Boston Children's Hospital

Multi-solving Population Data Use with SMART® Bulk FHIR Access

EXECUTIVE SUMMARIES

September 7, 2022

Sponsored by the Office of the National Coordinator for Health Information Technology and hosted by www.smarthealthit.org at Boston Children's Hospital

SMART®

TABLE OF CONTENTS

INTRODUCTION

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

CONTEXT

In introducing this meeting, Ken Mandl provided background by summarizing the SMART bulk FHIR journey. He pointed out relevant parts of the 21st Century Cures Act, laid out goals for the meeting, and shared his own bias and key questions to be considered.

OVERVIEW

Over the past decade, considerable progress has been made related to interoperability of healthcare data, with benefits for both individual patients and populations. But, opportunities remain to further improve interoperability to increase the value created from data in electronic health records.

As of December 2022, all certified HIT must support SMART on FHIR and SMART/HL7 bulk FHIR. This presents new opportunities to use data for multiple use cases, including population health use cases. But barriers remain to using data on populations, including CIOs who are overwhelmed with reporting requirements and highly technical challenges.

This meeting will focus on surfacing high-priority use cases across multiple stakeholders; understanding technical issues; understanding regulatory intent related to interoperability; and identifying practical, actionable next steps.

THE JOURNEY TOWARD INTEROPERABILITY

Ken Mandl highlighted a few key milestones on the journey towards interoperability in healthcare.

- **The WWW:** When Tim Berners-Lee invented the World Wide Web—one of the most stunning achievements in the history of information management and transfer—he standardized a few parsimonious rules for interoperability. This created a powerful engine for innovation and ecommerce. (Dr. Mandl asked meeting participants to consider, "How can a parsimonious approach apply to creating interoperability in healthcare?")
- **2009:** Dr. Mandl co-authored an article in the New England Journal of Medicine about getting more value out of the massive investment in EHRs by having an innovation layer on top of software that would be vendor independent. This layer would easily connect the web or mobile apps to the electronic health record. This would allow patients to access their medical data and would spur innovation. The article offered an analogy to the iPhone where substitutable third-party apps could connect to the iPhone without needing to do anything special.
- **2010:** ONC provided substantial funding to SMART focused on determining whether EHRs can behave like iPhones and Androids in that innovators can create and distribute substitutable apps across thousands of installs. Following this grant, an incredible ecosystem began emerging around the SMART on FHIR API idea.
- **2011:** SMART held a SMART Apps Contest, promoted by the White House. The winner developed a reusable, substitutable, working SMART app in one week that pulled in data about a patient's cardiac risk factors.
- **2014:** The Argonaut project was launched, which eventually led a consensus group of EHR vendors to implement the SMART on FHIR API, enabling interoperability. This interoperability was taken advantage of by Apple and others.
- **2016:** Based on Dr. Mandl's limited lobbying of Congress, one sentence was inserted into the 21st Century Cures Act, which was passed in December 2016. This sentence made APIs a requirement for certified HIT. Specifically, an API must give access to all elements of a patient's medical record without special effort.
- **2017:** ONC asked SMART to create a population-level analog to the SMART on FHIR API. After two meetings involving multiple stakeholders, it was determined to be doable and desirable to have standardized FHIR data in a streamable flat file from any EHR. The population-level version would make it simple to get population datasets (rather than data on one patient at a time) out of the EHR in a FHIR format. The project started in 2018 and halfway through 2018, with the first candidate API, CMS was using the bulk FHIR API to provision data to ACOs.
- **By 2018:** Apple began using the SMART on FHIR API to (eventually) connect to 800 health systems and 12,000 sites, caring for 200 million patients who can download medical records to their iPhone.

WHERE WE ARE TODAY

December 2022 is a key date because this is when all certified HIT must support SMART on FHIR and SMART/HL7 bulk FHIR. In anticipation of this date, important questions revolve around what data will be available; what are the barriers; and what are the opportunities.

WHICH DATA WILL BE AVAILABLE?

The US Core Data for Interoperability (USCDI) will be available.

WHAT ARE THE BARRIERS TO USE OF POPULATION HEALTH DATA?

Barriers include:

- CIOs are overwhelmed with reporting requirements. There are scores or hundreds of requestors, including public health, registries, payers, researchers, and more.
- Producing data requires specialized teams, expert in extraction, transform, and load (ETL).
- Currently, for interoperability, data must be mapped to common ontologies.
- The high technical requirements exclude most medical centers, causing inequitable representation of populations in things like federally funded research networks.

WHAT ARE THE OPPORTUNITIES?

- Pushbutton access to population data in a standard format, everywhere.
- Because the data may be used in payment agreements, health systems have a pecuniary interest in maintaining a high-quality bulk FHIR feed.
- Government agencies can align on use cases that rely on that feed.
- That feed becomes a common source of data for myriad uses.

THE MEETING GOALS ARE:

1. Surface high-priority use cases across government agencies, payers, providers.
2. Understand technical implementations and implementation plans for bulk FHIR in EHRs and other FHIR-based systems.
3. Examine technical suitability to meet use cases.
4. Define the contours of meaningful compliance with the spirit of the 21st Century Cures Rule.
5. Understand regulatory intent and other means to interoperability.

Dr. Mandl's Bias:

In proceeding to pursue these opportunities, Dr. Mandl took the moderator's prerogative to express his biases for consideration during the meeting. These biases were:

- Design government, private payer, reporting, and research programs around **available data**—for example, the USCDI exposed through the bulk FHIR interface.
- "Less is more."
- There is tremendous value in having metrics and measures that use available data rather than better metrics and measures that aren't practical because the data aren't available.
- When more data are needed, we can as a community advance USCDI or leverage USCDI+.

Fireside Chat

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program, Boston Children's Hospital; Donald A.B. Lindberg Professor of Pediatrics and Biomedical Informatics, Harvard Medical School (Moderator)
Amy Abernethy, MD, PhD, Health Data Expert and Former FDA Principal Deputy Commissioner; President of Verily's Clinical Research Platforms
Micky Tripathi, PhD, MPP, National Coordinator for Information Technology

CONTEXT

Ken Mandl led a fireside chat with the panelists, focused on challenges and opportunities related to leveraging data for population health.

OVERVIEW

As EHRs have become broadly used there has been a significant increase in demand for access and use of the data in EHRs for multiple purposes. But demand from multiple parties, each with varying needs, can be overwhelming. The approach being used within HHS is to start with USCDI, which provides a standard, consistent dataset, and then to add to the data accessed as necessary for specific use cases. This approach may be appropriate outside of HHS.

In addition, takeaways from the fireside chat include the iterative nature of regulation as a way to nudge industry forward and the vision not just of interoperability but of real-time interactivity.

USE OF FHIR REPRESENTS A SIGNIFICANT EVOLUTION IN MANAGING POPULATION DATA.

Amy Abernethy was an early employee of Flatiron Health, a pre-FHIR company that tried to clean up EHR data and make it useful for oncologists in their day-to-day practice, while also making data available for research. These efforts focused on a common data model and a common data quality standard. Challenges existed because much of the data was unstructured. Ultimately what Flatiron did was build software to allow people to hand-curate data faster and at scale. In doing so the company tried to leverage standards that already existed.

Now at Verily, Dr. Abernethy is taking this work to the next stage. This includes pulling together data that is routinely collected, for example in the EHR, in conjunction with data that is intentionally collected, such as through prospective collection of patient-reported outcomes. In starting to access more structured data across electronic health records in bulk, it will be necessary to continually evaluate data quality and ensure datasets are representative and to address potential biases.

HHS IS ADOPTING POLICIES TO CREATE BETTER ALIGNMENT ACROSS THE GOVERNMENT.

Micky Tripathi said, "The problem that we all wanted to have is now here, which is that everyone is trying to be able to access information from electronic health records systems." Since more data are now digital, multiple parties across the federal government want access to this data.

Within HHS, it was observed that many departments were embarking on programs that involved accessing data in EHR systems. Overall, the interest in this data was viewed positively; however, different groups had different programmatic requirements, different approaches, and used different standards for the data they wanted. As a result, HHS realized that it was necessary to achieve better alignment and synergies. This led HHS to put in place contract requirements, which include requiring starting with USCDI and with FHIR; this is the best way to get data in consistent, efficient ways. This also provides a greater opportunity for shared infrastructure across federal agencies.

ONC REGULATORY INNOVATION HAS THE POTENTIAL TO HELP FDA REGULATORY INNOVATION.

Dr. Abernethy, who was formerly the principal deputy commissioner at FDA, sees the role of the FDA as stating what data attributes are needed to inform high-risk regulatory decisions. (FDA is the "demand signal" for high-quality datasets.) However, one of the problems is that the FDA and ONC have not been as closely connected as they should be, given the great opportunity for FDA and ONC to advance the use of data from EHRs for regulatory decision making.

By developing consistency and standards, ONC and FDA can work together to enhance each agency's awareness of new opportunities for deploying EHR data. "FDA and ONC working together on projects starts to build comfort and actionability," said Dr. Abernethy. "The two agencies can work together to drive innovation in this space."

ONC ENVISIONS THAT FEDERAL AGENCIES START WITH USCDI AND ADD TO IT AS NECESSARY.

Dr. Tripathi thinks of ONC as a service agency supporting the business owners—which are groups and agencies within HHS. While each group has its own data needs, ONC is telling business owners to "start with USCDI and then work on developing the pipeline for the additional data elements that you are going to require in your programs." ONC will then work with its partners within HHS on their own programmatic requirements, on additional data elements to be added to USCDI, and on the agency's maturity path.

ONC SEES REGULATION AS A NECESSARY, ITERATIVE PATH IN NUDGING INDUSTRY FORWARD.

Because healthcare is so fragmented, it is very hard to discern a set of clear demand signals where there is industry consensus. To keep moving forward, Dr. Tripathi sees ONC taking an iterative approach where regulation has to play a role to nudge industry to continue moving forward.

Of particular interest to Dr. Tripathi is not just an open architecture system with interoperability according to open industry standards, but a system that has more real-time interactivity and a more real-time, dynamic exchange of information—like Expedia. He sees interactivity—which leverages APIs, FHIR, and interactive business models—as imperative for the industry.

Without going into specifics, Dr. Tripathi said he can envision some future rulemaking that involves FHIR-based capabilities; today these capabilities have just scratched the surface.

Dr. Abernethy commented that as the government nudges industry forward to leverage FHIR more, the increased interoperability will expose more next-order tasks that need to be done. She cautioned that there can be "magical thinking" where people believe that as soon as data starts flowing more freely, nothing more remains to be done. She said this isn't true. More data flowing freely doesn't mean we are done; it presents an opportunity for further innovation and progress for using bulk data.

Dr. Tripathi observed, "Data doesn't get better until it's used." It is only when data are shared and people try to work with data that they realize it won't work for their purposes without improvement.

21st Century Cures Act: Regulation and Dates

Steve Posnack, MS, MHS, Deputy National Coordinator for Health Information Technology

CONTEXT

Steve Posnack provided a quick recap of the regulatory components of the 21st Century Cures Act and the key dates.

OVERVIEW

Regulations and rulemaking for the 21st Century Cures Act contains requirements for both health IT developers and providers related to APIs. It is important to be familiar with these requirements and the timing, as deadlines are fast approaching.

MANY PROVIDERS ARE ALREADY USING FHIR-BASED APIS.

In ONC's 2015 certification criteria for HIT, API requirements were included. However, ONC did not require a specific standard or implementation guide; the decision was left up to the market.

As providers have participated in various CMS programs and reported their usage of certified EHR technology, many are already using FHIR-based APIs.

The map below shows ambulatory providers on the left and inpatient/hospitals on the right.

ONC HAS UPDATED THE REGULATORY REQUIREMENTS FOR APIS.

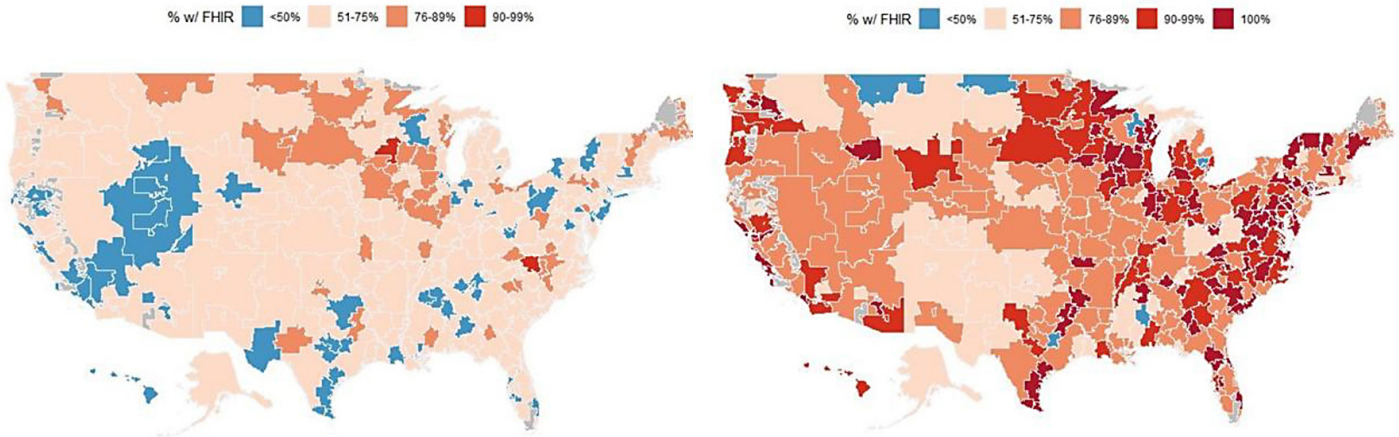
From ONC's perspective, there are two key elements of the API regulatory requirements:

1. **API conditions and maintenance of certification.** This is a wraparound set of requirements that apply to health IT developers related to their behaviors and business practices for APIs.

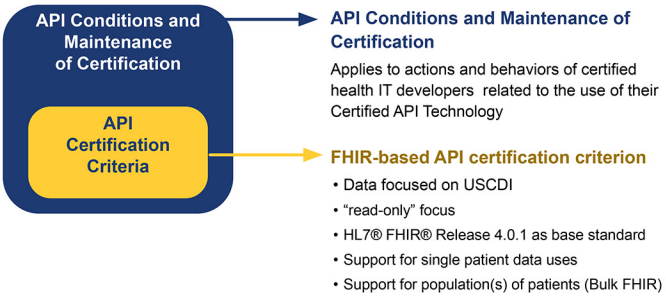
   When the 2015 HIT certification process was rolled out, the requirements were for API technology to be deployed, in general. That was translated and implemented to support patient access, while provider demand signals were not as well supported in the regulatory policies.

   In going through the 21st Century Cures Act rulemaking, ONC made clear as part of both the certification criteria requirements and the conditions of certification that there were multiple use cases of this new functionality and technology that ONC expected to be put into place. These use cases include patient access and supporting providers' participation in CMS programs. In general, the rulemaking supports general, creative, innovative types of data and FHIR APIs and FHIR services for all sorts of clinical care uses, as well as population analytic uses.

Percentage of Providers with EHRs—Ambulatory Providers (on left) and inpatient/hospitals (on right)



2. **FHIR-based API certification criteria.** These are new functional requirements that health IT developers need to meet. This is an updated version of ONC's API requirements. These requirements include:
   - Data focused on USCDI (version 1)
   - "Read only" focus
   - HL7 FHIR release 4.0.1 as the base standard
   - Support for single patient data uses
   - Support for population(s) of patients (bulk FHIR)



The two pieces shown above—API conditions and maintenance of certification and FHIR-based API certification criteria—helped reinforce the overall support for health IT developers, customers, and industry ecosystem participation. There are also requirements about transparency of documentation, positive competitive practices, and more.

For providers using certified API technology, there is broad authority to implement this technology as the provider sees fit.

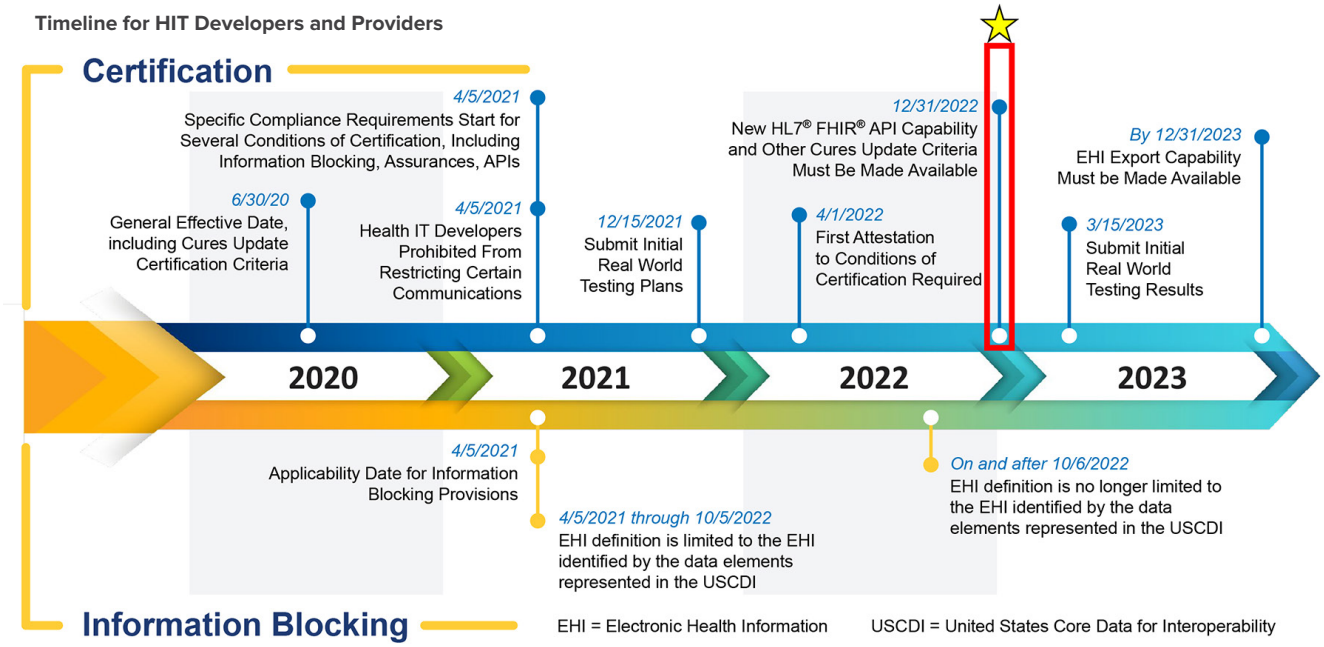
IT IS IMPORTANT TO BE AWARE OF KEY API TIMELINES.

As shown below, health IT developers must update APIs for both N of 1 and for bulk FHIR no later than December 31, 2022. Providers that participate in CMS programs must go live in deploying FHIR in 2023 .

Who	What	When

Health IT Developers	FHIR R4 APIs w/ support of N=1 and N>1
	• Using
	  • USCDI v1
	  • US Core IG
	  • SMART App Launch
	  • etc.
		Update and provide no later than 12/31/22

Providers	Deployment of FHIR APIs as part of CEHRT usage in CMS programs	2023



Bulk FHIR Status Update

Dan Gottlieb, MPA, Principal, Central Square Solutions, LLC

CONTEXT

Dan Gottlieb summarized capabilities in the current bulk FHIR API and where the adoption cycle stands.

OVERVIEW

While the standard FHIR API is effective in transferring data in many situations, when large volumes of data need to be transferred, there is a need for the FHIR bulk Data API. This API enhances FHIR to support population-level data access—and EHR support is required by the 21st Century Cures Act.

In planning to implement this bulk data API, it is important to understand the limits of its scope, including what is not part of the bulk API spec (such as legal frameworks for data sharing). It is also important to understand key aspects of the technical design, including the versions, request types, filters, and more. Extensive open source tools and resources are available to assist developers in planning and implementing the bulk FHIR API.

FHIR API DEFINED

When using the term "FHIR API," the concept is to retrieve data from a FHIR system, which often means an EHR or another clinical system.

The data volume being retrieved can be thought about in three levels:

- **Patient data.** This is the ability to identify and use data for an individual patient for a purpose such as a risk calculator that pulls data from the EHR. The regular FHIR REST API works well here.
- **Panel data.** This is the ability to pull data for a specific group of patients, such as all of the patients of one physician. Data could be used, for example, to rank the highest-risk patients. For panel data, the standard **FHIR REST API** will typically work fine, but it may be necessary to think about using the options in the API that limit the amount of data that is returned.
- **Population data.** This is data for a large population, such as all patients across an entire healthcare institution, which might be hundreds of thousands or millions of patients. At this point, the regular FHIR REST API starts to break down, because it wasn't designed for this use case. This is where the **FHIR bulk data API** comes in.

To support population-level data access, the FHIR bulk data API combines a number of existing FHIR capabilities:

- **FHIR Resources** as a standard data model to simplify data parsing and mapping
- **FHIR Operation API** to initiate the data extracts
- **SMART Backend Services Authorization** as a standard security model

This separates the setup step, where there might be human involvement, from the data retrieval step. Once the connection is made between the system retrieving the data and the system providing the data, that connection can continue automatically without requiring any manual work.

FOCUSED SCOPE FOR FHIR BULK DATA API + COMPLEMENTARY TECHNOLOGIES

While it is important to understand what the FHIR bulk data API does, it is also important to be aware of things that aren't currently in the bulk data spec that potential users may want to consider when thinking about data transfer using FHIR. These areas include:

- **The legal framework.** The FHIR bulk data API is a technical approach to sharing data but there also needs to be a legal framework for sharing data between partners that needs to be set up out of band. Other agreements might also be required such as service level agreements.
- **Real-time data transmission.** The FHIR bulk data API is a batch API and therefore doesn't directly address real-time data transmission. But, data loaded through bulk APIs can be supplemented with real-time FHIR REST API calls or FHIR Subscriptions. It may make sense to combine multiple approaches.
- **Patient matching.** The FHIR bulk data API doesn't address patient matching, which is a difficult problem given the lack of universal identifiers in healthcare. But, it is possible to include identifiers like subscriber number in bulk export FHIR resources and leverage common matching techniques.
- **Data transformation.** This isn't directly addressed in the FHIR bulk data API. A way to think about the bulk API is as one foundational step in a data pipeline.

> "I think about bulk data as one piece of the puzzle, but not the entire puzzle for data sharing."
>
> —DAN GOTTLIEB

TECHNICAL DESIGN

A summary of some of the key elements of the technical design include the versions, request types, and parameters.

VERSIONS

Currently, there are two versions of the FHIR bulk data API.

- **STU1 (v1).** This is the initial version, published in August 2019. This is the version required in the 21st Century Cures Act regulation.
- **STU2 (v2).** This version, published in November 2021, incorporates experience from early implementations in areas such as making queries more efficient. It is largely backward compatible with version 1. Vendors can implement v2 to satisfy the requirements of the regulation.

Some implementations are taking pieces of version 2 and implementing those on top of version 1 features to add some of these capabilities where it makes sense.

REQUEST TYPES

There are three request types that a system can make for bulk data. These are:

1. To request data on all patients in a system.
2. To request data on a group of patients, as is required in the regulation. This leverages the ability of FHIR to define a group of patients.
3. To export all data in a system, on a server. This would include all non-patient data.

Request Types

- FHIR Operation for all data on all patients (all data in the patient "compartment")
  `[FHIR Server Base]/Patient/$export`
- FHIR Operation for all data on a group of patients (eg. research cohort, plan members)
  `[FHIR Server Base]/Group/[group id]/$export`
- FHIR Operation for all data on the server
  `[FHIR Server Base]/$export`

PARAMETERS (FILTERS)

There are a number of filters that can be used when requesting bulk data. These are ways of limiting the data being requested. A few examples shown below include filtering by modified date, by certain FHIR data models (resources), or by certain fields (elements) within the data model.

_since	Filter by FHIR resource modified date *(required in v2)*
_type	Filter by comma delimited list of FHIR resource types
_typeFilter	Filter with FHIR REST API parameters
_elements	Limit FHIR resource elements returned e.g., `Patient.id, Patient.identifier` New in v2

RESOURCES AND ADOPTION

There are a number of open source developer tools that the SMART team makes available for working with bulk data and there is a growing number of implementations that developers can study and learn from (see https://bit.ly/fhir-bulk-api).

Panel 1: Quality and Value Use Cases

Aneesh Chopra, Care Journey (Moderator)
Mary Greene, MD, MPH, MBA, Director, Office of Burden Reduction & Health Informatics, Centers for Medicare & Medicaid Services (CMS)
Eric Schneider, MD, M.Sc., Executive Vice President, The National Committee for Quality Assurance (NCQA)
Anna Taylor, MS CIPCT, Director of Operations, MultiCare Connected Care

CONTEXT

Aneesh Chopra led a conversation with a leader from CMS, a provider with value-based contracts (MultiCare), and a leading organization focused on quality measurement (NCQA). They discussed implementing bulk FHIR APIs and moving to digital quality measurement systems.

OVERVIEW

The panelists all see the need for and value of digital quality measurement systems. The current state of quality measurement and reporting is manual, labor intensive, inefficient, and far from optimal. Transitioning to digital systems can improve quality measurement, close quality gaps, improve efficiency, and reduce costs. But, real-world experience shows that even at organizations that believe in this vision and are committed to it, this transition is extremely complex and will take time. However, initiatives are underway at CMS, at providers like MultiCare, and at The National Committee for Quality Assurance (NCQA) to accelerate this process.

CMS IS FOCUSED ON INTEROPERABILITY TO ENSURE THAT PATIENTS' DATA FLOW WITH THEM WITHOUT SPECIAL EFFORT FROM PROVIDERS OR PAYERS.

Dr. Greene shared that the Office of Burden Reduction and Health Informatics at CMS has three main workstreams:

1. Getting a pipeline of information from stakeholders about CMS's policies and operations and using this information to feed opportunities or reduce burden and shape CMS's priorities.
2. An interoperability workstream
3. An administrative simplification workstream

As part of the interoperability work, CMS is focused on ensuring that a patient's data follow them from provider to provider and from payer to payer and that patients can use whatever apps they want to see their data. In addition, CMS wants to ensure that providers don't require any special effort to see all of the patient data they need and that information is displayed to providers in a way that is easy to get insights from.

> "The idea for interoperability is not just sharing data but making data available in such a way that it's usable for decision making."
> —MARY GREENE

CMS is also looking at access to data for population health. This includes wanting real-time data to identify individuals who may be at risk and to assess performance for use in value-based care.

Dr. Greene noted that increasingly, providers and payers are making decisions jointly, such as prior authorization. In doing so, both parties need to be able to see the same information so they can collaborate on decisions.

Dr. Greene also committed to work on a journey map (or something similar) showing the flow, headaches, and overall journey for doing quality management using the 21st Century Cures Act regulated APIs.

MULTICARE'S REAL-WORLD EXPERIENCE SHOWS HOW COMPLICATED IMPLEMENTING BULK FHIR AND QUALITY MANAGEMENT CAN BE.

Ms. Taylor recounted that MultiCare—which has about 350,000 lives under risk—is in the process of standing up an agnostic product for bulk FHIR services with the EHR. She and her organization believe in this, have prioritized it, and are investing heavily, but dealing with the IT security related to exchanging data has proven far more complicated than was imagined. At the same time, MultiCare is in the process of improving the efficiency of quality reporting—with the need to report for electronic clinical quality measures (ECQM) by 2025. Today, reporting is highly manual and was compared to using duct tape and glue.

MultiCare knows that this journey can yield positive returns. For example, just automating prior authorization with one payer is projected to save one FTE, which is significant labor savings. However, the journey is complex because the solutions related to authorization don't exist yet and require development of custom solutions.

Amid the multiple projects that are underway, Ms. Taylor acknowledged, "Electronic quality measures are something that we know needs to happen." Doing so will reduce the labor required to collect data and develop reports, while helping the organization close quality gaps.

> "We've found that with our FHIR implementation, we increased our capability to report more accurately, meaning we are closing more gaps because we could mine the data differently and more effectively and it really improved. I think we ended up closing 60% more gaps because of that capability."
>
> —ANNA TAYLOR

In light of the positive results around gap closure, Mr. Chopra asked why the industry pushed back so strongly on CMS's mandate to require ECQM in order for every ACO to meet the requirements. Ms. Taylor said that scaling solutions is hard, complex, labor intensive, and expensive. It requires data mapping for all EHRs in use, which at MultiCare is 11, which is extremely difficult. "That kind of a systematic change is going to take some time."

Mr. Chopra thanked Ms. Taylor for sharing an example of the types of real-world experiences that providers are wrestling with each day.

NCQA IS FOCUSED ON ACCELERATING TRANSITION TO DIGITAL QUALITY MEASUREMENT.

NCQA is a nonprofit with 30 years of experience pioneering quality accountability programs. NCQA produces HEDIS, which is one of the most widely used measurement sets. Its primary purpose is to compare health plans but the measures get adopted and used for quality improvement. That's because there is a high level of stakeholder consensus and trust in the quality measures. These measures are used in payment programs and value-based contracting.

NCQA is focused on accelerating the transition to digital quality measures. This is a multi-year project but is driven by the challenges described at MultiCare. That is, current quality measurement processes are manual, slow, and costly. Transition to digital quality measures has the potential to improve efficiency and reporting, close care gaps, improve quality, and lower the costs associated with measurement. To date one of the key challenges has been having access to the data to do accurate, effective quality measurement and reporting. With FHIR and SMART on FHIR, there is the potential to move away from an approach of retrofitting systems to a more modern, more scalable quality measurement infrastructure.

NCQA envisions a dramatic refresh of the quality measurement enterprise which includes:

1. Incorporating measures from multiple settings, as care moves outside of hospitals.
2. Aligning around a core set (and possibly a narrower set) of very important measures.
3. Leveraging more clinically relevant data to serve the value-based contracting agenda.
4. Improving the quality measurement systems so that the effort that is required yields meaningful results.

In response to a practical question from Mr. Chopra about working with providers who want to adopt bulk FHIR earlier than the 2025 mandate, Mr. Schneider said that NCQA is moving towards digital quality measures (DQMs) that are agnostic to data source and has already started a pilot with several organizations. This pilot tests software solutions that cover the quality reporting use case and allow organizations to report their HEDIS measures while transitioning to a digital format, as well as covering other use cases.

Panel 2: Research and Public Health Use Cases

Paula Braun, CDC (Moderator)
Ken Gersing, NIH/NCATS, Director of Informatics for Division of Clinical Innovation, National Institutes of Health
Jason O'Meara, MHA, VP of Digital Strategic Imperatives, Pfizer
Jen Layden, MD, PhD, Associate Deputy Director for Public Health Science and Surveillance, CDC
Lew Berman, Branch Chief, Digital Health Technologies and Data Branch, NIH; Office of the Director, All of Us Research Program
Bryant Karras, MD, CMIO, Executive Office of Innovation & Technology, Center for Informatics, Washington State Department of Health
Danica Marinac-Dabic, MD, PhD, MMSc, FISPE, Associate Director, Office of Clinical Evidence and Analysis, FDA/CDRH

CONTEXT

Paula Braun moderated this session where individuals from across the research and public health ecosystem shared challenges, opportunities, and use cases (or "demand signals") in using bulk FHIR. Paula Braun emphasized that the end state is not interoperability; it is interactivity. She noted that the panelists are on the front lines figuring out what is feasible.

OVERVIEW

The comments and use cases shared by multiple research and public health organizations demonstrate strong demand signals for the ability to access population health data in a granular, efficient way.

PANELIST EXPERIENCES

CDC

Jen Layden commented that since the public health community is focused on better access to data and exchanging data, the bulk FHIR API has tremendous relevance for public health. It is important for those in public health to think innovatively and critically about leveraging technology and solutions. She recognizes that the data used in public health goes well beyond what is captured in the EHR at the point of care, but the EHR is an important source of data in public health.

For the public health community, there are multiple challenges in accessing, sharing, and exchanging data for public health purposes. And, public health is looking at solutions with a mindset of reducing burden and not imposing significant effort, as called for in the 21st Century Cures Act.

This has led public health leaders, including the CDC, to ask:

- What can we do in public health to accelerate public health readiness to act on data from EHRs and use this data more effectively?
- What can we do to ensure that our efforts to influence healthcare partners are strategic and aligned?
- How can we leverage policies and approaches to interoperability that have momentum and buy-in beyond public health?

Over the past two years the CDC has been working with partners to figure out how bulk FHIR can help provide timely access to necessary granular data to protect the health of populations and communities.

One lesson that has emerged from CDC listening sessions is that **local action is critical**; public health at the local level is where interventions happen and where early signals are identified.

> "As we develop and look for solutions, we're particularly interested in lightweight, scalable solutions that help our partners at the front line to get and share data in ways that are efficient."
>
> —JEN LAYDEN

PFIZER

Pfizer's purpose is breakthroughs that change patients' lives. This is anchored in two concepts: being science-driven and patient-centric. Pfizer pioneers breakthrough innovations to prevent, manage, treat, or cure diseases using cutting-edge science and technology. Pfizer reached approximately 1.4B people with their medicines and vaccines in the past year—more than 1 out of every 6 people on Earth. Yet the backdrop is that it costs an average of about $2 billion to develop a drug and bring it to market, and only one in 10 drugs in development are ever approved.

The only way for Pfizer to achieve reach, scale, and impact is by leveraging FHIR, real-world data (RWD), and AI across the entire value chain—in discovery, development, manufacturing, distribution, and engaging patients and providers. This entails using FHIR and RWD to inform preclinical discovery and development around new precision medicines through a deeper understanding of patient disease stratification and disease dysregulation. FHIR and RWD also drives clinical trial innovation to accelerate availability of efficacious and safe medicines and vaccines to patients. For

example, we accelerated our COVID vaccine trial and improved its diversity by leveraging RWD to understand the attack rates of COVID in different local geographies, so we could activate sites in areas of high risk. And, FHIR is used to generate insights and evidence in support of use cases like pharmacovigilance or health economics research. Pfizer looks forward to FHIR powering more use cases as we work to continue to improve the standards, improve data quality, and drive adoption in the United States and globally.

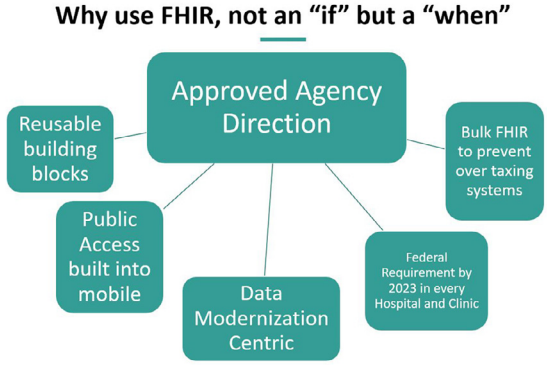
> "My core message and parting thoughts are that HL7 FHIR and bulk FHIR are very real. They are driving significant impact today across the industry. We've seen the power and potential of FHIR over the last 10 years, and we are absolutely committed to advancing and leveraging these standards to meet the needs of the diverse stakeholder groups across the global life sciences and healthcare the industry."
>
> —JASON O'MEARA

We are on a journey as a global healthcare & life sciences industry to improve health data access and quality. Pfizer recognizes that FHIR is emerging as the de facto standard for healthcare data interoperability globally across many use cases. In support of this standard, Pfizer participates directly in several HL7 FHIR accelerators. Pfizer also is a convening member of the Vulcan FHIR accelerator, which is dedicated to serving the needs of clinical and translational research communities through implementation of HL7 FHIR for standardized data exchange, including FHIR bulk use cases.

WASHINGTON STATE DEPARTMENT OF HEALTH

Washington's State Department of Health built its first SMART on FHIR app during the opioid crisis. Use during COVID involved sending information about COVID cases. One of the most exciting uses has been the ability to deliver vaccination information on a bidirectional basis with providers and patients.

This agency now looks at FHIR as a common binder for multiple programs. It is a common infrastructure capacity with "reusable building blocks." Investments for one program, like COVID or the vaccine program, can be reused, saving a tremendous amount of resources.



An example of the benefits of a FHIR API and bulk FHIR can be seen in that in the early days after the first COVID vaccines were released by the Agency's large program partners, the immunization registry was brought down. This was because the major partners were querying the system every day for every patient in their panel to see if they had gotten a vaccine at a drive-thru vaccination clinic; this crashed the agency's systems. The ability to stand up a replica instance of the immunization registry with a FHIR API and a bulk FHIR capability allowed those providers to get that critical information, without crashing the system.

> "I think this is the future of public health and what we'll be capable of doing."
>
> —BRYANT THOMAS KARRAS

FDA

Increasingly, the FDA uses data captured from real-world data sources. This requires extensive data-collection validation and standardization to assure relevancy and reliability for regulatory decision making. FDA is partnering with sister organizations within HHS to improve the capacity to study medical devices in the global setting. Partnerships have involved building the National Evaluation System for Health Technology, which builds on traditional legacy registries. But, to be used for regulatory decision making, there is a need for registries to evolve.

Both the standard FHIR applications and bulk FHIR can be immensely helpful in improving the data sharing that takes place related to regulatory decision making for medical devices. One example of data sharing is the creation of strategically coordinated registry networks in 13 clinical areas. These registries are not only collecting follow-up data post-procedure, but they are also systematically linked to administrative claims data and patient-generated health data, as well as other data sources where available.

> "The question remains, how much can we benefit at every single step from capturing the unique device identification by investing further into development of bulk FHIR?"
>
> —DANICA MARINAC-DABIC

ALL OF US

All of Us is a longitudinal research program started in 2018 that is on its way to enrolling one million participants, who will be followed for at least 10 years. One of the primary goals is to engage and enroll participants who are traditionally underrepresented in biomedical research. Thus far, All of Us is succeeding in achieving this goal, as 80% of enrollees are from underrepresented groups.

Many patients enroll in All of Us through participating providers, with more than 50 provider organizations participating. For these consented patients, the provider shares EHR data with All of Us.

A second pathway is volunteers who learn about All of Us—possibly through community outreach or media buys—and register through the program through a website. For these patients, All of Us gets data through participant-mediated means. None of this data is coming through bulk FHIR. Thinking longer term, there is an opportunity to use bulk FHIR in transferring data.

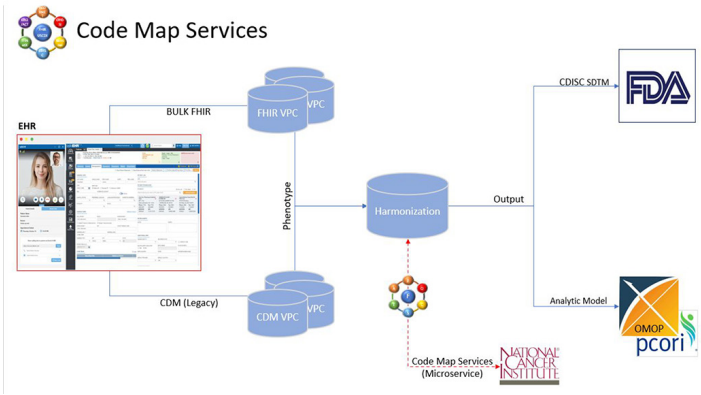
All of Us also plans to focus on ancillary studies, possibly among special populations. Use of bulk FHIR could be a great mechanism to pull the appropriate EHR data.

NIH

A group within the NIH focused on translational research that funds programs at 60 large academic medical centers set up a project to collect COVID data. The NIH told these AMCs to "send us your data any way you can, with whatever data model you have and we will harmonize it." As of September 2022, the NIH is receiving and harmonizing over 18 billon rows of data every week, now from 75 institutions. This data, brought together with a common data model, is being used by over 3,000 investigators.

> "I would say that the possibility of having a national repository of line-level data that is secure is possible."
>
> —KEN GERSING

Prior to COVID, the NIH had put together common data model harmonization, where all common data models were mapped to a canonical hub. NIH now views it as possible to create a service out of these mappings, and sees two use cases, as shown below. The first one uses bulk FHIR to bring in EHR data directly; the NIH can do that now. The second use case is getting data to the user—such as the FDA—in the format that they expect. The idea is not to make the people who collect the data adapt but to transform this data and keep the mappings up to date in a single source of truth.



PANELIST DISCUSSION

After each panelist shared relevant use cases for their organization, Paula Braun led a discussion on a variety of topics.

DATA USABILITY

A theme from earlier sessions was that the quality of data improves when the data is used. Ms. Braun asked the panelists to comment on this idea.

- **EHR data is not sufficient.** EHR data is good information about a human when they are sick, but EHR data alone is not sufficient and does not provide a complete picture of a human. This data must be supplemented by additional data. It is important to identify what other data sources are necessary to access and where that data is.
- **Adoption by biopharmaceutical industry.** For years, the biopharmaceutical industry had its own set of standards it used to interoperate and transmit data between industry participants and research institutions. A few years ago, the industry realized that the availability of FHIR APIs was more compelling than maintaining its own data standards. Now, through initiatives such as the Vulcan HL7 FHIR Accelerator, the industry is moving all standards toward FHIR.

PARALLEL ACTIONS

Panelists were asked if they could wave a magic wand to act in parallel and move more quickly, what would they do?

- **Common infrastructure.** Multiple entities within the federal government are all building the same infrastructure. Building a common infrastructure would be beneficial.
- **Open industry standards.** Approaches to interoperability need to be based on open industry standards and it is important to have real-world development and testing. Not only does this have value for the federal government, but there is also value in standards for industry to decrease variability when conducting studies across multiple sites.

A summary of some of the main ideas included a deliberate focus on open standards, collaboration, continuous improvement, and compatibility that is baked in from the beginning.

Panel 3: Health Systems Experience and Plans for Bulk FHIR

Dan Gottlieb, MPA, Principal, Central Square Solutions, LLC (Moderator)
Anil J. Saldanha, MS, Chief Cloud Officer, Rush University System for Health
William Gordon, MD, Director & Head of Product, Digital Care Transformation, Mass General Brigham; Assistant Professor, Harvard Medical School
Michael Berger, MSBA, Chief Data & Analytics Officer, MSHP; System VP, Enterprise Data, Mount Sinai Health System
Adam Wilcox, PhD, FACMI, Director, Center for Applied Informatics (CACI), Professor of Medicine, Division of General Medical Sciences, Washington University School of Medicine
Ashish Atreja, MD, MPH, FACP, AGAF, Chief Information and Digital Health Officer, UC Davis Health
Varun Anand, Co-Founder & COO, MphRx

CONTEXT

Dan Gottlieb moderated this panel, where leaders from five major health systems briefly summarized their experiences working with bulk FHIR and their plans for the future.

OVERVIEW

All of these health systems have Epic EHRs and are beginning to get experience with bulk FHIR. They see efficiency advantages in being able to export and see multiple use cases in being able to exchange bulk data both internally and externally, with payers, researchers, regulators, quality organizations, and other partners. All of these health systems are excited about future possibilities enabled by bulk FHIR.

PANELIST USE CASES

RUSH

Rush has had experience with Epic's bulk FHIR implementation over the past 8-9 months. The primary use case has been exporting data from cohorts of patients for analysis with cloud AI. This is a great benefit in being able to export some portions of the EHR data for analysis by the organization's data scientists.

> "This allows the health system to embark on ambitious projects. We have been using bulk FHIR in Epic for the last few months. It has opened doors to lofty, ambitious projects."
> —ANIL J. SALDANHA

Challenges with Epic's bulk FHIR include ingestion problems due to lack of tools from cloud providers for importing bulk FHIR files and data validation problems, which are a challenge but are relatively minor. Another challenge is that there can be a slight delay in the data, which can affect situations where real-time data is desired. Something to note is that the bulk FHIR feature has not affected performance of the clinical EHR systems.

MASS GENERAL BRIGHAM

Like Rush, Mass General Brigham also uses Epic and also recently became live with bulk FHIR. They are thinking about how they will use it related to chronic disease management. What makes bulk FHIR particularly appealing is being able to export data for multiple patients or for population-level bulk use cases. For example, a bulk FHIR use case could be pulling data for 1,000 patients with heart failure who participate in a patient registry. An advantage of bulk FHIR is the data would be aligned with data in existing applications.

> "I think the ability to closely align with the application or single-use APIs is particularly appealing."
> —WILLIAM GORDON

Two observations from Mass General Brigham's early experience with bulk FHIR are:

1. As implemented today, a lot of FHIR APIs require some interaction with the EHR vendor related to an application ID. This creates a barrier. It raises the question about what kind of relationship a potential user of bulk FHIR needs with their EHR vendor in order to use FHIR APIs. This is not well understood today.
2. Many health systems already have data lakes as well as deeply entrenched data analytics tools. FHIR will not replace these tools or data lakes; it will augment the ability to get the data into the data lakes in a standardized way.

MOUNT SINAI & MPHRX

Mount Sinai is both a large Epic customer and a large Microsoft Azure customer that has made a major commitment to move to the cloud. The organization has an ACO with about 500,000 lives. Mount Sinai wanted to decouple and disintermediate itself from Epic. At the same time, Mount Sinai—which had 35 different methods for sharing data internally and externally with payers, regulatory agencies, and others—wanted a more efficient way for exchanging data. They saw bulk FHIR as a major driver.

To enable the organization's bulk FHIR capabilities and to help manage their data, Mount Sinai partnered with MphRx. Working together, they have built a health data platform that sits on top of Epic. This platform is able to bring in data from the EHR as well as other sources, normalize it, and store it as FHIR resources in a common data model. This provides the ability to share data internally and externally using the same standard.

One area of focus for MphRx is creating a data filtering mechanism where Mount Sinai can create access rules that govern the access to data that external third parties have.

Now, Mount Sinai is viewing this health data platform as a service approach; a SaaS service where this entity manages everything: ingestion of data, normalization, and the availability and performance of bulk FHIR and FHIR APIs.

In envisioning potential bulk FHIR use cases for the future, these use cases include exchanging data with payers and other value-based care partners; bulk data export with clinical research partners; data export to regulatory agencies; and data replication to data warehouse/lake house infrastructure.

WASHINGTON UNIVERSITY

Adam Wilcox is currently at the Washington University School of Medicine. He said that WashU is just beginning to use bulk FHIR and sees it as a more sustainable approach to advance decision support than has been used in the past.

However, prior to being at Washington University in St. Louis, Adam was at the University of Washington, in Seattle. Early in the pandemic—in March 2020—the State of Washington was one of the first hot spots for COVID. The University of Washington was gathering significant amounts of data, and wanted to be able to share this data with others. An official at the CDC asked officials in Washington to fill out the table below—and to provide updates weekly.

Filling out this table required over 100 queries, which was enormously challenging, as was repeating the process to complete the table weekly. And, Washington was just one site. Doing all of the required calculations and scaling this up was all the more challenging. Using bulk FHIR would have been a better solution.

Table 1. Clinical COVID-19 testing practices and test positivity among patients with acute respiratory illnesses, by MMWR week, healthcare setting, and age group

MMWR week*	Healthcare setting		Age <5 yrs	Age 5-17 yrs	Age 18-49 yrs	Age 50-64 yrs	Age 65-74 yrs	Age 75-84 yrs	Age 85+ yrs
	Ambulatory care	Total visits							
		No. tested							
		No. positive							
	Urgent Care	Total visits							
		No. tested							
		No. positive							
	Emergency Dept	Total visits							
		No. tested							
		No. positive							
	Hospital non-ICU	Total visits							
		No. tested							
		No. positive							
	ICU	Total visits							
		No. tested							
		No. positive							

UC DAVIS

UC Davis is part of the University of California system, which includes five UC health systems and 20 professional schools. The scale provides the opportunity to create an enormous sandbox to test the latest technologies and to embrace open innovation.

In particular, UC Davis has been on Epic since 2003 and is actively engaged in federal and state interoperability efforts, including efforts involving bulk FHIR. These efforts are all focused on strengthening the ecosystem to allow for exchanging data with peers, other health systems, or industry partners.

> "What we believe between the digital and data strategy, the most important part of the equation is an open API strategy so the data can flow seamlessly."
>
> —ASHISH ATREJA

From Ashish Atreja's perspective, the number one reason for the adoption of bulk FHIR is the shift in the digital world from one-to-one to one-to-many. One-to-many capability enables looking at cohort data and population-level data in an efficient way.

UC Davis has tested bulk FHIR in pilots, will expand it to production for a limited number of use cases, and will then expand as a standard of care. UC plans to expand the use of bulk FHIR to quality measure calculation, decentralized, population-based quality reporting, and payer cohorts.

PANELIST DISCUSSION

- **Performance data.** Exporting data for around 1,000 patients might involve approximately 650,000 FHIR resources, which might take 6-8 hours to export.
- **Top priorities.** Panelists were asked their top priorities for bulk export. Among their responses were more NLP built into FHIR calls and more people using it, as more users will produce more value.

Panel 4: Vendors' Lightning Presentations

Jamie Jones, Project Coordinator, SMART Health IT (Moderator)
Chris Kundra, Director of Interoperability Development, MEDITECH
Jason Vogt, Manager and Technical Project Manager, MEDITECH
Sumit Rana, Senior Vice President, Epic
Andrew Fagan, Open Platforms Lead Product Manager, Oracle Cerner
Dharmesh Patel, Solutions Consultant, Google Cloud Healthcare and Life Sciences
Joe Ganley, JD, Vice President Government and Regulatory Affairs, Athenahealth
Danielle Friend, Product Lead, Epic

CONTEXT

Jamie Jones led this panel where representatives from several vendors briefly shared how they are enabling bulk data imports and exports.

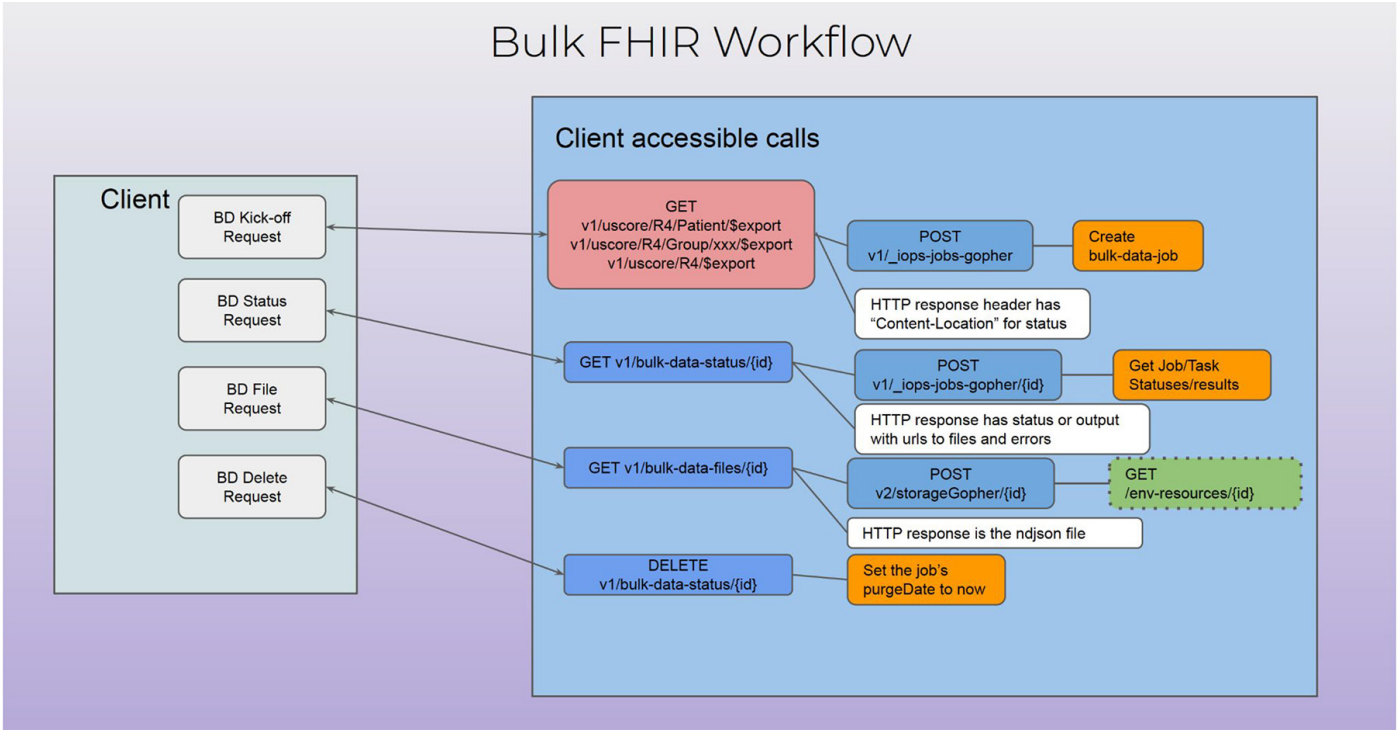
OVERVIEW

Driven by regulation and by clients' demand, all vendors are incorporating bulk FHIR APIs into their solutions and are having clients begin to get experience using these APIs for various use cases where bulk data has value.

VENDOR PRESENTATIONS

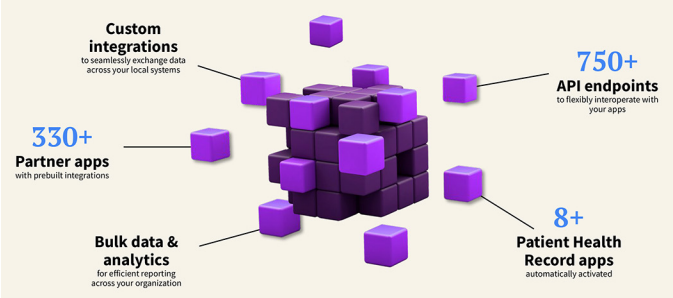
MEDITECH

To meet the December deadline, MEDITECH has developed and deployed a bulk FHIR solution and workflow to most clients. The solution starts with "get" calls, which are calls to export group or bulk data. These calls result in creating a job and specifying what the job needs to do. Jobs are chunked into grabbing data for roughly 1,000 patients at a time. So, a job involving 100,000 patients would be broken into 100 pieces, with each piece assigned to a different worker, who gathers the appropriate data. The separate pieces are done until a job is complete.



ATHENAHEALTH

Connectivity and population analytics are built into Athena's DNA. Joe Ganley confirmed that athenahealth is certified for bulk FHIR and is fully supportive of moving to a more standardized approach.



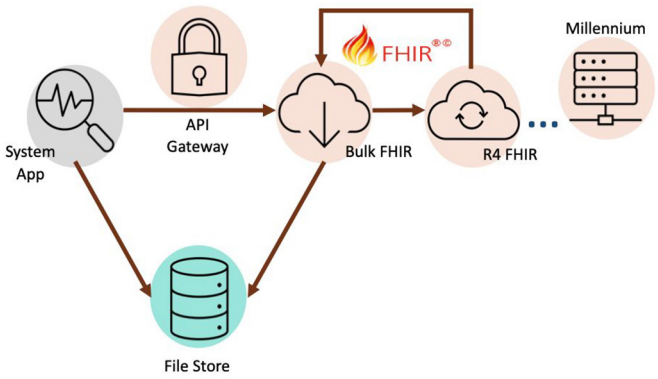
However, he raised a policy consideration. He stressed that in addition to leveraging technology for interoperability and interactivity, a third key element is healthcare outcomes. Mr. Ganley asked, "Are we using greater connectivity and greater interoperability and greater interactivity to forward the healthcare goals that we as a healthcare system have?"

Athenahealth's experience has been that the greatest success is achieved when iterating based on use cases and outcomes that customers want to achieve, and lack of success is when technology is built for technology's sake.

ORACLE CERNER

Oracle Cerner's bulk FHIR service is essentially deployed. It is a centrally managed service deployed on a per-region basis. This service leverages the company's existing single patient resources to compile bulk data, and the bulk data architecture is built on the same high-fidelity EHR data source.

Oracle Cerner – Bulk Data Architecture



The company is encouraging customers to be very targeted when making bulk data selection and to gather just the data needed. In the next few months, Oracle Cerner will publish recommendations regarding group sizes. Oracle Cerner requires that data is retrieved promptly, as it expires at 30 days. For developers, using bulk FHIR will be very consistent with the existing FHIR API experience. Also, Oracle Cerner is introducing a toolkit for clients to be able to define patient groups for export.

EPIC

Epic's interoperability toolkit includes RESTful FHIR APIs, bulk FHIR, SMART apps, CDS Hooks, provider-to-provider interoperability, and HL7 interfaces. In particular, Epic supports hundreds of FHIR APIs, including support for bulk FHIR. Currently, 83% of Epic sites can use bulk FHIR today. In recent years, the usage of Epic's FHIR APIs has increased exponentially, growing from 1.2 billion FHIR API calls in 2020 to 39 billion calls in the last 12 months.

Epic has provided support for bulk FHIR since August 2021. That includes support for the group export with FHIR content as well as support for backend services. Epic has focused heavily on performance and tailoring infrastructure to the use cases the company heard about from the community. Each Epic organization can now create rules to define the groups of patients they'd like to export and control the governance around which application should access which groups, and what data types should be exchanged for a given use case. Behind the scenes, Epic's bulk support is built on top of the existing FHIR platform, which runs on each organization's operational database.

Because the bulk FHIR response is built off of the system of record, this allows for dynamic group creation and real-time data retrieval. Controls have been added so that each organization can manage the performance and impact to the system, so that bulk FHIR doesn't take away from patient care happening in production. Again, because it is built with the existing platform, bulk FHIR workflows receive parity with new RESTful FHIR resources. And the data within those resources behave the same in bulk FHIR as if each API is called directly; clients have a consistent experience. Due to this consistency, bulk FHIR setup requires little time from a technical perspective to get up and running. This architecture allows organizations to use established access and security policies.

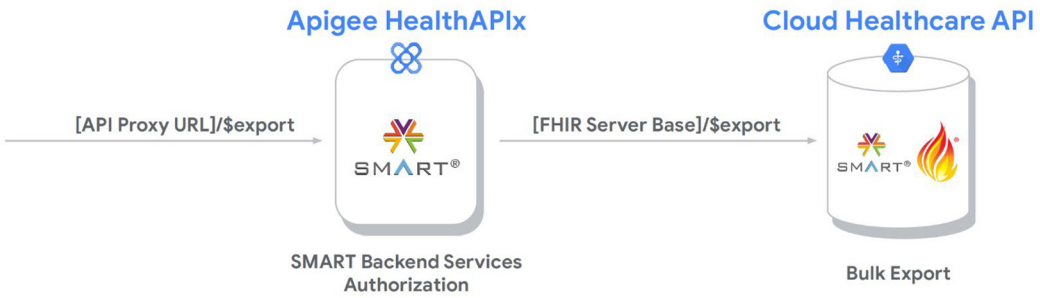
Epics calls to action are for the community to:

1. Identify and prioritize use cases that are most valuable to the community as a whole
2. Continue adoption
3. Continue to grow the standards so that Epic can keep supporting use cases

GOOGLE

Google has two offerings that support interoperability within healthcare. Shown below on the right is the Cloud Healthcare API, which is a managed service in Google Cloud. It lets users store FHIR resources in native format. This API also supports bulk import and bulk export capabilities. A proprietary export is already available and customers are using it extensively; the $/export and other group-level exports are in the pipeline—and all of the support parameters will be coming soon.

Population Data Access with Google Cloud



In front of the Cloud Healthcare API is Apigee HealthAPix. It supports security, authentication, authorization, application registration, application approval, and more. It also supports full SMART specifications, including the bulk export specification.

VENDOR DISCUSSION

- **Filtering.** Vendors are hearing from customers about the desire for filters around resources, filtering by type, and filtering by category on resource or data parameters. An example is the _since parameter, which is a blocker for many use cases.

Regulatory Approaches to Meeting the Use Cases

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program, Boston Children's Hospital; Donald A.B. Lindberg Professor of Pediatrics and Biomedical Informatics, Harvard Medical School (Moderator)
Steve Posnack, MS, MHS, Deputy National Coordinator for Health Information Technology, Office of National Coordinator

CONTEXT

Following the panels, which discussed several use cases for FHIR and bulk FHIR APIs, Dr. Mandl posed questions to Mr. Posnack about how ONC can use a regulatory approach to address some of these use cases.

KEY TAKEAWAYS

NOT ONLY IS ONC RESPONSIBLE FOR DEVELOPING EXTENSIVE RULES FOR THE 21ST CENTURY CURES ACT, BUT ONC IS RESPONSIBLE FOR ENFORCING COMPLIANCE IN A MEANINGFUL WAY.

As part of the 21st Century Cures Act, health IT developers have a condition of certification that involves real-world testing. Developers must conduct one year of real-world testing as part of their interoperability certification criteria where they self-monitor and then publish their results. This provides an open opportunity for the community to see the real-world testing. Also, there are information-blocking regulations that have certain oversight provisions that involve compliance.

ONC IS SENSITIVE TO NOT CREATE FRICTION BY ADDING COSTS TO THE SYSTEM.

ONC recognizes that there is a substantial amount of R&D and implementation work that goes into creating the FHIR servers and building out the functionality for both the "single serving" FHIR APIs and bulk FHIR, and continuing to maintain and update those FHIR resources over time.

In the information-blocking rules, the general principle is that there shouldn't be any friction or impediment to sharing electronic health information—and fees or cost recovery could be viewed as a friction point. Due to this, ONC has incorporated various provisions in the information-blocking regulations to recognize that there are legitimate purposes for recouping fees and reasonable profit.

When considering charging fees to access certified APIs, the regulatory language "without special effort" is important. Any cost could be seen as special effort because it imposes friction in the system. As a result, ONC's approach has been to say that health IT developers that have certified APIs need to make their fee information publicly accessible. That include the person or classes to which the fee applies, the circumstances in which the fee would apply, and the amount.

Also ONC recognized that there needed to be some cost recovery allowed for three types of permitted fees; this would be part of the conditions for certification. These three areas are: 1) around development, deployment, and upgrade—which is a great deal of the R&D effort; 2) around usage costs; and 3) around value-added services which are "above and beyond"-type activities that health IT developers may offer.

Panel 5: Forward Looking – EHI Export

Josh C. Mandel, MD, Chief Architect for Microsoft Health and SMART Health IT (Moderator)
Aneesh Chopra, MS, Former (and first) U.S. Chief Technology Officer; President, Care Journey
Jen Roberts, PhD, Assistant Director for Health Technologies, White House Office of Science and Technology Policy
Avinash Shanbhag, Executive Director, Office of Technology

CONTEXT

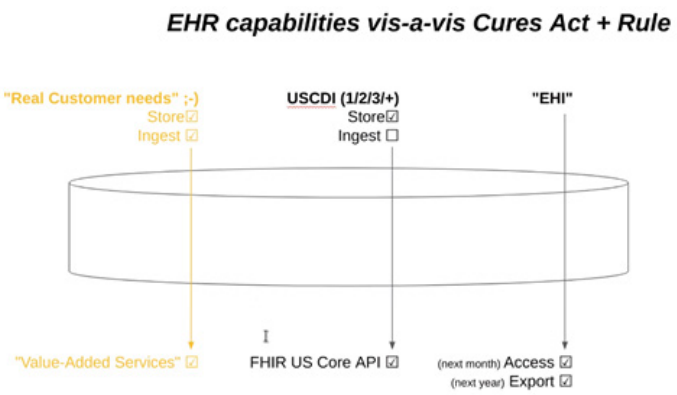
Josh Mandel led a discussion about use cases that aren't well met by bulk data today. He reflected on the meeting's previous discussions by observing that perhaps the most important thing that can happen right now is not to continue to invest in more standards or specifications and not to further expand functionality, but instead to gain real-world learning about the existing capabilities and to grow the community and implementation experience.

OVERVIEW

Some EHR capabilities are driven by regulation, while others are driven by customer needs and market signals. In looking forward, the panelists can envision several important use cases for electronic health information (EHI) data. Making progress on these use cases will require greater integration, collaboration, and shorter loops in turning feedback from the market into product capabilities.

A MENTAL MODEL TO FRAME THE CONVERSATION

In teeing up the discussion, Josh Mandel shared a mental map he developed during the meeting, attempting to recap and summarize some of what he had heard.



Slide source at https://docs.google.com/presentation/d/1ZEF6YjvwFIlfiqVZ8Y2lDz-TySfCzS8zuNRWTDd-H3h0/edit#slide=id.p

This model aims to categorize EHR capabilities that are informed by customer needs or by ONC rules for EHR certification, or are required by the 21st Century Cures Act. From left to right:

- A theme from the meeting is the importance of driving EHR capabilities from **real-world customer needs**. Any good product—including both certified and uncertified products—is going to strive to meet customer needs with its functionality. This includes the ability to **store** various kinds of data; it probably includes the ability to **ingest** various data; and it probably includes the ability to **expose** various kinds of data through "value-added services." If the market is working as intended, responding to customer needs might cover the vast majority of what users need. However, it could also lead to a huge diversity of (sometimes incompatible) implementations.

  Because of the diversity and incompatibility of implementations, there will be capabilities where it will be seen as necessary for rules and regulations to be created in order to standardize.
- **USCDI.** The middle section of the visual reflects all of the excellent work that has gone into ONC's regulations to define a core data set for sharing in the United States. Notably, this includes requirements around EHRs being able to **store** data. There is not a requirement around being able to ingest data. Then, the EHR will be able to **expose** the data, using the **FHIR US Core API**.
- **EHI.** Another category of requirements comes from the 21st Century Cures Act, which is the idea of access to the full electronic health information. Healthcare providers are required to make all EHI data available by October 2022, but there aren't necessarily standards for this data. Certified EHRs will need to have an export process for all EHI by the end of 2023.

LAYERS OF REGULATION

Avinash Shanbhag explained that there are "a bunch of regulatory layers." EHI covers all electronic health information. The initial EHI rules are based on information-blocking regulations. EHI can be different for different providers and different settings, but the information-blocking rule is broad enough to cover all EHI that a practice has, not just certified health IT products.

A new criterion in the regulations is "§170.315(b)(10) Electronic Health Information export". This EHR Export certification criterion is required of all health IT developers. In developing this criterion, one high-level use case was a single patient wanting access to their patient EHI. The other use case was when a provider wanted to switch their health IT system; the constraint was they needed some way to export the EHI. The requirement in the regulations is that vendors need to have the capability to export EHI in a computable format and need to make that format available.

Dr. Mandel pointed out a problem and a disconnect related to the timing of various regulations: regulations require that healthcare providers need to be able to provide EHI in October 2022; however, their EHR is not required to provide EHI Export until the end of 2023.

Mr. Shanbhag said that ONC was trying to balance the capabilities that are needed with the realities of industry readiness. "It was a balancing act," he said. The EHI that is required for providers to be able to provide in October 2022 does not require a certain standard, giving technology vendors the ability to innovate. For the more specific 2023 requirements, more time was provided to vendors to meet these requirements.

USE CASES

Dr. Mandel asked Jen Roberts from the White House about possible use cases driving real-world interest in bulk data. These might be where it would be valuable to collect additional data at the point of care or situations where data is already being collected at the point of care and it is desired to be able to surface data downstream. Dr. Roberts shared several use cases, observing that some will require more work from a USCDI-plus standpoint to make some kinds of data more understandable, and others may require additional filters or new capabilities such as FHIR questionnaires.

> "We could all benefit from this ability to see more about what is being collected in EHI."
> —JEN ROBERTS

- **Emerging pathogens.** Aggregate patient records can be used to detect trends as a new pathogen emerges. Analysis of records would enable tracking prevalence, symptomology, and emerging best practices—ideally with no additional effort from clinicians. Data can be pooled in the background, captured from health records. Then, technology such as natural language processing can be used. This use case is about collecting and using real-world evidence as new pathogens or outbreaks are discovered.
- **Equity and social determinants of health.** Currently, data is collected about patients from race or ethnic groups. But practically speaking, inside each of these groups there are multiple subgroups with very disparate health outcomes. Current groupings obscure these disparities and make it difficult to know what resources and treatments would benefit which communities. Being able to pool view data at a more detailed, granular level would help improve the health of different communities.
- **Cancer.** Aggregation of data about patients can inform clinicians and researchers. For example, the total number of women in the US currently living with metastatic breast cancer is currently unknown. This is because there are not good ways of collecting accurate data across the entire country on cancer recurrence or disease progression. Being able to aggregate data on disease cycles would help produce insights on allocating resources to treat these patients.
- **Non-infectious disease surveillance.** Building on data that the CDC is already tracking—such as non-fatal drug overdoses, suicide attempts, and more—it would be possible to augment that data with data from other healthcare providers to have a better sense of the real prevalence of drug overdoses and suicides.

Other use cases where bulk data would have value include value-based care and precision medicine.

LESSONS FROM A CMS EXPERIMENT

Aneesh Chopra summarized a five-year CMS experiment that involved an investment of many millions of dollars. Thousands of people in 30 cities were screened for social needs. If someone had two or more needs that were unmet, it was supposed to trigger a care coordinator who would work to meet those needs.

However, this experiment failed to show any improvement in terms of total cost of care. The follow-up report indicated that none of the providers delivering care to these patients had access to the screening assessments in their EHRs. Basically, CMS did massive data collection of social determinants of health, but there was zero integration. This experience indicates a major issue: there isn't a pathway for the EHI that is collected to be organized and then used in any kind of clinical workflow. There is not a requirement of any EHRs to ingest this data. So, while there is a clear demand signal for various data, such as social needs data, in the absence of integration it means that clinicians have to enter this data. This could mean duplicate data entry at national scale.

EHI export can help perform a supply chain review of how data is sourced and then made available in machine-readable format for reuse. But doing so is going to require pressuring the vendor ecosystem to do things that are not required of them.

Dr. Mandel said that this example, and others, indicate that the collaboration model is challenging. One of the needs is to make the feedback loop faster, which will enable the ecosystem to react more quickly in turning feedback into product capabilities.

Next Steps

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program, Boston Children's Hospital; Donald A.B. Lindberg Professor of Pediatrics and Biomedical Informatics, Harvard Medical School (Moderator)
Aneesh Chopra, MS, Former (and first) U.S. Chief Technology Officer; President, Care Journey
Jim Jirjis, MD, MBA, VP & CHIO, HCA Healthcare

CONTEXT

Ken Mandl led a discussion between Jim Jirjis and Aneesh Chopra about post-meeting next steps. Dr. Jirjis shared pain points that HCA experiences related to managing massive amounts of data and fulfilling reporting requirements, and where HCA would be interested in getting started to get experience with bulk FHIR. Aneesh Chopra shared his thoughts on the opportunities to use regulated standards moving forward.

OVERVIEW

Providers are experiencing significant pain points in managing enormous amounts of data, deriving insights from this data, and fulfilling various reporting requirements. Data standards and use of bulk FHIR have the potential to reduce the burden on providers while also providing benefits to recipients of the data. The next step is to begin getting experience with use cases, such as public health reporting.

KEY TAKEAWAYS

BULK EXPORT HAS THE POTENTIAL TO DECREASE THE BURDEN ON PROVIDERS.

Jim Jirjis, from HCA—which has 190 hospitals and 3,000 clinics—said that because of the enormous amount of information in healthcare, it is more difficult than ever for clinicians to find the needle in the haystack, since the haystacks keep getting larger.

Another pain point for providers is the tremendous amount of reporting that is required. This includes reporting for public health, for federal mandates, for states, and for payers. This reporting burden, which requires an enormous number of resources, places a huge onus on providers. This challenge is exacerbated by the lack of standards and lack of integration among different systems. Dr. Jirjis said that HCA has at least six electronic health records, which all speak a different language. He called the situation a "Tower of Babel."

He asserted that if there were more standards and an ability for bulk export from all EMRs, it would enormously reduce the time and effort required of providers.

Dr. Jirjis also suggested that data standards and use of FHIR will have benefits for recipients of data, who will have easier access to large data sets. With standards, recipients will be able to negotiate application access to regulated "bulk" FHIR data that is machine understandable. However, this will shift some of the work to the recipient to do the work of sifting through the data, which—while decreasing the burden on providers—may not be well received by all data recipients.

Dr. Mandl observed that because data in bulk FHIR is designed to come out in a completely standardized fashion, the analytics that are used could also be standardized. This could mean, for example, that an agency requesting data across many sites of care could standardize its data processing, which might reduce the burden on both the providers and the recipients of data rather than just shifting the burden.

THE NEXT STEP FOR HCA IS TO GET EXPERIENCE WITH USE CASES.

When asked what the next step is for HCA to get started with bulk FHIR, Dr. Jirjis said, "Let's get some use cases so we can work out the performance." The ideal use cases would involve working with a willing data recipient/partner (or partners). The partners would be upstream of the data and downstream of HCA. The goals would be to demonstrate performance and work out the kinks. One great place to start could be a pilot related to public health data that is reported.

ANEESH CHOPRA SEES THREE ESSENTIAL ELEMENTS TO MOVE FORWARD.

Mr. Chopra's three observations were:

1. **A catalyst is needed for B2B APIs,** similar to the role that Apple Health played in driving industry consistency of the consumer FHIR API. What happened was that Apple made the decision to only accept the FHIR API as designed by Argonaut in order to connect. The question at this moment is, "Who will be the Apple Health for bulk FHIR?" Mr. Chopra said, "I'm worried that I don't know who it is and if there isn't one, there is a growing risk for variable implementations across vendors and provider deployments, reducing the benefits of regulated standards."

2. **A multi-stakeholder approach is needed.** Providers are often focused on bilateral use cases, where a provider wants to connect, for example, to a registry or a lab. But this meeting is all about data sharing involving multi-stakeholders. It may be useful for regulators or public sector operators representing recipients of the data or any derivative analyses, to build a "public option" to maximize the benefits of these standards.
3. **Driving consistency even across non-certified technologies is desirable.** Mr. Chopra argued, "There is no reason why we can't make the G10 module a mandatory capability across many use cases and stakeholders." It isn't (currently) necessary for providers to administer patient requests for EHI (which otherwise could be as a machine-readable blob of text), or payers who are expected to administer a "physician access" API. But, he believes "this won't happen passively . . . it will require multi-stakeholder effort." This means effort from ONC, CMS as the country's largest payer, or the VA focused on integrating community care.

> "The takeaway for me from this meeting is to move from concept to action as we implement G10 nationwide—across payers and providers."
>
> —ANEESH CHOPRA