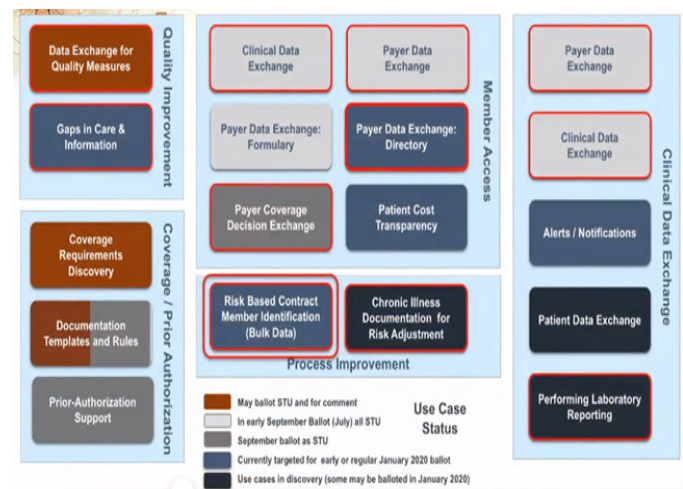
Da Vinci

Lenel James of BCBSA is a senior advisor to the Da Vinci project management organization. He explained that Da Vinci was born two years ago. Contrary to what many believe, Da Vinci is not just for payers. Da Vinci also has provider members, vendor members, and partners such as HIMSS and NCQA. Da Vinci's 6 initial use cases quickly became 9 and has now become 17. All use cases are summarized online.

Da Vinci's use case focus areas are shown in Figure 3. The boxes with a red border are use cases where bulk data can be used. In addition to FHIR, Da Vinci participants are exchanging data using flat files and several EHR vendors have services for exchanging data. But, these processes are bulky, which is why so many organizations are interested in FHIR.

Several health plans are in the process of testing bulk data exchanges with providers and one Da Vinci member has 10 providers in queue to start doing bulk data in 2020, related to four use cases.

Da Vinci is publishing implementation guides that include well-defined lists of the data elements.

Figure 3: Da Vinci Use Case Focus Areas (Red Borders = Use Bulk Data)

CIGNA

CIGNA is actively participating in Da Vinci and is testing the FHIR bulk data access specs. CIGNA is quite excited about what it is seeing. Patrick Haren categorized his comments as the good, ugly, and bad.

- **Good.** The vision of FHIR bulk data access (FBDA) is good. CIGNA likes this vision and wants to move forward with it. FBDA will address pain points and eliminate cumbersome one-off "science projects." It will provide an interoperability layer that will enable scaling data exchanges.

- **Ugly.** Elements of FBDA are ugly but are tolerable. These elements include Ndjson, which is text based and more verbose than delimited/CSV, but it is flexible and enables interoperability. Other ugly elements are that group/roster alignment is currently a work in progress and there is a need to assess file output options.

- **Bad.** Bad aspects are things that need to be worked on before moving beyond pilots into production. These include finishing the work about CPCDS, which is a key content profile; attribution lists and groups; and other high-value clinical resources and profiles. Da Vinci is defining some valuable use cases, especially around quality measures and clinical data exchange, but this may require additional fields that may not be part of the US Core.

BCBSMA

Blue Cross Blue Shield of Massachusetts has been doing risk-based contracting with providers for 10 years. As a result, BCBSMA has systems in place for exchanging claims data with providers that work, and that don't use FHIR. However, these systems are inefficient. This has BCBSMA interested in automation to improve efficiency.

While BCBSMA has not joined Da Vinci, the organization is working with payers and providers in Massachusetts to agree on a common file transfer data specification for flat file exchange. This would allow most payers to exchange data with providers in the same format on a monthly basis. This is the starting point for a standardized exchange of data. Eventually, BCBSMA would be interested in moving to some type of a FHIR bulk data standard.

Aetna

Kathe Fox agreed with comments of other payers. She stressed the need to keep in mind the perspective of members/consumers, who are often overlooked. Payers think about why certain use cases are good for the payer or the provider, but rarely think about why it is good for the member. Payers need to keep members in mind and consider how certain use cases are in the best interest of the member.

ADDITIONAL DISCUSSION AND COMMENTS

- **List of data elements.** Aneesh Chopra emphasized the need of payers to highlight the data elements that are requested out of an EHR. He stated it would be helpful to create a list of all of the data elements that are needed. He secured a commitment from Jamie Colbert of BCBSMA, based on BCBSMA's 10 years of experience sharing data in a risk-adjustment process, to help fill holes in the data elements that are required.

- **Keeping track of providers.** In Aetna's experience, not only is keeping track of the members a challenge but so too is keeping track of providers. Providers may leave, change jobs, or go to another network, and they are no longer there. When this occurs, what happens to the member? Is the member still attributed? This problem may be overlooked.

Cloud Provider Use Cases

Dan Gottlieb, MPA, Clinical Informaticist and Software Consultant (Moderator)

Taha Kass-Hout, MD, MS, General Manager, Healthcare and AI, and Chief Medical Officer, Amazon

Josh Mandel, MD, Chief Architect, Microsoft Healthcare

Jacob Miller, MS, Data Science Architect, IBM

Sean Kennedy, MS, PMP, MPH, Senior Director for Industry Solutions & Architecture, Salesforce.com Healthcare and Life Sciences

OVERVIEW

Dan Gottlieb led a conversation with panelists from major cloud providers about what they are building, how they are leveraging open standards, their approach to bulk data, and the capabilities they are exposing to healthcare organizations.

The major cloud providers on this panel are all working in the healthcare environment to assist payers and providers in exchanging large quantities of data. The processes and technologies for getting data in and out vary but are largely driven by the specific use case.

The panelists acknowledge that mechanisms for transferring bulk data are still at an early stage, but all are enthusiastic about working with and complementing EHRs with powerful cloud-based capabilities and services. Also, all see great potential for the FHIR bulk data API, but acknowledge that more work and learning are required.

KEY TAKEAWAYS
PROJECT DESCRIPTIONS

Each panelist described what their company is doing in healthcare and bulk data.

Microsoft

Josh Mandel leads a team of developers working on open source software to support health data standards. The goal is to make sure that anytime an implementation guide is being created, the community is actively testing the guide, and creating writing reference implementations and test suites. Based on this, Microsoft has been engaged in Argonaut projects including FHIR data subscriptions and CDS Hooks for advanced imaging orders.

Other teams at Microsoft are building production-level services that are fully compliant and ready to be deployed in healthcare. One of most interesting components is Microsoft's FHIR Server for Azure which recently went into general availability.

It is the first and only fully managed FHIR service from a cloud vendor in general availability production release and is fully backed by open source code, giving the community the ability to contribute changes. Support for bulk data export is built in as a standard Microsoft FHIR server capability. The team that built out that server is also working to help define the bulk import specification.

In general, cloud infrastructure is going to be powerful for healthcare because it supports:

- **More advanced data extraction**, particularly around clinical notes and summarizing a patient's complex history. There is a huge opportunity to replace or supplement manual work with automated technology. There will be a big role for machine learning.

- **Large-scale data analytics** through a host of tools to generate dashboards, keep track of metrics, and more.

- **Data mapping**, which is necessary to get data in a standard format. Getting data from various clinical databases into a FHIR representation generally involves a fair amount of data mapping.

Salesforce

Salesforce is focused on integration and interoperability. To achieve these goals Salesforce has defined use cases that help knit together different technologies. Salesforce's thinking on interoperability includes the following ideas:

- Your data is yours. Salesforce is a steward of the data and allows customers to move it freely.

- Salesforce has open APIs, standards-based APIs, and API-enabled fields.

- Salesforce is spending a great deal of time on standards-based exchange. The company is making sure it has a FHIR-aligned healthcare data model and is building out FHIR APIs.

IBM

IBM has made a variety of acquisitions in different spaces that came together as disparate solutions that use proprietary data acquisition methodology and proprietary formats. Its perspective is to do things once and do things efficiently, which is where FHIR comes in.

IBM's cloud is a public-private hybrid cloud. IBM provides open APIs and a FHIR server. As more components are based on the FHIR standard and can run on different clouds, it opens up the ecosystem. This makes it cheaper for everyone to use and allows companies to focus on delivering value. It also allows people to spend time on the hard problems, not the boring problems.

Amazon

Amazon invented the cloud and has been engaged in adopting FHIR for customers with the flywheel effect. Amazon sees a great deal of adoption of FHIR, particularly outside of the United States. For example, in the UK, Australia, and elsewhere, FHIR has become sort of a de facto standard for exchanging data.

One particular area of focus for Amazon is the huge amount of important data in healthcare that may not be easy to analyze. This includes structured data, a huge amount of unstructured data, images, voice, and more. Amazon is working to structure the unstructured, using AI and machine learning.

THE CLOUD VENDORS HAVE FAIRLY SIMILAR THOUGHTS ON GETTING DATA INTO AND OUT OF THEIR SYSTEMS, WHICH DEPENDS A GREAT DEAL ON THE USE CASE.

Cloud Provider	Overall	How get data in	How get data out
Salesforce	▪ Has lots of capabilities to move data in/out ▪ Big use case is around unified view of patient; patient 360	▪ Gets most data from EHRs via V2 messages ▪ Wants to marry clinical and nonclinical data with social determinant data ▪ Has some examples of getting data via FHIR	▪ Straightforward to get data out but depends on use case ▪ Wants to move away from point-to-point to enterprise scaling of APIs ▪ Wants to present data in workflows
Microsoft	▪ Diverse connectors for ingestion and export	▪ Many organizations are working with EHR vendor; may use an Azure SQL database as authoritative system of record—so data is already there ▪ Tons of data from outside gets moved into cloud buckets ▪ Pretty strong push toward requesting FHIR where feasible	▪ Healthcare provider organization needs a FHIR server with standardized APIs enabled—either work with EHR vendor because it's built in or work with an integration vendor who will bridge
IBM	▪ See proprietary stuff	▪ Most data ingestion is from a third party or a tool that does data mapping ▪ Drops it through FHIR and also offers some streaming cases ▪ Everything is driven by where the data is coming from, driven by the offering; many clients are using specific services and IBM asked them to do own mapping	▪ Driven by what the use case is ▪ Has clients put data in certain formats in databases and query that way ▪ Has bulk formats that are not FHIR that people are familiar with
Amazon	▪ Sees lots of new things built using FHIR ▪ Works through a flywheel effect—lots of partners familiar with serverless techs ▪ Has APIs, Lego pieces that innovators can use to put things together	▪ API gateway can be used for input and output ▪ Going to see more innovative things come out of Amazon with new modalities; will change the patient/provider experience	

THE ROLE OF THE EHR AND THE CLOUD SERVICE WILL VARY BASED ON THIS SITUATION.

Healthcare organizations are trying to figure out what role their EHR(s) play and their cloud service plays. Some of the responses from panelists are shared below:

- Josh (Microsoft) – I don't think there's a bright line where you would say these activities or workflows are definitely EHR things and these are definitely cloud services outside of the EHR. Within healthcare organizations the goal is to get something done, often through the easiest way. This could mean writing new software or using building blocks to make it as easy as possible. There are major building blocks related to accessing the right data:

  — A complete database copy to use for analytics-level queries

  — Access to streaming events as they occur

  — Some authoritative way to go back to the source of truth to answer questions

  > "If you've got those data building blocks it becomes easier for organizations to think about creating alerts, analysis, patient engagement strategies on the fly on top of those building blocks."
  >
  > — JOSH MANDEL

One other important principle is leveraging the system of record. If you are doing something outside of the system of record it is important to return of view of what was done back to the system. If you can't do that, then at least expose a clear API so the system of record knows how to get it and has the ability to fetch it in the future. Regardless, there needs to be a clear path for returning data.

- Jacob (IBM) – In developing an analytic tool or a service that might be used in the EHR, an organization doesn't want to do that on top of the EHR. There is a lot of data in the EHR and it is not always in the right analytic form, and building on top of the EHR could crash it. To get around that, the data needs to be in the right compute environment, which is often the cloud. To embed the analytic or service in an EHR a good solution is to use FHIR APIs and a SMART on FHIR integration inside of a workflow. But, you don't always want things to live inside an EHR; that's why it is important to have replicated copies. (IT teams are not always happy about running a workflow in production.)

- Sean (Salesforce) – The EHR and the cloud should absolutely coexist. Having them both is an opportunity to extend the value. There is a lot of activity where, for example, a screen pop happens within Salesforce that allows the user to context switch into the EHR to schedule the appointment. The user puts the record of the schedule in the EHR or the practice management system and it is then pushed back into Salesforce. From there, all kinds of activities can flow. It is important not to get stuck in a mindset of saying that all data needs to be in the EHR. The system of record may span a few different systems.

- Taha (Amazon) – The average health system in the United States is dealing with something like 18 different EHRs. This shows the need for data lakes and data warehouses but managing them is hard for a health system. The complexity of these systems and the volume of data demonstrates the need for and value of cloud infrastructure. With EHRs, cloud, and distributed learning, organizations need to think creatively about ways to leverage AI and ML at scale.

THE CLOUD VENDORS ARE THINKING ABOUT HOW THEY CAN HELP CUSTOMERS WITH BULK DATA.

Salesforce today can take a data set from an EHR flat file and pull it out. It is then possible to layer onto it. One thing many Salesforce customers have asked for, which is not in the specification, is tokenization. It is thinking about how to pull out identifiable pieces of data and tokenize them to feel more comfortable putting them into another system. This isn't required for many use cases, but for areas such as research it is important. Salesforce's Lightning platform has the capability to bring files in, store them in a compliant, secure manner, and provide access via the FHIR client.

This orchestration for bulk data between organizations is something that can happen and that can support a range of use cases, such as getting a unified view of the client, which includes data on social determinants of health and patient-generated data. This is an area where Salesforce is looking to become more of a server of information. This approach to bulk isn't implemented yet, but the only missing piece is the R4 specification.

From Josh Mandel's perspective, in regard to capabilities defined in the bulk data spec today there is a long way to go to take advantage of what is already there. Two areas Microsoft is focused on are: 1) making it easier for organizations that want to be on the server side of the bulk data situation, in other words exposing the APIs; and 2) bringing data from a variety of organizations into a common analytics platform.

Ways to be more efficient over time include being able to learn more about exactly what data has changed in a system. There is a basic capability for that in the bulk data spec today that is a time-based mechanism. More will be learned about this over time. Another place where the community needs more experience is with documents and free text notes. Currently there is a rough way of saying, if an organization wants to export a set of documents through bulk data, here is what is recommended, but it involves wrapping things up in FHIR binary resources and sharing a manifest of those. This is an area where there is limited experience and much to be learned.

From IBM's perspective, at this moment, not a whole lot is real yet in regard to bulk data. However, IBM is able to receive data in FHIR format—for a single patient or in bulk. Doing so makes life easier for everyone. All of IBM's services can accept data via FHIR. In regard to what is real regarding the cloud—not yet everything. IBM is still using many proprietary formats, but is moving slowly to FHIR or bulk FHIR. It will take time, depending on what the market wants to see.

Amazon is customer focused and committed to meet customers where they are. Amazon wants to hear about the use cases that customers want. Amazon has hundreds of serverless FHIR interfaces, which meet different kinds of demand and different kinds of use cases in different kinds of systems. Amazon has tremendous capabilities and needs to understand customers' priorities to keep pushing the envelope.

EHR Vendor Capabilities

Micky Tripathi, PhD, President & Chief Executive Officer, Massachusetts eHealth Collaborative (MAeHC) (Moderator)

Jim McDermott, Development Lead, Payer and Population Health, Epic

Matt McKenna, Director & IP Strategist, Cerner

Larry O'Toole, Associate Vice President of Strategy, MEDITECH

Jeffrey Danford, Senior Principal Software Engineer, Allscripts

OVERVIEW

Micky Tripathi led a discussion of representatives from major EHR vendors about bulk data capabilities and plans.

There is definitely demand in the market among providers for importing and exporting data in large quantities, driven by several use cases. And, even in the absence of a bulk data standard, EHR vendors and others in the ecosystem—such as data aggregators—are finding ways to try to meet this demand.

However, these vendors agree that having standards for accessing and publishing bulk data would be beneficial in improving efficiency of current bulk data practices. In particular, vendors believe the FHIR bulk data standard could be a good solution and support this standard.

These vendors would like to see the government/ONC take the lead in creating a rule involving the FHIR bulk data standard.

KEY TAKEAWAYS

BULK DATA TRANSFER IS ALREADY HAPPENING TODAY.

In open comments to frame the discussion, Micky Tripathi acknowledged that some may have the perception that the FHIR bulk data API is needed before any bulk data access happens. However, he confirmed today's reality by stating, "Just to level set for all of us, bulk data access is happening today and it is happening in pretty large scale in lots of different places."

Tripathi's own organization, a small nonprofit, receives 400,000 records each day from providers in 34 states. He sees a FHIR API as potentially helpful in making the transfer of data more efficient, but it is not the difference between transferring bulk data or not, since the transfer is already happening. In fact, to support current bulk data transfer, the EHR vendors have products that are offered to payers to support the import and export of bulk data. However, there is a great deal of variation in these products.

THE EHR VENDORS WORK WITH PROVIDER CLIENTS WHO HAVE SOMEWHAT COMMON DEMANDS RELATED TO BULK DATA. THEY WANT STANDARDS AND SEE VALUE IN THE FHIR BULK DATA STANDARD.

The panelists' companies work with a wide number of providers, ranging from large academic medical centers to smaller hospitals to all types of smaller, specialty providers. They are hearing from providers who want to be able to import and export data at bulk, and are working hard to find solutions to accommodate clients' bulk data needs.

Common uses cited by provider clients are:

- To help manage and improve patient care and identify care gaps, especially in situations such as patient-centered medical homes and ACOs where a complete picture of a patient's care is needed.
- To look at claims and clinical data together in a risk-sharing or value-based care situation.
- To look at groups or cohorts of patients.
- To perform analytics on "How are we doing?"

THE EHR VENDORS SEE VALUE IN BULK DATA STANDARDS, PARTICULARLY THE FHIR BULK DATA STANDARD.

These vendors have all found various workarounds to enable their provider clients to be able to import and export bulk data. But, due to the variability of the data, the technology, and the lack of standards, meeting customers' needs can be challenging.

As a result, these providers expressed strong interest and enthusiasm for bulk data standards (in general), and expressed a high level of interest and support for the FHIR bulk data standard (in particular). The common refrain was, "It could make our lives much easier."

Several of the panelists' companies already have some experience with the FHIR bulk data standard and are working on pilots and initial implementations. Of high importance to the vendors is focusing on specific use cases involving bulk data.

These vendors don't necessarily see significant technical challenges impeding bulk data. A more significant barrier is the lack of a broadly adopted standard. A related issue is the presence in the ecosystem of data aggregators who have businesses models related to transferring data at bulk and who don't use the bulk FHIR standard.

While somewhat reluctant to embrace the idea of "regulation," these vendors do see value in the government (ONC) saying, "These are the standards," especially for certain use cases. But participants want flexibility in being able to meet those standards.

ADDITIONAL COMMENTS

Other comments from attendees arising during the discussion included:

- **What is the threshold for moving from FHIR to bulk FHIR?** An attendee posed this question because he said that others have asked it of him. One participant responded that the threshold is not a "volume" threshold but is based on the number of patients. Another participant's organization decides on FHIR or bulk FHIR based on speed. If a query takes longer than 250 milliseconds to return the first byte of data, then an asynchronous process makes sense and bulk FHIR is appropriate.

- **Care gaps.** Da Vinci is kicking off an effort to identify what are the data concepts that are available from payers and needed by providers. Everyone is invited to participate.

Additional Federal Use Cases

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program (CHIP); Donald A.B. Lindberg Professor of Pediatrics and Professor of Biomedical Informatics, Harvard Medical School (BCH) (Moderator)

Adi Gundlapalli, MD, PhD, Chief Public Health Informatics Officer, Center for Surveillance, Epidemiology, and Laboratory Services, U.S. Centers for Disease Control and Prevention

Gideon Scott Gordon, PhD, Senior Health Informatics Officer, Office of Strategic Programs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Teresa Zayas Cabán, PhD, Chief Scientist, Office of the National Coordinator for Health IT

Adam Berger, PhD, Director of the Division of Clinical and Healthcare Research Policy, Office of Science Policy, National Institutes of Health

Paula Braun, MS, Entrepreneur-in-Residence, U.S. Centers for Disease Control and Prevention

OVERVIEW

Ken Mandl led a discussion among panelists from different government agencies about relevant use cases involving bulk data where a standard such as FHIR bulk data could make a significant difference.

There are several federal government use cases for a bulk data standard and these use cases are massive. They include sharing data for research to cure diseases and develop drugs, to conduct surveillance of drugs being used in the real world to ensure their safety, to aggregate data from disparate sources to monitor pubic health, and much more.

These use cases point to the need within the federal government—as well as at state and local governments and internationally—for bulk data standards. Agreed-upon standards will improve the ability to share data and will improve the ability of each of these health-related agencies to fulfill their mandates.

KEY TAKEAWAYS

Panelists from each organization represented provided an overview of use cases that would benefit from a standardized bulk data format.

CDC

It is important to understand the difference between population health and public health:

- **Population health** is generally defined as the health outcomes of a group of individuals. The metrics in population health are generally related to panel management. For example, it is looking at outcomes for a specific disease area, such as diabetes management.

- **Public health** is the science of protecting and improving the health of people.

In fulfilling its mandate, the CDC receives, manages, transfers, and transports data in many ways, and views itself as a data steward. An example of CDC's role in aggregating and using data is collecting data through the National Security Surveillance Program, which receives data on 68% of all ED visits in the country on a daily basis.

In managing data, the CDC has adopted FHIR in various programs, with varying levels of maturity. It is the view of the panelists from the CDC that the organization needs to coordinate all of its efforts involving bulk data to develop greater consistency.

This will pose challenges because the heartbeat of public health is in state and local jurisdictions, where there is tremendous variation in data collection. Due to this variation, when the CDC attempts to ingest data, it can experience a problem of tremendous indigestion. Moving in the direction of a bulk FHIR standard that is broadly adopted could yield major dividends.

It is CDC's hope that various use cases can be used to influence the processes, practices, and technology of collecting data from state and local organizations. When data is aggregated, it can be used for analytics, research, and other authorized uses.

While the CDC views public health as unique, at the same time it is CDC's hope to ride the coattails of bulk data activities already happening in healthcare. CDC also wants to have the ability to look at data on a very granular level, such as patients in a particular region with diabetes.

One potential issue for CDC is the asynchronous nature of bulk data. There are topics—like Ebola, Zika, or vaping—where aggregating data in real time is extremely important.

NIH

The NIH's mission is to understand and improve human health. NIH is the largest public funder of biomedical research in the world with a budget of $40 billion for research. This funding supports 50,000 grants in the United States and around the world.

The NIH encourages data sharing and has policies in place to ensure data is shared. The NIH is a major user of data, with efforts to get access to CMS and CDC data, specifically to help advance research aims as well as claims and administrative data.

The NIH has hundreds of different data repositories with all types of data that are currently available to the public and to researchers. However, these repositories are not standardized, which makes it difficult to be able to query them.

NIH sees multiple use cases for bulk data which include:

- Supporting clinical trials.
- Supporting observational studies.
- Being able to look at data granularly by, for example, comparing different regions or rates of incidence; looking at data based on gender or age; or looking at chronic conditions by geographical locations.
- Using data to identify research needs and set priorities for where research needs to be done.
- Using data to collaborate on research internationally.
- Thinking about research at state and local levels.

An important issue related to bulk data is bandwidth. For some research projects it would be extremely valuable to export radiological images as well as genetic and genomic data, but exporting and importing this data is currently limited by bandwidth.

Within NIH, FHIR is a priority, with Teresa Zayas Cabán leading FHIR initiatives. The NIH has released two notices related to the use of FHIR and has been encouraging researchers to use the FHIR standard for two purposes:

1. To pull data out of EHRs to do research.

2. To map research data into FHIR, which is seen as a potential way to aggregate and integrate existing data sets.

In addition, the NIH has published a notice of special interest for the small business community, encouraging them to develop FHIR apps that tie to specific functionalities of interest for a research project. This is an opportunity to bring the developer and research communities together.

NIH also has stood up two related projects:

1. Developing tools to make it easier for researchers to pull data out of EHRs and map datasets to the FHIR specification.

2. A project focused on genomics and phenotypic information.

The NIH believes that its FHIR initiatives are key to advancing scientific discovery.

FDA

The mandates of the FDA are to review and approve or deny applications for treatments, including drugs, and to ensure the safety and efficacy of these products. The FDA is also responsible for post-market surveillance related to safety issues.

In fulfilling this mandate, the FDA is interested in collecting real-world evidence or real-world data. This is data that was not collected through a protocol-driven trial. Real-world data can reveal important trends.

As part of the 21st Century Cures Act, the FDA is required to set up a program to inform industry how to submit and utilize real-world data. To do so, the FDA has released a framework spelling this out.

From the FDA's perspective, uses and benefits of bulk data include:

- **For clinical research.** The FDA doesn't conduct clinical research, but does review and evaluate it, and has many activities to improve research. FHIR is always part of this conversation, as having a common pool of data which is consistent with a known history would be extremely useful.

- **For surveillance.** The FDA's post-market surveillance differs in the details from the CDC's surveillance, but the general concepts are the same.

- **For comparative consistency.** In looking at data from multiple sources and even for different subjects, having data that uses a consistent set of standards is valuable in performing comparisons.

- **For greater cross-agency emergency preparedness.** Having a common, clear source of data makes it easier to coordinate a response without worrying about mixing apples and oranges.

ADDITIONAL COMMENTS

The agencies represented don't perceive an authority issue in getting data. They view the issues as more technological and practical. Ken Mandl termed the solution needed as "a social-technological solution."

ONC Regulatory Approach and Next Steps

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

Don Rucker, MD, National Coordinator at Office of the National Coordinator for Health Information Technology

Steven Posnack, MS, MHS, Deputy National Coordinator at Office of the National Coordinator for Health Information Technology

Aneesh Chopra, MPP, President, CareJourney

Josh Mandel, MD, Chief Architect, Microsoft Healthcare

OVERVIEW

In this wrap-up session, panelists shared their final thoughts and observations on potential regulatory paths for moving forward.

The meeting conveyed a great deal of optimism that the HIT community is moving forward toward a bulk data standard, with possibly some regulatory push to get over the hump. There are multiple use cases among payers, providers, and the government, including use cases for research and public health. High levels of demand along with fast adoption and implementation show much potential for the future.

KEY TAKEAWAYS

THIS MEETING SHOWS SIGNIFICANT MOMENTUM AROUND THE FHIR BULK DATA STANDARD.

A recap of highlights shared at this meeting includes:

- CMS has shown tremendous momentum in using the FHIR bulk data standard. Within six to eight months of the first meeting on this topic, CMS was already using the standard in pilots and 105,000 providers, which is perhaps around 20% of all physicians in the United States, have requested access to CMS data.

- EHR vendors are getting ready to embrace bulk data and view work on FHIR as a good foundational step, even though there are some technical issues.

- Cloud vendors have large initiatives under way along with collaborations with EHR vendors and health systems where bulk data will be very useful.

- Federal agencies have use cases involving bulk data that could potentially be addressed with some creative approaches to the regulatory regime.

THE REGULATORY EXPERIENCE OF MEANINGFUL USE 3 PROVIDES AN IMPORTANT LESSON.

Per Ken Mandl, during the development of the Meaningful Use 3 regulations, Aneesh Chopra was extremely influential in the regulatory process. While having interest in SMART on FHIR, Chopra advocated for language stating "an API for patients to access their data." When Meaningful Use 3 was published, Argonaut came together because many people saw a regulatory need. This created a hugely productive consensus working group. It demonstrates that the right regulation can be a catalyst for connecting health apps and health systems.

The 21st Century Cures Act planted the seeds for focusing on bulk data.

A FEW REALITIES HIGHLIGHT THE IMPORTANCE OF CREATING AND IMPLEMENTING BULK DATA STANDARDS.

Don Rucker conveyed a few points that focus on the importance of a bulk data standard.

- We live in an age when big data is going to be confronted, one way or another. The question is will it be elegant, computable, and efficient, or will it be expensive and inefficient. We have a choice of how we do it, not whether we do it.

- Many payers are unable to electronically get clinical data from their EHRs to figure out what they were paying for in care. Or, getting clinical data electronically is extremely expensive. This points to the fact that we have a payment system where we are relying on payers to figure out what they are buying, but if they can't get the clinical data there is something clearly amiss.

- The current SMART on FHIR specification works well for an N of 1, however, analytics require access to larger datasets.

Other thoughts from Rucker included:

- FHIR work to date has largely been in the clinical area, and not in payments. It was not a representation of claims; it was clinical. So, the obvious place to do a download of FHIR data was where there already was FHIR data and there had been a fair amount of work.

- There is much to think about in the various payer-side constructions, such as what would be the FHIR components there.

- ONC is also very focused on the topic of provider burden, which is a significant problem. A great deal of provider burden relates to prior authorization, which is ultimately a failure of data communication. There is a huge data transfer need here.

- There are also tremendous opportunities in sharing population data that is related to research on the nature of care, quality of care, and value of care.

- The public interest is served in being able to do queries where the N is greater than 1. That allows for all kinds of other queries into the same database.

- In our modern world with immense secondary uses of data, we have to be very thoughtful about privacy, which will likely require federal policies. (It is worth remembering that most health data sits outside of the EHRs and is not covered by HIPAA.) Also, in thinking about privacy, it is important to keep in mind the patient's right to access. There are essentially two separate privacy issues in play: 1) the individual's right of access; and 2) the HIPAA authorization under treatment of payment operations.

Steve Posnack followed up and offered some reflections:

- There is a broad interest in health information technology performing at scale and using data at scale, in a consistent, repeatable way. This will enable the players in the health care system to focus on delivering higher impact services. If each of the players has to separately implement, it creates waste and inefficiency in the system.

- Not only is work being done to standardize the data and how the technology is supposed to work, but there is work under way to rethink and standardize business processes. The bulk specification and other work is looking at business processes and asking if they can be done differently.

- The transaction or content standards being used today are not being replaced. It is rare that an organization is changing out an ETL that currently exists and replacing it with the FHIR bulk data specification. It is more building on or adding to. As a result, we're in a hybrid state where there are a lot of layers of in-production uses of existing standards.

- An Accenture survey found that one sixth of hospital CIOs and others in the provider community were completely unaware of both CMS and ONC regulatory work and two thirds were only vaguely familiar. For all those in the community who are aware, it is important to educate them and make sure that everyone is aware and prepared for upcoming changes to regulatory activities.

- To review comments about proposed regulations, go to regulations.gov. It is possible to do keyword searches on topics, such as FHIR 4, to see the many comments on this subject.

- ONC has proposed a transition from the CCDS common clinical dataset to the USCDI. It's a good first step. Even if what is proposed is finalized, it's not a big expansion from eight or nine years ago. The work ahead is to aggressively look toward expanding the USCDI to represent a lot of the other data that's already in systems today.

THE RAPID PROGRESS WITH THE FHIR BULK DATA STANDARD MAY BE ATTRIBUTABLE TO HAVING A NARROW SCOPE.

Josh Mandel pointed out that thus far the scope of the bulk data spec has been relatively narrow. As a result of this narrow scope, there has been quick development of the spec, vendor buy-in, standardizing through HL7, and seeing the real-world adoption. The initial spec hasn't solved all problems but has had enough scope to solve some meaty, real-world problems.

During this meeting, issues were raised of things that were not initially in scope, such as roster management, deidentifying or tokenizing data, and determining how to come up with authorization to access data for various purposes.

Mandel's perspective is that the community is just now at the stage where the core export specification has been defined and is starting to go into production. What is needed right now is implementation experience to determine what is working and what is not, to assess if anything is broken, and to identify gaps that need to be filled. Then, based on what is learned, improvements can be made. But, trying to broaden the spec at this time would make it hard for the community to remain focused.

"I would encourage us to focus on what we've got today. I think it's pretty powerful—actually surprisingly powerful—in a lot of ways. Don't be afraid to build on top of it and extend it and fill in the gaps. Absolutely let us know if the stuff we've written is working for you."

— JOSH MANDEL

THIS MOMENT IS AN OPPORTUNITY TO INFORM THE RULE MAKERS.

Drawing on the framework from an earlier session, Aneesh Chopra offered reflections as the good, bad, and ugly.

- **The good:** The demand in the market, especially from doctors and general participation levels, far exceeds what was expected.

- **The bad:** There are data model gaps. Absent a mechanism to get the data models harmonized, there is the risk of HL7 V2 tags in many flavors. USCDI, which has been broadened to incorporate all of the data elements talked about for payer-provider use cases, is screaming for governance. A concern is that where people are technically implementing FHIR, they may not be doing so in a manner that has been agreed upon by others. One version of a project may not be the same as at other sites, which is a problem.

- **The ugly:** There is a huge imbalance in ingestion versus publication. Demand among providers to pull in data is through the roof. And, while providers may want to publish data out, when they contact their EHR vendor they aren't getting a response.

The CMS and ONC rules, which are not yet finalized, raise the idea of a new certification criterion focused on population-level exports. The rule is in its final stages, with a final rule likely soon. The momentum in the room about bulk, the readiness of the spec, and industry adoption are critical as the final rules are being written.

In Chopra's view, possible paths that ONC and the White House take might be to punt, to make a broad statement about what needs to happen, to kick the can down the road by having rules come out that validate and confirm that single patient is the way to go, or to say bulk is required for certification according to a spec. Regardless of the decision, they need the fuel from the HIT community to do their jobs. This is an important moment for the regulatory world.

Chopra also commented (with input from Dan Gottlieb) that there are likely to be opportunities to leverage previous experience in mapping data to the SMART on FHIR APIs (one patient at a time) when mapping data to support a bulk data API.

Ken Mandl observed that the more evidence there is of work with the standard, the more it will help the process of developing the rule. A quick catalog of some of the work being done is:

- CMS has two implementations.

- Boston Children's Hospital is funded to test bulk data in a payor/ACO context.

- Microsoft has support on the supply side for exporting bulk data through implementations in an open source server and a managed service that allow any health system to expose that data to clients through the bulk data export specification.

- Aneesh Chopra has solicited pledges from multiple private payors to implement bulk data.

- A large academic medical center has stated that the primary barrier for a vendor-neutral adoption is that "ONC isn't telling everybody to do it yet."

Don Rucker commented that this moment is an opportunity to bring some sanity and accountability back into the health care system with data, in a rigorous, efficient way.

BIOGRAPHIES

DON RUCKER, MD
National Coordinator for Health Information Technology

Dr. Don Rucker serves as the national coordinator for health information technology. He previously worked as a clinical professor of emergency medicine and biomedical informatics at the Ohio State University and Premise Health, a worksite clinic provider, where he served as chief medical officer.

Dr. Rucker started his informatics career at Datamedic Corporation where he co-developed the world's first Microsoft Windows based electronic medical record. He then served as chief medical officer at Siemens Healthcare USA. Dr. Rucker led the team that designed the computerized provider order entry workflow that, as installed at Cincinnati Children's Hospital, won the 2003 HIMSS Nicholas Davies Award for the best hospital computer system in the U.S. Dr. Rucker has served on the board of commissioners of the Certification Commission for Healthcare Information Technology and Medicare's Evidence Development and Coverage Advisory Committee (MEDCAC) and has extensive policy experience representing healthcare innovations before Congress, MedPAC and HHS.

He has practiced emergency medicine for a variety of organizations including at Kaiser in California; at Beth Israel Deaconess Medical Center in Boston, where he was the first full-time emergency department attending; 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 a Master's degree in medical computer science and a Master of Business Administration, both from Stanford.

STEVEN POSNACK, MS, MHS
Deputy National Coordinator for Health Information Technology

Steven Posnack serves as the Deputy National Coordinator for Health Information Technology.

Prior to this role he served as executive director of the Office of Technology. In this role, Mr. Posnack advises the national coordinator, leads the ONC Health IT Certification Program, and directs ONC's standards and technology investments through the ONC Tech Lab, which organizes its work into four focus areas: pilots, standards coordination, testing and utilities, and innovation. He led the creation of the Interoperability Standards Advisory, the redesign of ONC's Certified Health IT Product List (CHPL), created the Interoperability Proving Ground, and developed the C-CDA Scorecard.

Prior to serving as the director of the Office of Standards and Technology, Mr. Posnack led ONC's federal policy division within the Office of Policy and Planning from 2010 to 2014. In this capacity, he led ONC's regulatory affairs, legislative analysis, and several federal policy development and coordination activities. From 2005 to 2010, he served as a senior policy analyst within ONC's Office of Policy and Research. In that position, he co-authored the Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information. He also led a cross-HHS policy team that worked with the Drug Enforcement Agency (DEA) as it developed its regulation for the electronic prescribing of controlled substances (EPCS).

Mr. Posnack earned a Bachelor's degree in computer science from Worcester Polytechnic Institute, a Master's degree in security informatics from Johns Hopkins University Information Security Institute, and a Master's degree in health policy from Johns Hopkins University Bloomberg School of Public Health. He also maintains a Certified Information Systems Security Professional (CISSP) certificate.

KEN MANDL, MD, MPH
Director, Computational Health Informatics Program (CHIP); Donald A.B. Lindberg Professor of Pediatrics and Professor of Biomedical Informatics, Harvard Medical School

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 PrecisionLink Biobank for Health Discovery.

DAN GOTTLIEB, MPA
Clinical Informaticist and Software Consultant

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.

WAYNE R. KUBICK
Chief Technology Officer, Health Level Seven International

Wayne R. Kubick is Chief Technology Officer for Health Level Seven International, an ANSI-accredited Standards Development Organization (SDO) dedicated to the vision of a world in which everyone can securely access and use the right health data when and where they need it. He was formerly Chief Technology Officer for CDISC, the leading SDO for pharmaceutical clinical research, and has held many senior executive roles with BBN Software Products, Parexel International, Lincoln Technologies and Oracle Health Sciences.

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 U.S. 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, the New Jersey Innovation Institute, and earned his MPP from Harvard Kennedy School and BA from The Johns Hopkins University.

AMY GLEASON
Digital Services Expert, United States Digital Service, HHS/CMS

Amy Gleason is a Digital Services Expert with the United States Digital Service at the White House. She is currently detailed at HHS/CMS and is working on projects that provide valuable claims data to patients and providers and on efforts to improve interoperability as a whole. Amy began her career in nursing and quickly found that she loved technology. She has worked with several different electronic medical records and was a cofounder of CareSync, a care coordination company. She joined the US Digital Service for a tour of duty last November, and she is enjoying working on projects that have such a large impact on healthcare in the US.

KIRK ANDERSON
VP/CTO, Regence

Kirk leads technology strategy and execution for Cambia Health Solutions. Kirk has over 20 years of experience in health care technology including 16 years in health care information security. Prior to becoming Cambia's CTO, Kirk served as the Chief Information Security Officer at Cambia for 6 years. In his current role, Kirk leads Cambia's digital transformation initiatives, cloud strategy, and interoperability initiatives. Kirk is a current steering committee member of Project Da Vinci—a national effort to accelerate the use of FHIR APIs between payers and providers. Kirk is also a board member of the CARIN Alliance, focusing on consumer-driven access to health care data.

LENEL JAMES
Business Lead – Health Information Exchange, Blue Cross Blue Shield Association

Lenel James has over thirty-five years of experience in management, systems consulting, and standards development – and over 25 years of focused experience in the healthcare industry & 5 years of engagement in health equity.

He is a Business Lead for Health Information Exchange & Innovation at Blue Cross and Blue Shield Association, on the Industry Standards and eHealth team. His responsibilities include working externally (at standards-setting organizations) and internally (within the commercial market for eClinical data exchange) on many of the key Health IT challenges and clinical/administrative interoperability issues. He is also co-chair of the HL7 Payer User Group and a member of the Program Management Office of the HL7 Da Vinci Project. His engagement in the community has been reflected by membership of the executive committee of the Great Lakes Regional Health Equity Council (RHEC-V), as co-chair the Social Determinants of Health Committee of RHEC-V and as co-chair of the Cross-RHEC Community Health Worker Coalition.

As part of his extensive experience in clinical information systems, and information technology strategic planning, Mr. James worked with health care, state and federal clients on a broad array of projects for a leading international consulting firm. He also spent five years as the Acting Director of Clinical Systems for the IT Department of the third largest public hospital in the USA.

PATRICK HAREN
Architecture Director, Cigna's IT Architecture for Health Engagement and Clinical Interoperability

Patrick Haren leads Cigna's IT Architecture for Health Engagement and Clinical Interoperability. He has a background in software engineering and innovative large-scale systems design. He is currently enjoying the challenges and opportunities for technology in Healthcare, particularly related to optimizing the quadruple aim.

KATHE FOX, PHD
Informatics Consultant

Kathe P. Fox, PhD has more than 30 years' experience in healthcare Informatics with a particular emphasis on chronic disease epidemiology, research methods and evaluation, and big data and data integration. Recently retired from Aetna, Kathe is currently devoting her energies to emerging technology companies that are grounded in healthcare data and insights. She is currently working with axialhealthcare, ACT.md, and a yet to be named start-up looking at new ways to manage disability benefits. Kathe is also an advisor to Springboard Enterprises.

Kathe holds a PhD from Yale University (Department of Epidemiology and Public Health) and a BA in History from Skidmore College. She is Treasurer of the Alumni Board of the Yale School of Public Health and a Lecturer in the Department of Biomedical Informatics, Harvard Medical School.

JAMES A. COLBERT, MD

Senior Medical Director, Delivery System Innovation & Analytics, Blue Cross Blue Shield of Massachusetts

Dr. James Colbert is Senior Medical Director for Delivery System Innovation and Analytics at Blue Cross Blue Shield of Massachusetts (BCBSMA). He is the clinical leader for provider analytics and provider perfor-mance support within BCBSMA. He is responsible for engaging with at-risk provider organizations to enable them to achieve success within their value-based contracts through managing TME and improving quality. He represents BCBSMA on the Board of Directors of the Healthcare Transformation Taskforce.

Prior to joining BCBSMA, he served as the VP of Population Health for Benevera Health, a joint venture between Harvard Pilgrim Health Care and four health delivery systems in New Hampshire. Other experiences include serving as Senior Medical Director for Population Health at Verisk Health and serving as a core faculty member of the Brookings Institution ACO Learning Network. He was the lead author of a 2014 Brookings Institution report entitled Adopting Accountable Care: An Implementation Guide for Physician Practices.

He received his bachelor's degree from Harvard College and medical degree from Stanford University. He completed a primary care internal medicine residency at Brigham and Women's Hospital as well as a fellowship in medical research and health policy at the New England Journal of Medicine. Dr. Colbert maintains an active clinical practice, and he holds faculty appointments at Brigham and Women's Hospital, Ariadne Labs, and Harvard Medical School. In 2015 he was selected by MedTech Boston as one of 40 healthcare innovators under age 40. He lives in Jamaica Plain, MA with his wife and daughter.

TAHA A. KASS-HOUT, MD, MS

General Manager, Healthcare and AI, and Chief Medical Officer, Amazon

Taha A. Kass-Hout, MD, MS, is a trailblazer, with a successful track record over the past two decades innovating on behalf of consumers and pioneering in healthcare and life sciences, precision medicine and artificial intelligence. A physician and bioinformatician, whose signature includes building scalable products and agile teams.

Taha is a General Manager, Healthcare and AI, and Chief Medical Officer at Amazon focusing on healthcare and AI-related initia-tives, including Amazon Comprehend Medical, Amazon's first health care-specific machine learning service offered by AWS. Prior to joining Amazon, Taha was a public servant in the US Fed-eral Government (2009-2016) bringing about change through his role as the first Chief Health Informatics Officer for US FDA (2013-2016), where he created openFDA and precisionFDA, part of President Obama's 2015 Precision Medicine Initiative. Both efforts were referenced in the 2015 White House Strategy for American Innovation, and precisionFDA was awarded the top prize at the 2016 Bio-IT World Best Practices. Additionally, Taha spearheaded groundbreaking programs at the US CDC for electronic disease surveillance (2009-2013), including the quick disease surveillance scale-up during the H1N1 influenza pandemic taking it from less than 6% to >90% coverage of the US population ahead of the 2nd

wave of the pandemic. During his one year transition from the US Federal Government, Taha served as SVP and Chief Digital Health and Analytics Officer at Trinity Health (2016-2017), one of the leaders in value-based health care systems in the US, and led the development of the American Heart Association Precision Medicine initiative.

Taha received his medical training at Beth Israel Deaconess Med-ical Center, Harvard Medical School, and during his time there, was part of the BOAT clinical trial. He holds a Doctor of Medicine and Master of Science (Bioinformatics) from the University of Texas Health Science Center at Houston.

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 Instructor at the Harvard Medical School Department of Biomedical Informatics, Josh works closely with the standards development community to lay groundwork for fric-tionless 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.

JACOB MILLER, MS

Data Science Architect, IBM

Jacob Miller is a data scientist/hackr/architect at IBM Watson Health where he leads the analytic delivery strategy for the payer/provider segment. His current mission is to enable data scientists to efficiently deliver their analytics to end users.

Jacob joined Watson Health via acquisition in 2015 from Explorys where he developed the risk model and patient matching frameworks.

Jacob is most comfortable with hands on keyboard solving challenging healthcare problems through the intersection of data, technology and analytics.

SEAN KENNEDY, MS, PMP, MPH

Senior Director for Industry Solutions & Architecture, Salesforce.com Healthcare and Life Sciences

Sean Kennedy, MS, PMP, MPH is the Senior Director for Industry Solutions & Architecture for Salesforce.com Healthcare and Life Sciences. In this role, Sean leads HLS strategy, solution architecture, integra-tion, compliance and security efforts, advises on product devel-opment and go to market strategies, and supports customers as they work to build scalable, frictionless and secure solutions that generate enormous value. Sean served as the first Chair of the HIMSS Exploring CRM Technologies in Healthcare Task Force, which recently completed their 2-year charter to define and edu-cate the HIMSS community on what CRM in Healthcare is.

Prior to Salesforce, Sean served as the Director Health Information Exchange for the Massachusetts eHealth Institute (MeHI) where he led the State's HIE & HIT adoption efforts. Before MeHI, he worked at Massachusetts General Hospital where he directed key technology and innovation leadership activities. And, prior to Mass General he served in the United States Army for 13-years where he was a Medical Service Corps officer specializing in Health Information Systems. Sean is a certified Project Management Professional and holds graduate degrees in Telecommunications and Public Health from the University of Maryland and the Johns Hopkins School of Public Health, respectively.

MICKY TRIPATHI, PHD
President & Chief Executive Officer, Massachusetts eHealth Collaborative (MAeHC)

Micky Tripathi is the President & Chief Executive Officer of the Massachusetts eHealth Collaborative (MAeHC), a non-profit health IT advisory and clinical data analytics company. Micky is also active in the industry at a local and national level, including serving on the Board of Directors of the New England Health Exchange Network (NEHEN), the Sequoia Project, the CommonWell Health Alliance, the CARIN Alliance, the FHIR Foundation, HL7 (starting in 2020) and as Co-Chair of the HL7 Advisory Council. He is also the Project Manager of the Argonaut Project, an industry collaboration to accelerate the adoption of FHIR, and an Affiliate at the Berkman-Klein Center for Internet and Society at Harvard University.

Prior to joining MAeHC, Micky was a Manager in the Boston office of the Boston Consulting Group, a leading strategy and management consulting firm. While at BCG, he served as the founding President and CEO of the Indiana Health Information Exchange, an Indianapolis-based non-profit company partnered with the Regenstrief Institute to create a state-wide health information infrastructure in the state of Indiana. As a manager in BCG's health care practice, Micky also served a variety of US and international clients in the non-profit sector as well as in the bioinformatics, biotechnology, and pharmaceutical industries.

Micky holds a PhD in political science from the Massachusetts Institute of Technology, a Master of Public Policy from Harvard University, and an AB in political science from Vassar College. Prior to receiving his PhD, he was a senior operations research analyst in the Office of the Secretary of Defense in Washington, DC, for which he received the Secretary of Defense Distinguished Civilian Service Award.

JIM MCDERMOTT
Development Lead, Payer and Population Health, Epic

Jim has a background in software development. He has worked at Epic since 2006 in Epic's revenue cycle, managed care, and population health products. He currently leads Epic's population health and payer product teams.

MATT MCKENNA
Director & IP Strategist, Cerner

Matt McKenna has been with Cerner for more than 23 years. He is currently Product Manager of Cerner's HealtheIntent Platform's Data Ingestion and Data Syndication services.

Matt received his bachelors degree in management information systerm from Iowa State University.

LARRY O'TOOLE
Associate Vice President of Strategy, MEDITECH

Larry O'Toole is an Associate Vice President of Strategy at MEDITECH. His team is responsible for business development, product management, and interoperability, as well as government affairs. The mission of his division is to provide innovative industry-leading solutions for MEDITECH customers. Larry is an advocate and active supporter for national health information interoperability and is currently serving on the Board of Directors for the CommonWell Health Alliance and will assume the position of Vice Chairman in January 2020. Larry has a strong technical and business background earning advanced degrees that support his role. Larry proudly served in the United States Army & Army National Guard, where he was awarded the Army's prestigious Meritorious Service Medal for outstanding military leadership. He is also active outside of Meditech, sitting on the board of a charity that fights Duschenne's Muscular Dystrophy and also lectures for MBA programs.

JEFFREY DANFORD
Senior Principal Software Engineer, Allscripts

Jeffrey Danford is a Senior Principal Software Engineer with Allscripts' New Product Innovation group and leads Allscripts' FHIR development project. Jeff has over twenty years' experience in Health IT in the areas of practice management, revenue cycle management, insurance processing, electronic data exchange, electronic health records, mobile health applications, standards development and interoperability. He is a voting member for Allscripts at Health Level Seven and represents Allscripts on the Steering Committee for the Argonaut Project and on the Operating Committee for HL7's Da Vinci Project. Jeff is also a member of the American Medical Informatics Association and a Founding Member of the HL7 FHIR Foundation. Jeff holds a Bachelor of Arts in English from the University of North Carolina and a Master of Science in Medical Informatics from Northwestern University.

ADI GUNDLAPALLI, MD, PHD
Chief Public Health Informatics Officer, Center for Surveillance, Epidemiology, and Laboratory Services, U.S. Centers for Disease Control and Prevention (CDC)

Dr. Gundlapalli is a physician-informatician and the Chief Public Health Informatics Officer at the Center for Surveillance, Epidemiology, and Laboratory Services in the Centers for Disease Control and Prevention (CDC). In this role, he is a liaison for informatics with external partners and advocates for enhanced informatics capability in public health. He completed his

training in medicine and informatics at the University of Madras, the University of Connecticut, and the University of Utah. Prior to joining the CDC, he was at the University of Utah School of Medicine and the VA Salt Lake City Health Care System.

GIDEON SCOTT GORDON, PHD

Senior Health Informatics Officer, Office of Strategic Programs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Scott Gordon is a Senior Health Informatics Officer for the Office of Strategic Programs in the Center for Drug Evaluation and Research at FDA since 2016. Dr. Gordon is responsible for a range of activities to standardize data for clinical research, submissions to FDA, and post-market surveillance. A significant aspect of Dr. Gordon's work includes a focus on "real-world data" derived from health information technology and other non-traditional sources for use as an adjunct to data from traditional clinical trials and current pharmacovigilance methods. In parallel, Dr. Gordon also works to standardize pharmaceutical quality and manufacturing data for submission to FDA.

Previously, Dr. Gordon worked at the Association for State and Territorial Health Officials (ASTHO) from 2011 with a focus on public health informatics, including interactions between federal, state, and local public health information systems and healthcare information technology such as the CDC's National Syndromic Surveillance System. He entered the public health domain in 2005 as a subcontractor for the Department of Homeland Security for public health emergency preparedness activities with the Massachusetts Department of Public Health. Prior to a post-doctoral position at the Whitehead Institute for Biomedical Sciences, Dr. Gordon received his core scientific training with B.A. in Biology from Case Western Reserve University and a Ph.D. in Molecular Microbiology from Tufts University Medical School.

TERESA ZAYAS CABÁN, PHD

Chief Scientist, Office of the National Coordinator for Health IT (ONC)

Dr. Teresa Zayas Cabán is ONC's Chief Scientist and is responsible for developing and evaluating ONC's overall scientific efforts and activities. Her division develops, establishes, or recommends scientific policy to the National Coordinator. She directs ONC's precision medicine initiative (PMI) activities and provides oversight of ONC's patient-centered outcomes research (PCOR) projects.

Dr. Zayas Cabán was previously the Chief of Health IT research and acting director of the division of health IT at the Agency for Healthcare Research and Quality (AHRQ). While at AHRQ, she set new directions for their funding opportunities and coordinated with federal partners, such as the National Science Foundation.

Before joining AHRQ, she served as a postdoctoral trainee in the computation and informatics in biology and medicine program at the University of Wisconsin-Madison. Dr. Zayas Cabán obtained her doctorate in industrial and systems engineering at the University of Wisconsin-Madison where she was a National Science Foundation graduate research fellow in industrial engineering.

ADAM C. BERGER, PHD

Director of the Division of Clinical and Healthcare Research Policy, Office of Science Policy, National Institutes of Health (NIH)

Adam C. Berger, PhD is the Director of the Division of Clinical and Healthcare Research Policy in the Office of Science Policy at the National Institutes of Health (NIH). In this role at NIH, Dr. Berger oversees a wide range of policy issues related to clinical trials, biospecimen research, privacy, bioethics and human subjects protections, and translation of biomedical discoveries. He also serves as a senior advisor to the Associate Director for Science Policy. Prior to joining NIH, Dr. Berger was part of the personalized medicine staff at the U.S. Food and Drug Administration (FDA). In his role at FDA, Dr. Berger addressed a wide range of policy and regulatory issues related to precision medicine, next generation sequencing, real world evidence, and digital health. Dr. Berger also previously served as a Senior Fellow to the Secretary of Health and Human Services, overseeing the development and implementation of the Precision Medicine Initiative (PMI), a precedent setting and transformational medical initiative to accelerate the development of disease treatments by taking into account patients' individual characteristics, across all operating and staff divisions of the Department of Health and Human Services. Dr. Berger also served as the main liaison between and representative of HHS to the White House and other United States Government Departments involved in the PMI. Prior to working in government, he was a Senior Program Officer and Director of the Roundtable on Translating Genomic-Based Research for Health in the Board on Health Sciences Policy at the Institute of Medicine (now the National Academy of Medicine). Dr. Berger received his doctorate from Emory University in Biochemistry, Cell and Developmental Biology, his B.S. in Molecular Genetics from The Ohio State University, and completed his postdoctoral training at the National Cancer Institute of the NIH.

PAULA BRAUN, MS

Entrepreneur-in-Residence, U.S. Centers for Disease Control and Prevention

Paula Braun is an Entrepreneur-in-Residence at the U.S. 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.

Paula began her career as a Presidential Management Fellow at CDC's National Center on Birth Defects and Developmental Disabilities in 2005. After that, she served as an analyst at the Government Accountability Office and later lived and worked at the US Embassies in Iraq and Afghanistan from 2009-2011. Immediately prior to her role as an EIR, she worked as a data scientist for a predictive analytics firm called Elder Research and taught a course titled Informatics Solutions for Public Health Decision Making at Emory University's Rollins School of Public Health.