The Intersection of Technology and Policy: EHR Population Level Data Exports to Support Population Health and Value

EXECUTIVE SUMMARIES

December 15, 2017

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

This meeting brought together key stakeholders from across health care, including the Director of the Office of the National Coordinator for Health Information Technology (ONC) and other members of the ONC staff; representatives from payers, health systems, and EHR vendors; and technology innovators.

The goals of the meeting were to:

- **Understand** the existing and planned population level data use cases of ONC, payers, analytics and population health software vendors, EHR vendors, and other parties to guide the technical roadmap in this area.
- **Obtain feedback** on the initial Fast Healthcare Interoperability Resources® (FHIR®) population level data API (Application Programming Interface) proposal developed by SMART® and Health Level Seven® (HL7®).
- **Discuss** how to structure the regulatory environment to promote the implementation and adoption of population level data APIs.
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CREATING A LEARNING HEALTHCARE SYSTEM
REQUIRES POPULATION LEVEL ANALYSIS OF DATA.

The published APIs 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. Population level data combined with new technologies such as machine learning and AI has amazing potential to improve the health and lives of Americans.

There will be many users of population level data, including payers, providers, researchers, vendors of machine learning technology, and entities such as the Centers for Disease Control and Prevention (CDC).

MAKING PROGRESS REQUIRES UNDERSTANDING THE CHALLENGES AND REALITIES.

This may prove difficult and presents numerous challenges. Among them, aggregating and analyzing population data can’t shut down existing electronic health record (EHR) systems. Efforts will be needed to develop solutions to state, timing, transactional burdens, computational efficiency, and more. All data are covered by provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

There will be contractual relationships, likely with contracts between payers and providers as well as between employers and third-party plans, and other resources.

Thus, the need for data sharing is great, the potential uses and benefits are many, but the challenges are significant.

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OVERVIEW

National Coordinator Don Rucker welcomed attendees, provided context for this meeting, and described the importance of analyzing population level data in creating a learning healthcare system.

In particular, he noted that in the 21st Century Cures Act, Congress expressed a clear interest in interoperability and has called for published application programming interfaces (APIs) without special effort. It is now the role of the Office of the National Coordinator for Health Information Technology (ONC) to provide the specifics. An important consideration is enabling population level data analysis, which in combination with technologies like machine learning and artificial intelligence (AI) has the potential to improve the health of populations. Getting there will be challenging. In particular, it is important to have easily implemented, systemic solutions, rather than expensive one-off interfaces.

KEY TAKEAWAYS

ONC IS CHARTERED WITH DEFINING KEY ELEMENTS OF THE 21ST CENTURY CURES ACT.

ONC, an agency within the U.S. Department of Health & Human Services (HHS), is the principal federal entity responsible for the coordination and implementation of nationwide efforts for the electronic exchange of health information. ONC is the lead HHS division responsible for implementing Title IV of the 21st Century Cures Act.

The 21st Century Cures Act expresses a clear interest in interoperability, demands no information blocking, and requires that various networks be able to exchange information and talk with each other. Most important for this meeting is language in the Act about published APIs “without special effort.” This will enable health care providers to exchange patient information across different vendor systems. This points in the direction of RESTful1 web services and the HL7 FHIR standards.2

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1 https://en.wikipedia.org/wiki/Representational_state_transfer
2 http://www.fhir.org/
KEY TAKEAWAYS

THERE HAS BEEN TREMENDOUS PROGRESS IN MAKING INTEROPERABLE FRONT-END HEALTH IT A REALITY.

Over the past eight years, ONC and many individuals and organizations have been working to make front-end health IT services interoperable.

The SMART project (also called SMART on FHIR) is driven by the vision of creating an app store–like model for healthcare. The idea is that, as shown in Figure 1, by standardizing the connection of apps to EHRs—resembling how apps connect to iPhones or Android devices—health systems, providers, patients, or other researchers can select an app, connect it to an EHR, and the app can access core data resources.

Figure 1. How SMART Is Working to Make Interoperable Health Care Apps
The apps model has proven effective and is being successfully implemented across multiple health systems on top of multiple EHRs, including Cerner, Epic, Allscripts, Athena, and more. In addition, the SMART standard (though still emerging) and the FHIR data model are being adopted by major health systems. These standards, and apps that use these standards, are resulting in an innovative, modular format. Numerous apps are being developed and implemented, as are entire app stores, with apps that can be easily integrated with any clinical system that supports the SMART standard. Meaningful Use 3 actually covers the front-end API for patients. Much progress has been made with front-end apps, APIs, and standards.

“We see that with persistence we can actually achieve a very dynamic form of interoperability in healthcare.”

— KEN MANDL

**Meducation by Polyglot**

Early on, the SMART project ran a challenge that encouraged the development of SMART apps. With a prize of just $5,000, 15 apps were developed. The winner was Polyglot, a small company, with Meducation, a software product that provides patient-facing, dynamically generated, user-friendly medication instructions in multiple languages. In just 48 hours Polyglot turned their existing product into a SMART app. Users could pull a medication list in a standard way across the API and provide medication instructions.

Since creating the SMART app, Polyglot (now First Databank) has done very well. The company has created versions of its app that run on different installations of Epic and Cerner, and has versions that run in a patient-facing mode, a provider-facing mode, and a pharmacist-facing mode. These apps can easily be added to or deleted from EHRs, making them substitutable and replaceable (the “S” and “R” in SMART).

**THE 21ST CENTURY CURES ACT PROVIDES THE OPPORTUNITY TO CREATE A ROBUST DATA ECOSYSTEM.**

The 21st Century Cures Act states

“... has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used **without special effort** through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including **providing access to all data elements of a patient’s electronic health record** to the extent permissible under applicable privacy laws ... “

This language requires that certified health IT products have an API that allows for the exchange of data, getting closer to the vision of data liquidity and providing an opportunity for a robust data ecosystem and an apps economy. In this ecosystem, sharing population level data is essential for population health. Examples of use cases are discussed below.

**Health System Population Health Analytics**

A simple anecdote conveys the power of population health data in identifying trends. As shown below in Figure 2, the rate of myocardial infarctions (MI) at Massachusetts General (MGH) and Brigham and Women’s (B&WH) hospitals increased dramatically in 1998, when Vioxx came to market, and fell when Vioxx was removed from the market. Observing such trends is not possible without population level data.

![Figure 2. Rate of MIs per Year at MGH and B&W from 1997-2005](image-url)
**Deep Learning Algorithms**

In one study, Google acquired 10,000 images of eyes used to detect diabetic retinopathy. The company then developed and validated a deep learning algorithm that reviewed these images—and outperformed ophthalmologists in detection accuracy. This shows the potential of large data sets combined with powerful AI and machine learning technologies.

“We have the opportunity to do very large analyses with very large amounts of data. But the ETL at the individual site is one of the most expensive and difficult parts for health systems.”

— KEN MANDL

**Predictive Diagnostics**

A practical use in healthcare of predictive analytics is using data gathered upon presentation in an emergency room to identify signs of likely future domestic violence. Work is also being done to analyze data to predict suicidal behavior, providing an opportunity to intervene in advance.

All of these use cases show uses of population level data, but require access to EHR data at scale.

**CURRENT APPROACHES FOR SHARING POPULATION LEVEL DATA NEED TO BE IMPROVED UPON.**

Recognizing the importance of population level data, what has emerged—and been funded to the tune of hundreds of millions of dollars by the federal government, the National Institutes of Health (NIH), and other entities—are federated EHR networks. These networks have access to large amounts of data, which presents multiple opportunities such as finding patients eligible for clinical trials or observational cohort studies and large-scale analyses.

In operating these networks, data are extracted from EHRs, transferred, and loaded into other databases. Transferring population level data today is problematic for health systems in that it involves expensive, labor-intensive extraction, transformation, and loading (ETL) processes. Because of the massive expense, this method of accessing population data may not be sustainable.

With the emergence of FHIR there is now an opportunity to standardize transferring data, which will reduce the costs of these networks and make them sustainable. Further, an automatic data export that is part of an electronic medical record could become a core function of the health system. This would provide data liquidity and enable population health analytics.

Making the transfer of population level data a reality is the opportunity for this meeting. Areas of focus include:

- A technical approach
- Use cases
- EHR developer approaches
- Standards development
- Possible real-world implementations to inform standards development
- Identifying what regulation is necessary to support a FHIR population level data world and promote real-world data exchange tied to real-world implementations

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[Development and Validation of a Deep Learning Algorithm for Detection of Diabetic Retinopathy in Retinal Fundus Photographs, Varun Gulshan, Lily Peng, Marc Coram et al., JAMA. 2016;316(22):2402-2410]
The Proposal: Extend FHIR to Support Population Level Data Use Cases.

The idea of enhancing and extending FHIR to support population level data access is based on positive aspects of FHIR, which include:

- A standard data model to simplify data parsing and mapping. FHIR's data model has been developed through hundreds of thousands of person hours from people around the world. Rather than using CSV formats and manual mapping, FHIR's data model could be leveraged for bulk export.
- FHIR API semantics could be used to create a standard API to request data extractions.
- FHIR has a standard security model through SMART, which has already been validated for many use cases.

An advantage of moving to a standards-based data extraction approach is the creation and use of pipelines to support different scenarios, such as: creating a deidentified view for researchers, sharing data with a partner, and sharing data with several partners. The idea is to have standard components and modules that can be put together for a wide range of scenarios.

The Proposal Lays Out Design Goals and Provides a Focused Scope.

Key design goals are:

- Automated communication between backend services and EHRs/clinical systems. The idea is that systems should be able to communicate with each other without a user having to log in once a connection is set up.
- Use mature, stable technologies wherever possible. There are exciting early-stage technologies, but the design goals are based on using reliable, proven technologies.

Overview

Dan Gottlieb presented an overview of a draft FHIR population level data API proposal. The proposal builds on the summer 2017 SMART meeting, where the need to move large amounts of data between systems in a standard way was identified as a key need.

A FHIR population level data API draft proposal aims to address many of the difficulties associated with transferring and accessing population level data. This proposal involves extending FHIR, due to FHIR's many strengths, and lays out design goals and the initial scope, as well as the architecture, flow, and security. The proposal includes a timeline, which calls for publishing version 1.0 of a FHIR Implementation Guide for population level data in 2019. Along the way, open policy and technical questions need to be addressed, and it is important to form a community ecosystem to develop, implement, and refine the population level data API.

Key Takeaways

Today, Sharing Population Level Data Is Cumbersome.

Several difficulties that parties face when sharing EHR data include:

- Extremely manual, labor-intensive processes.
- Use of custom data fields and proprietary data models.
- Variance in data extraction across systems.
- Currently FHIR is inefficient for large queries.

There is a need for a standard way to share data that avoids the constant need for customization and gets the data in a file that can be written and read as a stream.
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- **Keep the API surface area small.** It is important not to have too many query parameters or API calls, which would make implementation a burden.

- **Reuse FHIR as much as possible,** rather than invent new things.

- **Use existing open standards for authentication and authorization.**

- **Structure the design for efficiently generating and loading large datasets,** which implies asynchronous operations. Other recommendations include having one data type per file for ease of loading and enabling streaming use cases. In addition to articulating design goals this proposal identifies areas initially out of scope. They are:

  - **Legal matters.** This is a technical standard and assumes agreements are in place.

  - **Real-time data.** The initial plan is to move population level data in batches, rather than in real time. But batches can be supplemented with synchronous FHIR Representation- al State Transfer (REST) API calls.

  - **Data transformation** is out of scope for the initial API calls, but can be addressed via pipelines.

  - **Patient matching** can be done with population level data imports but is initially out of scope.

**KEY ELEMENTS OF THE ARCHITECTURE ARE DESCRIBED BELOW.**

Important elements of the population level data API architecture include:

**FHIR Resources**

With FHIR, resources are the data models, which represent discrete clinical and administrative units. About 100 resources have been developed. FHIR resources can reference other resources by their URL. For example, a FHIR resource for a vital sign could reference a resource about the patient, the provider who took the vital sign, and the encounter where it was taken.

**Additions to FHIR**

A few additions to FHIR are needed to make the population level data approach work. These are:

- **FHIR operation for all data on groups.** FHIR has the concept of “groups.” It is possible to imagine a group of patients enrolled in care management or a group of patients from a particular payer. The idea is to be able to only export data for a particular group.

- **File format** of NDJSON to support streaming. This is a tweak on the JSON format in FHIR.

- **Enabling asynchronous requests** by adding a header to process the request asynchronously.

**Query Parameters**

The proposal provides the absolute minimum parameters that might be used to restrict a query. They are start date, type, and group ID.

**Request Flow**

The envisioned request flow between a backend service and a population level data server is shown in Figure 3 below. It begins with an initial query, which results in a response with the content location. The location can then be queried, which produces a response about the status, followed by further communication about file links and FHIR resources.

**Figure 3. Request Flow for FHIR Population Level Data Proposal**

There are separate steps for SMART authorization and flows for security. Steps for SMART authorization include out-of-band app registration, the backend service providing a public key to the server, and token requests signed with a private key. After putting in a signed request, a short-lived access token is provided. This is a standard approach to security used in the tech world by companies like Google.
The point was raised that development of this population level data API using FHIR can be decoupled from ongoing FHIR releases which occur roughly every 18 months.

An additional next step is creating a community ecosystem. This ecosystem can collaborate on the development of the API spec and multiple organizations in the ecosystem can initially implement the population level data API. There is also a need for a test suite to make sure everyone is implementing it the same way.

“As these components become more plug and play, it will be nice to have the community start building an open source ecosystem that institutions can use when working with the data.”

— DAN GOTTLEIB

Proposed timeline

Next steps are proceeding with the timeline shown in Table 1 below and addressing open policy and technical questions.

Table 1.

<table>
<thead>
<tr>
<th>Timing</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2017</td>
<td>Initial SMART Flat-FHIR proposal.</td>
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<tr>
<td>September 2017</td>
<td>FHIR Connectathon discussion/blog post.</td>
</tr>
<tr>
<td>November 2017</td>
<td>January FHIR Connectathon proposal posted. SMART backend services authorization implementation.</td>
</tr>
<tr>
<td>December 2017</td>
<td>Stakeholder meeting to validate targeted use cases, consider other use cases, and begin thinking through longer-term technical roadmap.</td>
</tr>
<tr>
<td>January 2018</td>
<td>SMART population level data reference implementation server. Initialize Connectathon for interested parties to start experimenting with proposed technical specification.</td>
</tr>
<tr>
<td>2018</td>
<td>Multiple FHIR Connectathon events to refine and develop the technical specification. Continue discussions around future use cases to target. Publish draft implementation guide.</td>
</tr>
<tr>
<td>2019</td>
<td>Publish version 1.0 of FHIR implementation guide for population level data.</td>
</tr>
</tbody>
</table>
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Payer Population Level Data Use Cases and Experience

Jon White, MD, Deputy National Coordinator for Health Information Technology (Moderator)
Kirk Anderson, Chief Technology Officer, Cambia Health Solutions (Regence BCBS)
Kathe Fox, Vice President of Informatics, Aetna
Patrick Haren, Enterprise Architecture Group, CIGNA
Lenel James, Business Lead, Health Information Exchange & Innovation, BCBSA
Sagran Moodley, Senior Vice President, Clinical Data Services & Technology, UnitedHealthcare

OVERVIEW

Representatives from leading payers shared their perspectives on population level data, described use cases where population level data has value, and offered other thoughts on the importance of population level data.

Payers see great value in being able to access bulk clinical data from EHRs. They support the concept of a population level data API and want to be part of the process.

Uses of population level data by payers include measuring the clinical performance of their plan and networks, especially related to value-based program care measures. Payers would use population level data to look at transitions of care, would seek to gain insights and assess risks about particular patient segments, and would want to look at the clinical performance of particular providers. Being able to request data for specific groups of patients is extremely important. Payers also want data on a timely basis to quickly initiate interventions where it would be valuable to do so.

KEY TAKEAWAYS

ONC IS FOCUSED ON STRATEGIES TO ADDRESS HIGH PUBLIC LEVELS OF HEALTHCARE SPENDING.

In 2016, total U.S. healthcare spending was $3.3 trillion. Of this, the U.S. government spent about $1.2 trillion, including $672 billion by Medicare and $565 billion by Medicaid. These high and growing levels of public spending have ONC focused on all possible strategies, including use of population level data from EHRs, to address spending levels and spend more efficiently.

LEADING PAYERS ARE FOCUSED ON AND ENGAGED IN EFFORTS TO MAKE POPULATION LEVEL DATA MORE ACCESSIBLE.

Payers are deeply engaged in standards development, particularly relating to any standards that support the advancement of value-based care. Representatives actively participate in task forces, working groups, and summits. They are also active in Connectathons and in other initiatives related to population level data.

“As a payer, we don’t want data on just one patient or 100 patients, but on thousands of patients.”

– PANEL MEMBER

IN GENERAL, PAYERS SHARE A COMMON SET OF POPULATION LEVEL DATA USE CASES.

A general theme is that payers want data, and have an attitude that “more is better.” Common payer use cases involving population level data generally relate to revenues, costs, and risk. Use cases include:

• Using bulk clinical data for quality measures. Payers must report on the performance of their plan and networks. Payers want to measure their network’s performance related to various clinical quality measures (CQMs), and performance on HEDIS⁴ and Star⁵ measures. Payers want to be able to look at data dynamically, in near real time, for specific groups of patients, such as the patients in an

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accountable care organization (ACO), patients with a particular disease such as diabetes, or patients who haven’t received immunizations.

- **Using population level data for value-based care program measures.** In value-based programs payers have incentives to improve clinical quality and want to track clinical measures that impact revenue. Other uses of population level data related to value-based care include lab testing and provider risk adjustments.

- **Using population level data to monitor transitions of care.** Population level data from EHRs can be used to show admits, discharges, transfers, and care management progress. It can identify patterns, like 30-day medication reconciliation for diabetic patients, and gaps in care.

- **Population level data can be used to address unnecessary costs.** This includes inpatient and emergency department avoidance, readmission reduction, high-cost referrals, site of service, high-cost pharma, specialty labs, and specialty radiology.

- **Using population level data for risks and insights.** This is using population level data to analyze patterns and risks among certain groups of patients. Again, being able to look at groups of patients based on disease state or another attribute is extremely important.

  “The request has to somehow reference some group of patients.”
  — PATRICK HAREN

- **Using population level data to identify where and when to intervene.** Payers are driven by using data in situations where it can provide the greatest value. One issue is around timeliness—how important is it to know something sooner? A specific use case where data has value is identifying patients newly diagnosed with acute conditions, where intervening quickly can make a difference. The window here is short, at just about six weeks, requiring timely data.

**SEVERAL PAYERs ALready HAVE EXPERIENCE WITH POPULATION LEVEL DATA.**

Examples include:

- **Aetna.** Aetna routinely shares data back and forth with provider organizations, as Aetna has extensive data sharing arrangements with its ACOs. Aetna shares some data daily and other data monthly, including claims information or information from care management systems.

About 50% of provider organizations have never even downloaded the claims files that Aetna sends. They have no capacity to ingest this information; they are not equipped or ready to deal with it. Further, when providers receive population health information there is a disconnect between what the population view says and what a unique physician thinks he or she is doing. Physicians look at information and say, “That’s not me. That’s not my patient. That’s not how I practice.” This shows the need for payers to be able to share information to providers in ways that get used and have practical value.

“I’m really, really in favor of population level data. . . . But I want to make sure that when we’re thinking about this we’re concentrating our efforts around collecting and accessing and using those data that really produce value, not just for payers—our business case is pretty clear, we’ve all articulated it, but also for providers and our members.”
  — KATHY FOX

- **Cambia.** Cambia has been playing with FHIR for a few years. The organization’s first effort was building an encounter query API. Population level data on members was pulled in on admits, discharges, and transfers from clearinghouses and facilities. Data were imported via CSVs and then mapped to FHIR resources for internal RESTful API access.

A second effort involved taking claims data from the organization’s Facet system, and combining it with member and provider data in a data lake. This population level data was used for data science and machine learning purposes by Cambia’s data science team. Cambia is now re-architecting its business, moving to microservices.

“Being able to pull data directly through a population level data export . . . is definitely exciting . . . the more clinical data we have, the smarter our models are, the more value we feel like we can provide to the healthcare consumer.”
  — PANEL MEMBER
DISCUSSION

Other comments population level data included:

- There are considerations regarding who has the right to see what data and what information providers have a right to see beyond their own practices.
- Some attendees believe population level data will ultimately have an impact on precision medicine.
- One payer representative suggested that EHR data should be treated as a public good.
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Population Health Population Level Data Use Cases and Experience

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program, Boston Children's Hospital (Moderator)
William Harty, Principal Architect, Premier
Dan Malloy, Optum Analytics
Hiten Patel, Managing Director, Advisory Board

OVERVIEW

The panelists represented organizations already involved in the difficult process of bringing together data from multiple sources. The panelists discussed their experiences and offered perspectives on the benefits that FHIR population level data could unleash for population health innovation.

Organizations that bring together large volumes of data from multiple sources experience significant pain and bear significant costs in this process, with slow, expensive, labor-intensive customized work. If a FHIR population level data API became available, it would be embraced and would have multiple benefits in more easily and less expensively being able to bring together data from multiple sources, especially small providers. It could dramatically lower costs of aggregating and accessing data, could lead to development of new products and apps for new use cases—since accessing data is now easier and less expensive—and could lead to new types of quality metrics, since more data will be readily available.

KEY TAKEAWAYS

THERE ARE CHALLENGES TO AGGREGATING AND MAKING POPULATION HEALTH DATA USABLE.

Optum Analytics’ goal is to build the most comprehensive, holistic patient-level record. Optum currently maintains longitudinal records on approximately 100 million patients and supports about 80 health systems. Its customers are increasingly considering entering into value-based risk contracts, but need better data to be comfortable proceeding with such agreements. Today, there are considerable gaps in their data.

To create a holistic picture, Optum brings in data from numerous sources, which involves building customized interfaces. Just opening a pipeline and getting EHR data doesn’t mean the data will be usable. There may be issues with patient identification and provider attribution, and mapping and normalizing the data is typically required. Malloy estimated that a solution such as FHIR population level data might reduce the costs associated with this work by 30% to 40%.

Hiten Patel of Advisory Board sees healthcare organizations wanting to use clinical analytics to improve clinical decision making and to become more data-driven organizations. But all of the costs associated with bringing together the data impose a tax on the system. They also limit the development of products and apps to just those use cases where the return on investment (ROI) is great enough to overcome the cost of data acquisition.

One use case example shared by William Harty of Premier—a hospital group purchasing organization with data on approximately 40% of the country’s hospital encounters—illustrates the potential and value of FHIR population level data. A physician developed software to provide early detection of outbreaks or clusters in hospitals. After an initial implementation the physician/software developer wanted to do a large-scale study in 40 hospitals. Premier agreed to use its data center and capabilities to support this project, which requires an ugly ETL process that transfers data to a folder every night. It took considerable time and money to do this project. If FHIR population level data were available population level data it would have expedited the project and lowered the cost.

“There are multiple use cases where organizations could benefit from a FHIR population level data API.”

— WILLIAM HARTY
Improving predictive capabilities. When the costs of aggregating data are high, the amount of data is limited, which, in turn, limits the predictive capabilities. Lower costs of aggregation provide the ability to pull together more data, improving the predictive capabilities.

**DISCUSSION**

Additional comments from the discussion about population health population level data include:

- **Data integrity.** Even with a population level data API there will still be issues with data integrity. Standardized communication protocols decrease barriers in moving data around, but don’t address data integrity issues. Efforts need to proceed in parallel to improve data integrity.

- **CCDS.** A comment was made that even with the Common Clinical Data Set (CCDS), sometimes the quality of data received is not good. This led to a question about whether the problem is a failure by stakeholders to follow standards or if there are other influencing factors leading to these data quality issues. Multiple participants answered “yes” to both. There is a lack of compliance, and depending on use cases, CCDS only provides a narrow slice of clinical information.

- **Rethinking quality measures.** Today quality measures are largely based on what data are readily available and acceptable. But as more data become accessible, there is an opportunity to rethink the types of quality measures used.

- **Limited IT resources.** Often data-related projects within healthcare organizations take longer than desired because those in the organization wanting access to population health data have limited access to the organization’s IT resources—who are necessary to provide the data. A project might just take one day of an IT person’s time, but it can take months for a person wanting IT assistance to get that one day of an IT expert’s time. This is often a limiting factor. An API wouldn’t completely solve this problem, but it would accelerate it.

- **Need for a balanced approach.** There are situations where organizations would be users of data accessible through an API as well as providers of data. It is easy to be excited as a user or consumer, being able to easily access data. But being a provider where others can easily query against a data repository creates concerns for organizations that own large data sets; they worry about potential for large numbers of uncontrolled queries of their data. Those with this concern believe that making data accessible through an API needs to be done in a reasonable, manageable, scalable way.

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Health IT Developer Population Level Data Capabilities and Experience

Josh Mandel, MD, Harvard Medical School; Health IT Ecosystem Lead, Verily (Moderator)
Tony Confrey, Executive Director, Integration Services, athenahealth
Peter DeVault, Vice President, Epic
Mark Gingrich, CIO, Surescripts
David McCallie, MD, SVP Medical Informatics, Cerner
Manoj Sharma, Innovations Architect, Allscripts
Micky Tripathi, President & CEO, Massachusetts eHealth Collaborative

OVERVIEW

In this session, each panelist gave a short presentation about his organization's population level data activities followed by a discussion about how these EHR developers are thinking about population level data.

To date, developers have found ways to provide population level data extracts for clients, though the processes are custom and manual. In several instances developers have a transactional database used in real time, and transfer data to an enterprise population database, where additional non-EHR data are brought in. If a standardized population level data API could improve the efficiency and consistency of the data extract process, which many panelists believe it can, they would support it in some way.

Some of the considerations include data attribution, data profiling, and the need for piloting, as well as data access rights. Most of the panelists in this session do not want to have features capabilities related to population level data extracts included as part of the ONC Health IT Certification Program.

SUMMARIES OF PANELISTS’ PRESENTATIONS

MASSACHUSETTS EHEALTH COLLABORATIVE (TRIPATHI)

Massachusetts eHealth Collaborative (MAeHC) is a small organization with 30 people focused on clinical quality measures. MAeHC receives approximately 30 million records per year; approximately 100,000 per day. These include different types of data, from different sources, as shown in Figure 4, shared electronically, as well as through a manual data entry portal. The image on the right shows where data come from: approximately 60% comes from various EHRs and 40% via intermediaries.

Figure 4: Sources of MAeHC’s Consolidated Clinical Document Architecture (C-CDA) Records

![Figure 4: Sources of MAeHC’s Consolidated Clinical Document Architecture (C-CDA) Records](image)
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Kit is Epic’s standardized data extract capacity. It provides the ability to expose the data needed for a particular app, including both clinical and administrative data.

CERNER (MCCALLIE)

Currently most population level data requests for Cerner are custom requests from payers, mostly done through custom SQL queries. The custom nature adds to the cost. But only standardizing the API and data feed won’t reduce the cost unless there are standardized use cases. Cerner views emerging EHR-based FHIR API services as designed for transactional apps, but not good for population level data.

From Cerner’s perspective the desired future state is to standardize payer data needs as much as possible, to minimize manual configuring; and for exports to come from population health databases, not EHRs. Population health databases that aggregate data from multiple sources would be better than EHRs at supporting population level data extracts.

Cerner already aggregates data from multiple sources, normalizes this data, stores it in its HealtheIntent data warehouse, and distributes data for population health and research purposes. In doing so, Cerner has developed and supports more than 500 interfaces, which are sunk costs. To retrofit these to FHIR would make sense if it reduces costs associated with mapping.

In regard to the population level data access proposal, Cerner sees both technical and policy issues:

- **Technical issues:** The current FHIR population level data proposal is a good start but needs to be piloted. Details need to be worked out regarding the group query parameter and the data returned in the population level data API. Exports will still require extensive customization for each non-standard request. Attribution of data to specific payers and plans is still challenging, and profiling FHIR data is still far from complete; there is a long tail of data that hasn’t been profiled and a great deal of mapping still to be done.

- **Policy issues:** Provider groups want data to be scoped to specific use cases (i.e., HIPAA’s “minimum necessary” requirement). They want reciprocity so data flow in both directions, when feasible, between providers and payers. Providers want clear rules about access rights. Also, there needs to be reasonable expectations about costs; “without special effort” doesn’t mean “free.”

Micky Tripathi’s observations were:

- Population level data export is already happening, but is inefficient and imposes a tax on the system. Multiple sources and interfaces require costly engineering support.
- Data validation has to happen with every new source system, which takes time and effort.
- Claims data have the same data quality issues as clinical data.

An API-based approach that doesn’t require engineering support to build an interface for each source system would make population level data more efficient. A FHIR-based API could do this, but so too could a more constrained Consolidated Clinical Document Architecture (C-CDA)-based approach.

EPIC (DEVault)

Most of Epic’s customers, which include both payers and providers, house their own data. Over the past few decades Epic has had extensive experience performing population level data extracts to support clients.

Today, when clinicians, administrators, schedulers, or others enter data into Epic or export data out they do so in Chronicles, Epic’s transactional database. Chronicles is highly optimized, but the data it contains are not normalized.

As is shown in Figure 5, data in Chronicles move via ETL to Clarity, a separate Epic database where data are organized into tens of thousands of tables. Those who use Clarity need to know the data model to ensure they’re getting data from the right tables. To work with these tables, customers must do a great deal of manual work or hire a consultant. To solve this problem Epic introduced Caboodle, an enterprise data warehouse where data are normalized. About half of Epic’s customers use Caboodle, which may increase to 80% or 90% in the next few years.

*Figure 5. How Epic Handles Population Health Data*
Considerations regarding the technical population level data proposal include:

- Large patient data sets.
- Understanding the data policies.
- Accessibility, while ensuring security and that agreements are in place.
- Providing value to each client and partner.

**DISCUSSION**

Panelists responded to questions and shared perspectives on a wide range of topics.

- **Using a population level data API to import population level data.** Panel members were asked whether payers and other stakeholders would use a population level data API to import data. One representative said that for organizations transferring data using CSVs and one-off solutions—which are time consuming and expensive—moving to a more efficient way using FHIR is worth considering.

Another panelist said that as a small organization taking in data in different ways, a scalable API to do this consistently across all implementations would be helpful. The biggest problem is payload consistency. If FHIR forces people to greater standardization—great. If not, then it doesn’t save time. He added that he sees value in using a FHIR population level data API for outbound data, as long as customers authorize it. The concept of exposing all data on a patient is scary.

Several developers have already done the work and incurred expenses to build multiple interfaces to pull import data. In these instances it doesn’t make sense to revise the interface and incur additional expense just to use FHIR, unless there is a compelling reason. But if a new interface was needed and it was based on FHIR, that could make sense. It would also be valuable if developers could spend less time and effort on mapping.

Another developer encouraged consideration of use cases requiring multilateral communication between providers and payers, such as prior authorization and referrals, as opposed to just one-way communication. Yet another use case mentioned was providers being able to share up-to-date patient data with each other at the time of a patient visit.

- **Could a FHIR population level data API be “good enough”?** Josh Mandel pointed out that some developers have mapped their data to FHIR and it has been “good enough” to release patient APIs. Even that level of standardization is valuable for many use cases. A participant
asked if this would apply to population level data export as well and satisfy much of what organizations are seeking to accomplish.

One panel member responded that mapping the underlying data structures into FHIR resources is probably valuable, but a concern is that not much has been mapped compared to the long tail of everything that exists. Mandel commented there still might be value even if only 50-70% was mapped, which would be a starting point. Others see value in mapping the common clinical data set, but have concerns about the scope of the population level data query, which is vast and uncertain. Epic, for example, has 150,000 discrete data elements along with non-structured notes.

Another participant said that today organizations start with the use case, and then proceed to normalization, mapping, and access. If access and mapping were free, it would shift the focus to normalized data, but that’s not currently the case.

- **Bulk APIs as a tool.** Representatives from Cerner and Epic don’t envision rearchitecting their relational and transactional databases to support bulk access using FHIR. As one representative said, “To imagine doing population level data extracts from the transactional database sounds foolish.” But they see the possibility of supporting bulk APIs to extract data from their population health platforms.

For developers with cloud-based products, such as Allscripts, where 60% of smaller clients are hosted in the cloud, it would be relatively easy to enable a population level data API. For non-cloud clients with on-premise solutions, using a population level data API would be carried out on a case-by-case basis, based on the client’s infrastructure.

- **Certification related to population level data.** Given the early efforts to develop a specification, health IT developers thought it would be premature to require certification related to population level data. They also acknowledged that if they didn’t have a population level data warehouse they would have difficulty meeting certifications.

Cerner favors incremental certification, where the bar is raised over time. An approach used in MU3, which is seen favorably, is that developers and the community who would benefit from APIs get a chance to test them in the real world before any regulatory language is adopted that specifies a particular technical approach.

- **CMS’ role.** One participant believes that further the implementation of population level APIs, CMS could mandate that payment data be provided to CMS through APIs for providers to be reimbursed. CMS must require this not as regulation, but as a major payer. If CMS requires it, all other payers will follow.

- **Data access rights.** One participant argued that “the hard part is going to be figuring out data access rights and specific use cases.”

- **Different latencies.** Discussion of latency raised the thought that for some use cases, it may be appropriate to have a bulk API for the initial load, with ongoing data sent via synchronous APIs.
OVERVIEW

Wayne Kubick summarized the vision and mission of Health Level 7 International (HL7), described what's new in FHIR R4, and explained the rationale for creation of the HL7 FHIR Foundation.

HL7 is the organization responsible for development of the FHIR standard. As part of the next release of FHIR, targeted for December 2018, the plan is to include normative content and the population level data extract implementation guide, as well as other features. HL7 has also created the HL7 FHIR Foundation to support the community of users in the implementation of FHIR. The HL7 FHIR Foundation will serve as a trusted third party in providing resources and tools.

KEY TAKEAWAYS

FHIR IS A TOP PRIORITY.

HL7 is a non-profit, American National Standards Institute (ANSI)-accredited, consensus-based healthcare standards development organization with more than 2,500 members in over 55 countries. To date HL7 has developed over 300 standards products for multiple areas of healthcare.

HL7's mission is to provide standards that empower global health data interoperability. The organization’s vision is: a world in which everyone can securely access and use the right health data when and where they need it.

In addition, HL7 is the organization responsible for the development of the FHIR standard. HL7 is excited to take advantage of capabilities of FHIR to make population level data transfer doable and achievable in a relatively short period of time.

A GREAT DEAL WILL BE NEW IN FHIR R4, INCLUDING POPULATION LEVEL DATA EXTRACT SUPPORT.

Since FHIR was conceived in 2011, the goal has been to put out a new release roughly every 18 months.

The last release was in March of 2017. As shown in Figure 6, the next release (“R4”) is currently being worked on. It will go through multiple rounds of comments and is expected to be posted in the fourth quarter of 2018.

Figure 6. The Path to FHIR

FHIR Timeline

- The first normative content is scheduled for FHIR R4 late next year (2018).

Among the important new features of R4 are:

- R4 will be the first release of FHIR that will contain normative content. This means no breaking changes; it has to be backward compatible. This provides a new layer of stability. The idea is that each successive release will be adding more and more normative content.

- R4 represents a start with population level data, which could move very quickly. It is layered on and fits with the FHIR specification.

- R4 formalizes the SMART App Launch Protocol.

- R4 includes significant analytics pieces such as GraphQL support for FHIR queries.
"It’s pretty exciting to be able to apply these analytical tools directly on top of the FHIR resource model. That means these files will actually be useful directly to support analytical applications.”
— WAYNE KUBICK

- **New content** in areas such as public health case reporting, occupational data, and insurance plans.
- **Expanded content** for areas such as CDS Hooks, terminology services, and more.
- A newly rolled out **proficiency program** and proficiency exams for FHIR engineers. In the next year there will be efforts for a full certification program.

"By the end of [2018] we’re going to have a new release which will have normative content and a much more mature environment in terms of being able to qualify and recognize the capabilities of people working in the FHIR environment.”
— WAYNE KUBICK

Three Connectathons will be held in 2018: in New Orleans in January; Cologne, Germany in May; and Baltimore in September. The Baltimore event could be especially important because it will be on the eve of the release of R4 and due to the proximity to Washington D.C., many government representatives will be able to attend.

**THE FHIR FOUNDATION PROVIDES ADDITIONAL SUPPORT TO THE USER COMMUNITY.**

The focus of HL7 is creating the standard. But historically, after a standard was provided to the world, the work ended. However, with FHIR, there is recognition of a need to provide more support to the community of users who have implemented FHIR. Thus, a new, totally separate organization—the FHIR Foundation (www.fhir.org) —was created. The FHIR Foundation is a 501(c)(3) nonprofit.

This organization won’t be creating standards. It will be a trusted third party that puts infrastructure in place to help the community work together. It will also provide tools and resources that help organizations adopt and realize value from the standard. This includes implementation guides to help organizations avoid unnecessary duplication of effort and capitalize on what other organizations have done. The FHIR Foundation will work to expand the FHIR community. It will be funded and operate like a grassroots professional association with relatively inexpensive dues.

**ADDITIONAL COMMENT**

- **Include pharma.** While the meeting has included diverse stakeholders and use cases, a group that is not represented is the biopharmaceutical industry. Mr. Kubick encouraged including representatives from those areas in future discussions, as well as the Food and Drug Administration (FDA), which could be an important partner.
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Health System FHIR Innovators

Aneesh Chopra, President, CareJourney (Moderator)
Natasha Alexeeva, New Service Incubator Team, Amazon
Sandy Aronson, Executive Director of IT, Partners HealthCare Personalized Medicine
Eyal Oren, Product Manager, Google Brain Team
Kash Patel, Vice President, Information Technology, Mount Sinai Health System
Shafiq Rab, SVP & CIO, Rush University Medical Center

OVERVIEW
Aneesh Chopra led a discussion among technologists from major health systems that have used FHIR to extend their existing EHRs and capabilities, along with representatives from major technology companies (Amazon and Google) that are playing an active role in the healthcare technology ecosystem.

Major health systems are innovating by using FHIR APIs to extend their existing EHRs. They have visions of digital transformation that involve aggregating data from multiple sources, using multiple services and applications, supporting various use cases, and being able to easily export data. These health systems are finding workaround solutions today, but all are in favor of standards. They support greater use of APIs, including a FHIR population level data API. All participants agreed to be test beds to gain experience with a population level data API.

Major technology companies—such as Google, which is aggregating multiple types of data for machine learning, and Amazon, which has cloud capabilities to support providers—are important players in the health information ecosystem. They want to leverage their capabilities to support the ecosystem, and also want to see standards and a population level data API to make the process of gathering and sharing data easier.

KEY TAKEAWAYS
THE PANELISTS WERE ALL WILLING TO TEST A POPULATION LEVEL DATA API.

RUSH IS USING FHIR AS AN ENABLER TO EXTEND EPIC.
Rush University Medical Center uses Epic. But Rush has extended Epic by creating its own common services layer which uses FHIR; Rush uses FHIR services and about 30 FHIR resources that came out of Epic. Rush is taking in data from multiple sources; it can take anything from HL7 and convert it into FHIR or from FHIR back into HL7.

A use case at Rush involves SMART on FHIR and CDS Hooks to help patients needing medical and social assistance. Rush created a FHIR server that pushes secure patient data with information about a patient’s health information, as well as information about a patient’s need for lodging, clothing, and food. That information goes from Rush in real time, using FHIR resources, to a social welfare system, which finds donors to assist patients. Patients receive real-time notification about assistance. This is using FHIR to extend Epic to connect with a third-party provider of social services.

REUSABLE APIS ARE THE CORE ENABLER FOR MOUNT SINAI’S DIGITAL TRANSFORMATION VISION.
Mount Sinai Health System has 7 hospitals and more than 200 community locations around New York. This health system utilizes 7 different EHRs—including Epic, Allscripts, and athenahealth—and has approximately 90 systems generating clinical data. Mt. Sinai is bringing all of its clinical data into a central data warehouse and has created its own set of models for the exchange of data, which is essentially through the FHIR API. Mt. Sinai currently has an API Connect Portal and is working toward a longer-term vision of creating a set of shared services around APIs (see Figure 7).
Mt. Sinai is using APIs for a tool the health system has created called Patient 360. Another use case involving APIs for population level data is for marketing. Mt. Sinai is running campaigns where it is sending 300 or so scheduling messages every 30 minutes. It is tracking conversions and appointments. Yet another use case is sema4, which is an external vendor that provides genetic analysis based on clinical data sent by Mt. Sinai via APIs.

What is envisioned is freeing up data as an asset and as a service, where data can be exported or imported, using APIs. With this as the vision, Mt. Sinai is hopeful about a standards-based approach and is open to participating in pilots to gain experience and bring ideas to scale.

Figure 7. Use of Reusable APIs at Mount Sinai Health System

PARTNERS HEALTHCARE IS BUILDING A HEALTH INNOVATION PLATFORM TO REDUCE THE COSTS OF BUILDING SMART APPS.

Partner HealthCare’s Personalized Medicine group works with clinical teams that have an idea to change a clinical workflow or create a new workflow, where it is not appropriate to do so within an existing EHR system. To solve this, Partners HealthCare is building the Health Innovation Platform (HIP), which is an extension within Partners HealthCare’s environment of the SMART on FHIR standard. HIP is an open source, microservices-based platform that is trying to reduce the cost of building SMART apps.

Today, HIP and SMART apps take in data from multiple sources, in multiple formats. Aronson wants to get to exposing data through FHIR-based endpoints, based on profiles that are optimized for the data that is built, and wants to move toward standardization wherever possible.

At the moment, the biggest challenge is obtaining clean patient-by-patient data, as opposed to population level data. But there are scenarios where accessing population level data is critical. There are, however, mechanisms within Partners HealthCare for obtaining population level data from Epic. A greater issue related to population level data is importing external data, such as data streams from other genetics laboratories.

GOOGLE WANTS A POPULATION LEVEL DATA API TO PROVIDE EASIER ACCESS TO DATA.

Google, which is actively involved in healthcare, acknowledges there is a great deal of data within EHRs, but there is even more health data outside of EHRs—and most health data are never used. For example, most analytical and predictive models ignore notes within health records.

As a result of such little data being used, predictive models within healthcare don’t tend to be very accurate. Google is working to improve predictions by using all of the data that are available. This includes working with various providers and medical centers to develop accurate predictions in important areas, which could lead to early interventions that improve health. Google’s efforts are not tied to any specific vendor. It also wants the models it builds to be scalable across the health system, and not focused on a particular disease or situation.

Today Google is importing data from multiple sources, including anonymous patient records, claims, notes, laboratories, medications, and encounter histories. Google is spending a great deal of time converting data to FHIR and applying machine learning and deep learning. However, they find this to be a challenging undertaking: obtaining the data can be difficult, data may be corrupt, resources within provider organizations to support these types of endeavors are limited, there is a great deal of “one-off” work for data transfers, and things can go wrong.

Ultimately, population level data is critical for machine learning. Therefore, a bulk FHIR API would be extremely beneficial for Google’s purposes. In providing population level data, the timeliness of this data is essential.

AMAZON WANTS TO ASSIST HEALTH PROVIDERS—BOTH LARGE AND SMALL.

Amazon sees providers that have standalone technology services and have data in silos not being used. Amazon assists providers in moving data from multiple sources into a virtual private cloud, and getting greater use from this data. This approach uses FHIR, is scalable, and has value for both large health systems and smaller providers in remote locations.
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ONC Regulatory Approach and Next Steps

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program, Boston Children’s Hospital (Moderator)
Don Rucker, MD, National Coordinator for Health Information Technology (Moderator)

OVERVIEW

Ken Mandl led a wrap-up discussion on conclusions and next steps from this meeting. Don Rucker shared observations about the meeting and on regulations that might be required to proceed.

Interest in a FHIR-based population level data API is high, as is support for the technical specifications that were proposed. Participants are more enthusiastic about working collaboratively on real-world use cases where an API can relieve significant pain, improve efficiency, and reduce costs. Possible use cases include using population level data for quality reporting and to identify appropriate patients for care management programs. Even with a FHIR API there will still be a need for defining and mapping data and for getting access to data on a timely basis.

While providers, payers, and vendors see the immediate benefits as improving efficiency and decreasing the costs of accessing population level data, in the view of ONC’s National Coordinator, the greater benefit is improving the entire healthcare system by enabling data liquidity. This will increase transparency and competition, lower overall costs, and improve the care provided—all of which benefit patients.

KEY TAKEAWAYS

ONC IS EXTREMELY INTERESTED IN INTEROPERABILITY AND SEES GREAT POTENTIAL IN A FHIR-BASED POPULATION LEVEL DATA API.

Don Rucker sees this as an exciting time in health information technology. Almost every person has a powerful computer in their pockets and there are networks that share data in most parts of the country. Political leaders want to see more interoperability and want to make the healthcare infrastructure more efficient.

However, there is a great deal in healthcare that is not working. HHS understands this and is working to improve it. For example, there is documentation burden on providers, which was intended to provide greater institutional and provider accountability. But there is interest in different, more modern ways of having accountability, data transparency, and data liquidity while lowering the costs of healthcare.

Rucker sees FHIR on an individual and a bulk basis as a wonderful opportunity, and sees the RESTful standards and concepts that underpin FHIR as exciting.

Some participants said that a population level data API will improve efficiency in transferring data, but don’t see direct benefits for consumers. Rucker countered that increasing data liquidity lowers costs, increases transparency, increases competition, and spurs innovation, all of which benefit consumers.

MOST PARTICIPANTS SUPPORT THE GENERAL TECHNICAL DIRECTION.

No one opposed the general technical direction that was articulated for a FHIR-based population level data API. Several participants discussed the need to address specific details and others expressed support for moving forward to pilot and get experience.

MOST PARTICIPANTS DO NOT FAVOR REGULATION AS THE WAY TO PROCEED WITH A POPULATION LEVEL DATA API.

A representative from a major EHR vendor said that it is important for the vendor community and the healthcare ecosystem to get clarity regarding the regulatory direction. But multiple participants said that a regulatory push is not necessary, and participants did not favor a regulatory push.
Don Rucker concurred, saying he was optimistic that it would be possible that progress being made through existing regulatory authority could preclude the need for additional legislation. The prevailing view was that use cases will drive adoption and use of a population level data API.

The most interest among EHR vendors, payers, and providers was in instances where population level data are already being aggregated, transferred, and extracted, but doing so is difficult, inefficient, and costly. Some EHR vendors expressed reluctance to spend time and effort where they have already created interfaces, but are open to a population level data API for new situations where there is not an existing interface.

Possible use cases mentioned were:

- Exporting population level data to automatically compute quality measures.
- Gathering data required under CMS alternative payment models in a more automated way could be done more quickly and much less expensively.
- Aligning various CMS data requirements with private payer data requirements.
- Using an API to allow information needed under CMS Innovation Center® care models for specific diseases to be loaded into an app.
- Using population level data to identify the most appropriate patients to enroll in care management programs.
- Combining data of different types, from different sources, such as claims data and laboratory data. This provides a greater ability to mine data for clinical purposes, such as providing early notice of pre-diabetic patients.
- Amassing a significant enough volume of population level data to provide the ability to effectively use machine learning technologies to analyze data. For machine learning to be valuable, enormous amounts of data are required.

One participant said that for a use case to be compelling, it has to be something that is urgent, important, and new. If it is only urgent and important, other solutions would have already been developed, even if inefficient and painful.

Multiple participants stressed the importance of the timeliness of data, with one participant saying that high volumes of granular real-time data, down to the second, were more important than the cleanliness of the data.

Another participant commented that just defining the resource that can be exposed isn’t sufficient; it is also necessary to define the data and to have mapping.

This led to recognition that some use cases don’t provide complete solutions, but they may still provide significant incremental value.

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8 [https://innovation.cms.gov/](https://innovation.cms.gov/)