Computational Health Informatics Program

Boston Children's Hospital

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SMART Decisions

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EXECUTIVE SUMMARIES

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SMART Goals

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program, Boston Children's Hospital

OVERVIEW

Since the original vision of substitutable apps for EMRs was conceived in 2008, tremendous progress has been made in terms of technology development and policy, including the 21st Century Cures Act which requires an API for certified HIT products.

Still, much more work needs to be done including support for an open, industry standard API; giving patients and providers the ability to choose and connect to any app; and enabling connected apps to continue to work for some period of time after they are installed. Additional work should focus on giving developers confidence to invest in developing apps, eliminating variation in API implementations and business rules, eliminating the need for physicians to have to remember to launch an app at the right point in the workflow, and enabling apps to both read and write.

With agreement and concerted action by the entire community, in a short period of time this vision can become a reality.

CONTEXT

Ken Mandl kicked off the meeting by providing background on where SMART is, described how we got here, laid out goals for the future, and summarized hurdles to be addressed.

KEY TAKEAWAYS

THE QUESTION HAS ALWAYS BEEN, CAN EMRS BEHAVE LIKE IPHONES?

At the end of 2008, when there were just 10,000 iPhone apps, Ken Mandl and Isaac Kohane wondered if EMRs could behave like iPhones with substitutable apps and if there could be a healthcare app store.

To enable substitutable apps—and knowing in 2009 that a meaningful use program was being developed—they suggested an API for EHRs that would be common and open. But this idea was ignored. Still, Mandl and Kohane got funding to pursue the idea of an app store for health.

Key enablers that followed were:

- The SMART team jumped in to use and help develop FHIR.
- In an Aneesh Chopra-led charge, MU3 opened the door to API access in EHRs on the basis of patient rights to data.
- The Argonaut project has formed consensus around implementation of the SMART API and includes EHR vendors, technology companies, and health systems. Now a conforming API is emerging.
- The Precision Medicine Initiative gives patients an opportunity to use a version of the SMART API to get a copy of their data and deliver it to the Precision Medicine Initiative. This is the beginning of a patient-facing app and the ability of a patient to move their data in the healthcare system.
- The SMART/FHIR Apps Gallery creates an open directory for listing and finding apps.
- The 21st Century Cures Act contains language that requires an API for certified HIT. This language says that to be a certified health information technology, the developer needs to publish an API that allows health information from the technology to be exchanged without special effort.

> "I would argue that if there's no special effort, it's got to be the same API everywhere, because otherwise it is very special. . . . So I think we can read into the intent of this that we're looking at what could be a common API."
>
> — KEN MANDL

As various efforts took place, the idea has remained to get interoperability so that if an app is written once it can run anywhere.

WHILE MUCH PROGRESS HAS BEEN MADE, MUCH STILL REMAINS TO BE DONE.

In assessing the current situation, Ken Mandl and the SMART team articulated six desiderata:

Desiderata	Comment
Certified HIT requires support for an **open, industry standard API** making accessible the preponderance of structured clinical and demographic data, diagnostic imaging, and unstructured text notes.	This means apps have accessed data sources from the health system in a standard way.
Health systems and office practices can connect any third-party app of their choice that is conformant with the API **without pre-registering the app** with the certified HIT vendor.	This means working together as a community to empower health systems, office practices, hospitals, and other providers to select and connect apps of their choice.
Patients can connect **any third-party app of their choice** that is conformant with the API **without pre-registering the app** with the certified HIT vendor.	This is about giving patients the ability to choose and connect the app of their choice.
Connected apps can continue **accessing data for a minimum of 1 year** without requiring additional user action. However, the user that connected the app may remove its access at any time.	The 1-year timing is open for discussion but the idea is that once an app is connected it should work for a while.
Certified HIT must publish and update a list of the **patient-facing API endpoints** in a computable format and update it on a minimum of a monthly basis.	An updated list of patient-facing endpoints is critical to see the progress that has been made.
Certified HIT must be configurable to **trigger third-party decision support** services through an industry-standard API when a patient chart is accessed.	Automated triggers will mean that doctors and other clinicians don't have to always remember to launch an app. Forcing doctors to remember to open an app would be a formula for failure.

FURTHER PROGRESS ON THE PATH TO SUBSTITUTABLE APPS REQUIRES OVERCOMING SEVERAL HURDLES.

These hurdles and an explanation of them include:

Hurdles	Comment
Thousands of software developers need more confidence to invest in this technology.	For the economy of apps to blossom, more confidence is needed by developers to invest. There is an initial trickle, but more investment by developers is needed to turn this into a flow.
There is variation in API implementations.	There is still some variation in API implementation, even though the consensus process has gotten us very close.
There is variation in business rules for connecting apps.	The variation in the business rules needs to be addressed.
Physicians need to "remember" to launch an app at the right point during a workflow.	Right now, physicians need to remember to launch apps. Triggers need to be built in.
Apps are more focused on read than write.	Today, it is possible to write to the genome but not the electronic medical record. The vendor community is working to address this, but it's not a simple problem. Solving it is extremely important.

> "There is a tremendous amount we can do with read only, but if you can't write back in, people begin to lose enthusiasm quickly."
>
> — KEN MANDL

Political Perspective: Senator Cassidy and Representative Burgess

Bill Cassidy, MD, U.S. Senator, Louisiana
Michael Burgess, MD, U.S. Congressman, Texas 26th District

OVERVIEW

Political leaders realize the potential of health information technology to transform healthcare. They are also keenly aware of the challenges currently faced with HIT due to lack of interoperability, lack of a common API, and EHR technology that disrupts the patient-physician experience.

Recent legislation—particularly provisions of the 21st Century Cures Act—will improve interoperability, create a common API, and spark creation of a healthcare app economy.

CONTEXT

Senator Cassidy (a hepatologist) and Representative Burgess (an OB/GYN) are two of the most influential voices on healthcare policy in the U.S. Congress. Both have been deeply involved in provisions of the 21st Century Cures Act dealing with interoperability. They shared thoughts on the use of technology in healthcare, on the 21st Century Cures Act, and on the role of legislation.

KEY TAKEAWAYS

INFORMATION TECHNOLOGY CAN HAVE A PROFOUND IMPACT IN HEALTHCARE, BUT IT MUST BE MORE USABLE.

Years ago Representative Burgess was not a believer in using computers in healthcare. He saw added costs and complexity, without commensurate benefits. He reluctantly began using computers in the 1990s when Medicare required electronic claim submission.

But it wasn't until after Hurricane Katrina in 2005 that he truly saw the value of digitizing health information. He saw thousands of paper medical records in hospital basements that were destroyed and all information lost. At the same time, doctors treating evacuated patients in Dallas were able to access prescription information in databases at places like Walgreens, which could help recreate a patient's medication list and medical history.

Senator Cassidy sees today's EHR as just the beginning in the creation of a health information platform. He sees the technology evolving to speak a common language, become interoperable, and integrate with billing. He also sees an evolution of the EHR to add more personal medical information including pharmaceutical information, genomic data, and biome information.

However, there are many problems and concerns with today's EHRs and health information technology:

- **HIT has hurt productivity.** In most industries technology boosts productivity, but in healthcare software has hurt productivity.
- **EHRs aren't patient focused.** Doctors often spend more time looking at a computer screen than looking in patients' eyes, which has eroded the patient-doctor relationship.

> "The way the current system works, it incentivizes tapping on the computer and disincentivizes looking patients in the eyes."
>
> — SENATOR CASSIDY

- **It has worsened the experience for physicians.** Many doctors feel EHRs have worsened the experience of providing care and that EHRs are more about billing than patient care.
- **Systems aren't interoperable.** Many patients and doctors have significant frustration that data in different systems can't be easily exchanged. There is also lack of one lingua franca to create a common language between different systems.

PARTS OF THE 21ST CENTURY CURES ACT HAVE GREAT POTENTIAL TO IMPROVE HIT.

Senator Cassidy was involved in developing the Trust IT Act, which was folded into the 21st Century Cures Act. Several HIT-related provisions are very positive:

- **A rating system that compares different HIT products, administered by a third party.**
- **Interoperability metrics.**
- **Attestation to no information blocking.**
- **CMS and ONC will study how to decrease administrative errors.**
- **HIT developers must publish their API.** This enables developers to develop plug-and-play apps.

Representative Burgess concurs that provisions in the 21st Century Cures Act will help improve interoperability. In particular he mentioned working with existing organizations like the American National Standards Institute to achieve standards for interoperability. He also sees MACRA (Medicare Access and Chip Authorization Act) as legislation that will bolster HIT.

In addition, Senator Cassidy noted that Donald Rucker's plans as the National Coordinator of ONC to refocus meaningful use phase three on blocking and usability is a positive direction.

WHILE RECENT LEGISLATION WAS VIEWED POSITIVELY, AT TIMES GOVERNMENT CAN OVERREACH.

Both Senator Cassidy and Representative Burgess are optimistic about the impact of the 21st Century Cures legislation to improve interoperability, which will in turn improve healthcare delivery. However, they both feel that at times legislators and regulators impede progress:

- Previous meaningful use requirements have been problematic, bogged down clinicians, and forced technology into practice.
- The HITECH Act created a standards committee which took a long time to set up and was tasked with implementing standards, even though organizations in the private sector had already created standards. Per Representative Burgess, "It wasn't necessary to do this entire process again at the federal government."

In being asked about the government's role in promoting the boon that can come from the creation of a U.S.-based healthcare app economy, Representative Burgess replied, "Make sure we don't get in the way."

Importance of API Language in 21st Century Cures Act

Ken Mandl commended Senator Cassidy and Representative Burgess for their role in including API language in the 21st Century Cures Act. The law now states that certified health IT needs an API to enable healthcare information to be accessed, exchanged, and used without special effort.

> "I cannot overemphasize the importance of this. . . . What you have done is pave the way for the healthcare Internet."
>
> — KEN MANDL

Steve Jobs changed the world with an API. Because of the iOS API, within a few years more lines of code had been written for the iPhone than any other project in computational history. The apps economy exploded.

The app space in healthcare has not yet exploded. The only way to achieve that is a single, common, public API. The 21st Century Cures Act now makes that possible. There is now potential for a massive healthcare apps marketplace, which could create an economic boon for the United States.

Deep Learning and Applications in Medicine and Science

Jeffrey Dean, PhD, Senior Fellow, Google Research Group

OVERVIEW

Creating systems that learn from observations, along with advances in computability and access to more and larger datasets, has led to a revolution in artificial intelligence and machine learning. The future that computer scientists once envisioned of intelligent computing systems is becoming a reality.

There are numerous uses in healthcare for intelligent computing systems. These systems can help doctors to review and assess images faster, better and more consistently. They can review the data in electronic medical records and predict a patient's future. They can inform a doctor about potential diagnoses for a patient and can recommend tests to run. And, they can be used to expedite the drug development process.

Also, in the future, because most organizations lack machine learning expertise, models will generate other machine learning models and will train those models.

CONTEXT

Google's Jeff Dean described what machine learning is, why it has become more exciting in the past few years, and how it may be used in healthcare to improve the speed and accuracy of decisions.

KEY TAKEAWAYS

THERE IS INCREASING OPTIMISM ABOUT BUILDING INTELLIGENT COMPUTING SYSTEMS.

The dream of building intelligent computing systems began in the 1940s and 50s, but has been elusive. For years the approach used involved logical rules, but it turns out that a better approach for building intelligent systems is creating systems that learn from observations.

> "We've realized that learning from observations about the world is the way to make intelligent systems."
>
> — JEFF DEAN

Machine learning is a subset of AI involving neural networks that makes computers learn. It has caused a major revolution over the past few years in the field of computer science. Deep learning (also referred to as deep neural networks) is a type of machine learning where layers of computers work together to solve extremely complicated problems.

As an example, a model could be trained by analyzing pixels in an image and predicting whether the pixel is of a cat or a dog. If the prediction is wrong, the model assesses why it was wrong and makes adjustments to improve its accuracy.

Other, more sophisticated examples of machine learning include models that can:

- Distinguish raw pixels not just from two categories (cat or dog), but from 20,000 categories.
- Take raw audio data in a recording and predict what was said.
- Take a sequence of characters and words and predict the translation in a different language.
- Take in pixels and create a sentence that describes the image in a human way.

New over the past few years is the scale of computability (due to Moore's Law) and the scale of large datasets. This has reignited excitement about building intelligent systems that can learn through observation. In just the past six years a contest at Stanford has shown a dramatic decrease in the error rate of AI systems.

GOOGLE'S BRAIN TEAM IS DOING ADVANCED MACHINE LEARNING RESEARCH IN HEALTHCARE AND ELSEWHERE.

The Brain Team at Google is doing advanced machine learning research focused on augmenting humans with machine intelligence. This includes long-term research, creation of open source systems, collaborating on the creation of new products, training new researchers, providing internships, and conducting applied machine learning research in emerging areas, including in healthcare. This team also:

- **Produces software** that makes it easy to do machine learning. Goals include speeding up the cycle time for trying machine learning ideas from weeks to hours.
- **Built an open source machine learning platform** (TensorFlow) that enables taking a machine learning idea and expressing it in executable code that people can share as a community. It enables ideas to spread faster. Google's Brain Team uses TensorFlow for all of its own research. Because it is open source, there are many external contributors who are making improvements. It is starting to be used in machine learning classes in universities.

OFTEN SOLUTIONS IN ONE DOMAIN CAN BE REPURPOSED IN ANOTHER DOMAIN.

For example, a solution developed by Google's Street team to read text in images was repurposed by the Google Earth team. That same model can be applied to solve medical problems.

A starting point in healthcare was to focus on medical imaging, looking at a vision problem diagnosed by an image of a patient's retina. Today, ophthalmologists review images and grade them on a scale of 1 to 5, with different treatments based on the grade. However, there are two problems:

1. When two different ophthalmologists review the same image, they only give it the same grade 60% of the time, showing variability between doctors.
2. When the same ophthalmologist reviews the same image a few hours later, they only concur with themselves 65% of the time, showing variability by the same doctor.

Using machine learning Google created a model that reviews images and provides a grade. This model's performance is slightly better than the median of an U.S. board-certified ophthalmologist. The model can review and provide grades for 100 images per second. The model is currently being reviewed by the FDA and is part of a clinical trial in India.

Google is also developing a model for pathology that reviews images, though these images are often 100,000 by 100,000 pixels. This model yields far fewer errors than human analysis. Machines can be trained on far more data than a human can ever see, and can review and process data faster and better.

GOOGLE IS WORKING TO SEE IF DATA IN A PATIENT'S EHR CAN PREDICT THE FUTURE.

The idea is to think of a medical record as a whole bunch of events, and to use the data about these events to predict future events. For example, a type of event that would be good to predict is a patient being admitted to the hospital in the next 10 days.

An interesting question and prediction is what are the five most likely diagnoses for the patient right now? What tests should be considered? Which patients have the highest risk for X? (Because of the uncertainty of the medical data it will be necessary to give bounds of the uncertainty.)

A doctor has a broad perceptual lens in assessing a patient. However, a doctor may see 15,000 patients over the course of a career and an AI model might be able to scan the data from a million patients, providing far more information, especially for rare or uncommon diseases.

> "What I'm most excited about is being able to offer real-time advice that lets doctors say, 'OK, maybe I should consider the second most likely alternative to see if that could be it. It could be something I've never seen before.'"
>
> — JEFF DEAN

GOOGLE IS TRYING TO BUILD LEARNING SYSTEMS THAT LEARN HOW TO LEARN.

Today, solving machine learning problems is a sequential process requiring human machine learning expertise. As a result, while there are perhaps 10 million organizations that have good data and should be using machine learning, there may only be 1,000 organizations in the world with machine learning experts.

To extend the use of machine learning, Google is trying to use technology to automate the creation of machine learning models. This is already happening and is working, and there is a drop in the error rate of these models over time.

> "We are creating a model that can generate machine learning models. And we're training that model to generate good machine learning models."
>
> — JEFF DEAN

SMART Update, SMART FHIR App Gallery

Daniel Gottlieb, Technical Lead for SMART Health IT Project

OVERVIEW

SMART makes it easy to connect healthcare apps to clinical systems by creating technical specifications for apps and clinical systems to connect and by providing tools and resources to developers—including a software library, sandboxes, and datasets. SMART has also created an App Gallery where developers can post apps and healthcare providers can access them, with the ability to try them with sample data before using them with their own data.

CONTEXT

Dan Gottlieb provided a brief overview of exactly what SMART does, described key elements of SMART's technical specifications, and outlined key tools and resources. He also explained the SMART App Gallery.

KEY TAKEAWAYS

SMART IS FOCUSED ON MAKING IT EASY TO CONNECT HEALTHCARE APPS TO CLINICAL SYSTEMS.

SMART was initially funded through a grant from ONC and received another grant to expand the SMART App Gallery and provide developer tools. As part of the grant, the SMART team worked with KLAS to survey clinical and IT leadership at healthcare institutions to understand the types of apps they are using today and want in the future, as well as barriers in using apps.

One of the physicians surveyed commented about having a wonderful population health tool but lamented that it did not interface with the EHR system. As a result, this health system had to enter information by hand. They abandoned this effort because they couldn't keep up. This is the core of the problem SMART is trying to solve: making it easier to connect healthcare apps to clinical systems.

- **Healthcare apps:** People often think of healthcare apps as patient-facing apps on an iPhone. That is one use case, but most apps in healthcare are running as web apps within an EHR.
- **Clinical systems:** Many people's minds jump to EHRs, which are a major clinical systems use case. SMART also works through patient portals and data warehouses, which are important use cases as well, as data flows into a clinical data warehouse for multiple EHRs.

In making it easier to connect without custom integration, there are four necessities the SMART specification focuses on:

1. **Clinical data:** SMART uses FHIR, which is an international standard for data models and API access.
2. **Single sign-on:** This is important so that when a provider launches an app they don't have a separate account they have to log into.
3. **Authorization:** With authorization a user is in control of which apps can access data elements in the EHR.
4. **User experience integration:** It is important for the EHR to pass context information through the app.

> "From a developer perspective using SMART means that everything's based on open web standards so there's a large community, which makes it easy for developers to get started."
>
> — DAN GOTTLIEB

The SMART project mainly does three things:

1. Works on the standards-based technology stack
2. Provides open source tools and resources that streamline work for developers
3. Provides a public app gallery

SMART PROVIDES TOOLS AND RESOURCES FOR DEVELOPERS.

These tools and resources include:

- **Software libraries:** It doesn't make sense for developers to start from scratch in developing an app. So, the SMART team maintains libraries for web apps, iOS apps, and server apps using iPhone, and has other libraries for Java, .net, and more.

> "If you're a developer and you're getting started building SMART apps, using SMART on FHIR if you want to plug into EHRs, you can start working on these libraries, which encapsulate all these standards for you and streamline the process."
>
> — DAN GOTTLIEB

- **Sandboxes:** The SMART Sandbox simulates an EHR environment, so a developer can test their app against sample data as if it were being launched from within the EHR. In addition to the online server, SMART also provides an installer for developers to create a local version of the sandbox.
- **Datasets:** The SMART STU3 sandbox hosts sample data for over 1,500 patients, including real patient reported outcome surveys for 100 patients from the National Health Service in the UK. In addition to the data in the sandbox, SMART licensed a longitudinal dataset from Geisinger Health System with about 10,000 patients over a 10-year period with millions of observations. SMART app developers can request access to this data through the SMART website.

THE SMART APP GALLERY IS A SITE WITH A COLLECTION OF HEALTHCARE APPS.

App developers can post app listings and users can browse for apps based on category, pricing or licensing structure, intended user (patient, provider or IT), FHIR version compatibility, operating system compatibility, and EHR vendor support. Any FHIR app can be posted to the gallery, and can be demoed against the SMART sandbox using the 'Try App' button from the app listing page.

SMART Extensions: SYNC for Science, CDS Hooks

Josh Mandel, MD, Harvard Medical School; Health IT Ecosystem Lead, Verily

OVERVIEW

SMART Extensions are efforts to take SMART to the next level. One is SYNC for Science, which uses SMART on FHIR to enable patients to access their health data (in an EHR) and share this data for research. Work is progressing and 15 pilots are anticipated by the end of the year.

A second extension is CDS Hooks, which envisions using triggers (called hooks) in an EHR workflow to make clinicians aware of external services and apps that may be beneficial at a specific point of care. This extension is early in the development cycle, but has tremendous potential.

CONTEXT

Josh Mandel described SYNC for Science, which is a use case being built on SMART on FHIR API capabilities, and explained CDS Hooks.

KEY TAKEAWAYS

SYNC FOR SCIENCE ALLOWS PATIENTS TO DONATE THEIR DATA FOR RESEARCH.

SYNC for Science is a use case of SMART focused on something that is important to many patients. It allows patients to access their data and gives them the ability to donate this data for research.

This use case results from meaningful use stage 3, which gives a patient the right to access their data using an app of their choice, through an API. ONC asked Josh's group for help in using technology to enable patients to share data for research. The aspiration is that at the click of a button a patient can voluntarily share their health data with scientists engaged in research.

Today, clinical research typically uses one of two models:

- **Hospital-centered.** Patients are recruited to participate by a hospital or network of hospitals. The participating institutions are able to recruit patients at the point of care in a trusted environment. The hospitals can agree on data formats and how data is shared, and can put someone at each hospital in charge of how to extract data from the patient's EHR, code it appropriately, and send it to a central database.

  The downside is that creating a hospital network for research can be slow and expensive, and recruiting enough patients with a particular disease—especially a rare disease—can be difficult.

- **Person-centered.** Patients are recruited directly to participate in research, often by advertising, as well as by working with disease foundations, patient advocacy groups, and community outreach. This meets patients where they are. The downside is that once patients volunteer to participate, collecting their EHR data from different sources can be difficult, slow, and expensive.

  This is where SYNC for Science fits in. It is a technology solution that builds on top of tools that EHR vendors are putting together as part of MU3.

  Josh's team didn't want to create a new way to share data just for researchers; they wanted to take what is already existing in the MU3 landscape and use it to help patients if they decide to share data.

Josh's group has been working with a technical team at Harvard Medical School and with EHR vendors, including Cerner, Epic, AllScripts, and eClinicalWorks. These vendors have patient portals, let patients view their data online, and enable patients to download files. The goal became to get consistent implementation of FHIR APIs inside each of these portals so researchers can put together apps that request data in a consistent way and connect to any of these systems. The vendors have all been participating in this project on a voluntary basis because it fits nicely into the regulatory landscape.

In creating SYNC for Science, the team has provided vendors and researchers with open standards and automated tools.

The result is an ecosystem in which:

- Many vendors and portals can provide support for APIs.
- SYNC for Science is building on SMART on FHIR as the layer in the middle.
- Anyone (including researchers) can build and connect an app. The workflow and experience for consumers will be consistent with standard apps.

In SYNC for Science's first pilot, the app asks the patient where they might have EHR data and then redirects the patient to the right portal.

> "[The patient] never shares their EHR password with the research app, but the research app can still get access to their data in a way that they control."
>
> — JOSH MANDEL

The goal for SYNC for Science is to have pilots running at 15 organizations by the end of this year. Goals include making it easy and inexpensive for patients to share their data, and to be ubiquitous.

CDS HOOKS AIMS TO GIVE EXTERNAL SERVICES A WAY TO PLUG INTO THE EHR.

As the idea of a common API and substitutable apps gains momentum, it is possible to imagine a future workflow challenge: how does a provider, while working within an EHR to deliver care, know what apps are available that would be relevant at that moment?

The idea is that when specific events happen in an EHR workflow the EHR would trigger something called "hooks." When a hook is triggered, external decision support services are notified and those services can decide whether to return information for a clinician to see (packaged in a "card"). If an external service returns cards, they can be displayed in the context of an EHR session for clinicians to see.

There are many potential hooks within different points of a workflow, and those hooks differ based on the type of EHR system, such as a general internal medicine system, a specialty system, or a pediatric system. The team working on CDS Hooks has worked to define a common set of activities and hooks for all EHR systems. Hooks might include notification that a new patient record has been opened or notification when prescribing a drug. A hook might provide a prompt informing a clinician that a particular tool is available to assist them.

The kind of interaction that CDS Hooks wants to support is dynamic and integrated into the EHR experience, but is standardized in the sense that if building a service, a new version doesn't need to be built for every different EHR.

CDS Hooks is an active development project. A CDS Hooks demo is available at cds-hooks.org.

The Last Mile: Delivering Apps and Services to the Point of Care

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program, Boston Children's Hospital (Moderator)
Paula Braun, Entrepreneur-in-Residence, Centers for Disease Control & Prevention
Nate Gross, Co-founder, Doximity
William Harty, Principal Software Architect, Clinical Surveillance Division, Premier Inc.
Rachel Petersen, Product Manager, Critical Performance Improvements Team, SureScripts
Jeremy Warner, MD, MS, Assistant Professor of Medicine and Biomedical Informatics, Vanderbilt University

OVERVIEW

Early adopters are developing apps that access data in EHRs via SMART on FHIR and fit with the EHR's workflow. These apps help clinicians address specific problems, like selecting the most appropriate medication, ensuring no medication safety issues, helping cancer patients understand treatment options, and aggregating cause of death information. SMART on FHIR has the potential to fundamentally change the game by providing the real-time information that is needed at the right moment.

CONTEXT

This panel of early adopters described the SMART on FHIR app(s) their organizations are developing, followed by a discussion of issues related to apps.

KEY TAKEAWAYS

MULTIPLE HEALTHCARE CLINICAL APPS HAVE BEEN DEVELOPED AND ARE BEING USED.

The panelists described their unique apps, the problems they solve, and how they work.

- **Doximity — app provides information from referring providers.** Doximity is the largest secure medical network in the United States. Over 70% of doctors are members, across all specialties and health systems, as are 90% of graduating medical students.

  Doximity has created an app that uses SMART on FHIR to link with EHRs. This app enables a physician to send a message through the EHR to the referring provider. The message can be used to coordinate care, share information such as lab results, or thank the provider for the referral. Messaging can take place through an iPhone.

  Previously, providers may have hardcoded a similar feature into their EHR, but doing so was a one-off customization that wasn't scalable. With SMART on FHIR, this app makes interacting with referring physicians easy and scalable.

> "We tried a few implementations of our EHR products that were hard coded. You get some flexibility to have the UI of your choice, but it doesn't end up being really scalable."
>
> — NATE GROSS

- **CDC — an app to modernize mortality reporting.** The CDC is focused on public health. In the earliest days of tracking public health, mortality reporting led to recognition that diseases and deaths followed predictable patterns. Now, hundreds of years later, cause of death information is still primarily captured on paper.

  The CDC wants to bring mortality surveillance into the modern world by creating a SMART on FHIR clinical decision support tool that uses deep learning to assist clinicians in making cause of death determinations. This tool fits within the physician's workflow, saves time, improves accuracy, and fits with predictive models the CDC is building to make real-time recommendations.

Long term, determining the cause of death is best done when combining the patient's diagnostic history, biometric information like toxicology results, and a physical examination through an autopsy. For now, the starting point is information in the EHR.

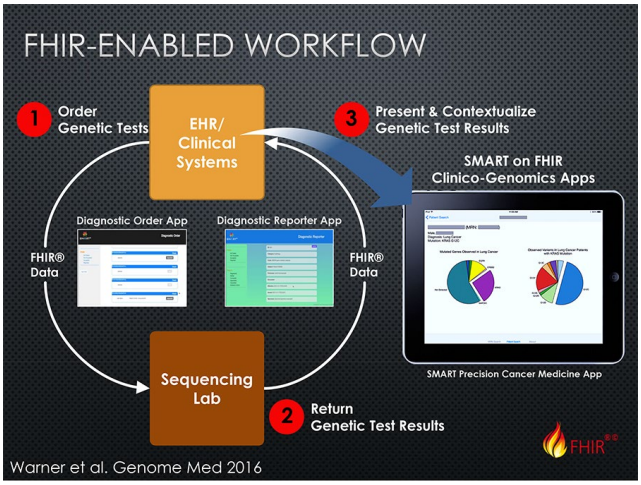
> "You can save lives by counting the dead. Let's honor this practice and use technology to make it simpler."
>
> — PAULA BRAUN, PARAPHRASING INSCRIPTION FROM MEDICAL EXAMINER OFFICE IN NEW YORK

A team at Georgia Tech is developing this SMART on FHIR app on a Cerner app platform. Creation of this initial app is a catalyst for other SMART on FHIR apps being developed by the CDC. It is likely that CDC-developed apps will be in the App Gallery in the next few years.

- **Premier — using CDS Hooks to advise clinicians on medications.** Premier provides a wealth of software for its members, including clinical surveillance tools which help providers at the point of care. Premier is working on apps that use CDS Hooks. Two examples of uses are:
  - *Medication advice*. Imagine a physician using an EHR to order a medication. The EHR calls out to the Premier clinical support app for medication recommendations based on relevant information contained in the patient's medical record. Results are displayed to the user within the EHR user interface.
  - *Identifying medication risks.* Similar to the first example, at the time of ordering a medication, the EHR calls out to the app. The app comes back with information indicating if any tests should have been conducted to eliminate risks prior to prescribing the medication.

  William Harty made an analogy of apps using CDS Hooks to Google Maps. Google Maps provides real-time decision support at the exact moment it is needed, but allows users to retain control. Google Maps is seamless and natural for users. It wouldn't be possible without an API. Like Google Maps, SMART on FHIR and CDS Hooks are game changers.
- **SureScripts — apps that enable the best medication decisions for patients.** SureScripts products provide useful, succinct data when clinicians are dealing with patients. It starts with selecting the right medication and helping patients adhere to their medications. SureScripts has built an app that can be rolled into an EHR in three ways: 1) an accelerator product outside of the EHR; 2) an app that plugs into a SMART container, giving clinicians the ability to access the app from the EHR workflow; and 3) rebuilding the functionality into the EHR.
- **SMART Precision Cancer Medicine.** When a patient is diagnosed with cancer, they wonder, who is like me? How long have I got? What are my options? Using the SMART Precision Cancer Medicine app, clinicians can begin to truly answer these questions.

  With the genomic era of cancer medicine, a FHIR-enabled workflow is shown below. It begins with ordering genetic tests, getting the results, and presenting and contextualizing the results.



Jeremy Warner has been involved in developing SMART Precision Cancer Medicine, a SMART on FHIR App developed to contextualize and visualize the genomic test results and to connect the provider with a third-party knowledge base. Providers can learn about a patient's specific cancer variant from a knowledge base called My Cancer Genome. This can help providers educate patients about their options and answer questions.

DISCUSSION

After learning about these apps and uses of SMART on FHIR, attendees asked questions and shared comments. Key takeaways include.

- **Changing EHRs is not scalable.** At the height of the Ebola scare, after one patient presented with Ebola, the CDC worked with EHR vendors to change workflows to better screen for and detect potential cases of Ebola. The vendors scrambled to make it work. In the end, no other cases came in and the decision support system was never used. This exercise was painful. Something like CDS Hooks would make it faster and easier to respond in such instances.
- **Investors' perspective.** Many entrepreneurs are developing apps, but few investors understand this space. There is a basic knowledge of interoperability and integration,

but not of clinical apps. In general, there is a reluctance to invest in a startup that is not 10X better than the existing EHR feature. Also, in adopting apps, CIOs are generally cautious and risk averse, choosing leading EHRs with known brands that are the current gold standard.

- **Changing the patient experience.** As was mentioned in an earlier session, during a patient encounter, clinicians often spend more time looking at a computer screen than directly at the patient. One app developer mentioned that apps used on a tablet could allow clinicians to interact with patients in a more personal way.
- **Having technology help with prioritization.** Clinicians wrestle with information overload and constant alerts. A significant opportunity is for machine learning to present information in a way that helps clinicians better prioritize their limited time with each patient.
- **Due diligence prior to adopting apps.** An attendee expressed concern about malicious apps being developed and implemented. To avoid this, providers will need to create rational decision-making processes for reviewing and selecting technologies, including reviewing an app's security. Having ratings of apps will help reduce risks and make informed decisions.

Current State: Native EHR API Capabilities and Business Models

Daniel Gottlieb, Technical Lead, SMART Health IT Project, Boston Children's Hospital (Moderator)
Tony Confrey, Senior Architect, Executive Director of Integration Services, athenahealth
Sharma Manoj, Innovation Architect, Allscripts
David McCallie, Senior Vice President, Medical Information, Cerner Corporation
Isaac Vetter, Software Developer, Leader of Interoperability Efforts, Epic

OVERVIEW

The vendors on this panel understand the desire of the marketplace—clients (mainly providers) and app developers—to have open APIs and access to third-party apps. They have proprietary APIs for their EHR products, while also generally supporting SMART, FHIR, Argonaut, and CDS Hooks. They are providing tools and resources to support developers, like sandboxes, and are providing app stores.

These specific steps are seen as an evolution in the role of EHRs as "platforms."

CONTEXT

Representatives from four leading EHR vendors described how they are thinking about APIs, apps, CDS Hooks, and more.

KEY TAKEAWAYS

ALL OF THE VENDORS ON THE PANEL ARE FULLY EMBRACING APIS, FHIR, APPS, AND CDS HOOKS TO SUPPORT THEIR CUSTOMERS AND THE EVOLVING MARKET.

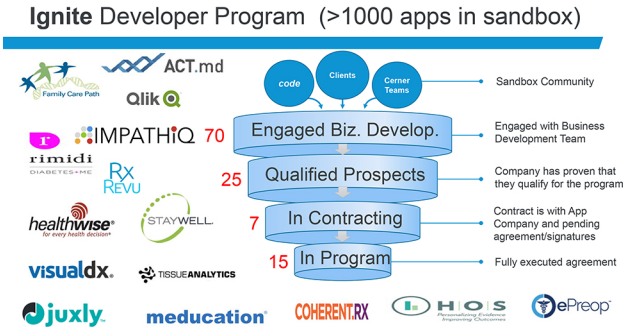
Each vendor briefly shared their perspective.

- **Epic.** Epic began supporting SMART on FHIR in its software in 2015, and this is the company's recommendation for developers building apps on Epic's developer platform. At the end of 2017 about 95% of organizations using Epic will have access to FHIR. Overall, Epic believes that standards-based interoperability decreases complexity and cost, and increases reliability for customers. Epic has a developer program, with tools, sandboxes, services, and documentation. Epic also has a marketplace (App Orchard) where community members can review and acquire commercial or free apps.

> "We encourage the use of APIs like FHIR and SMART and other loosely coupled web services. And we're generously defining an app to mean things like CDS service or even content."
>
> — ISAAC VETTER

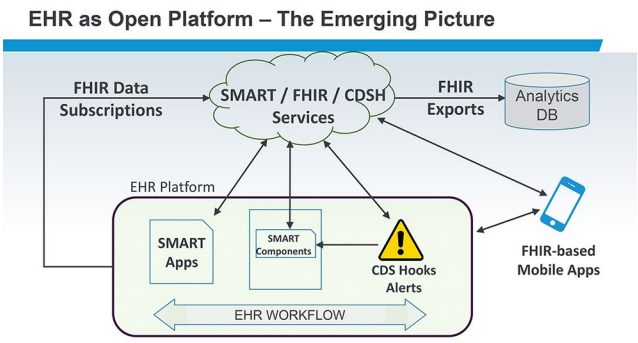
Looking ahead, Epic thinks the future will be market driven. Epic will continue to increase its interoperability features and marketplace features based on customer interest and demand. Epic is basing its roadmap on specific and high-value use cases, including CDS Hooks, and is taking an early look at the FHIR subscription spec.

- **Cerner.** Cerner is focused on the emerging standards of SMART and FHIR that make apps a reality. Cerner offers multiple tools and resources for app developers, with more planned. Shown below is Cerner's Ignite Developer Program, its business development process for app developers. The funnel begins with roughly 1,000 app developers expressing interest. Cerner's business development team works with developers to enter into a commercial relationship and deal with licenses. (Licensing and fees differ by category: provider facing, patient facing, and patient MU3.) Currently about 25 qualified prospects are working through that process and about half are running at client sites.



Longer term, Cerner sees EHRs evolving and emerging as open platforms. Important requirements of these platforms include SMART apps, CDS Hooks, and FHIR data subscriptions.

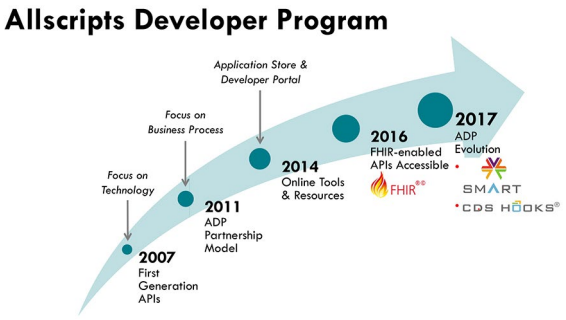
> "EHRs will become more like platforms."
>
> — DAVID MCCALLIE



But platforms are not necessarily as open as some might want. There is a distinction between what gets done by the EHR and what gets done by apps that plug into an EHR.

EHR-as-Platform – EHR Responsible for:	**Platform Extensions**
▪ User and patient management	▪ Address functional gaps
▪ Core workflows (orders, etc.)	▪ Increase user choice
▪ Legal medical record (data persistence)	▪ Encourage innovations
▪ Regulatory requirements	

- **Allscripts.** Allscripts introduced an initial API within its core EMR products in 2007 and this technology matured as the company built partnership models to support developers. This model provided accessibility to the solutions offered by partners. In 2014 Allscripts introduced an application store and the Allscripts developer portal that helps developers access tools and documents to code and use the API.



Today, Allscripts' proprietary open API has been used over 2.5 million times with Allscripts products. In the roadmap for 2017, Allscripts will start leveraging the FHIR-based API for provider and patient access. Allscripts is also looking to leverage Argonaut, CDS, and SMART in either its 2017 or 2018 products.

Allscripts provides free developer access as well as integrator- and partner-level tiers, and has a dedicated team that supports client activations of products and onboarding. A priority for 2017 and 2018 is to create an open, interoperable, connected network for all products within Allscripts.

- **athenahealth.** athena supports creating a marketplace where the best ideas, products, and services are available. It involves satisfying all players in the market:
  - Providers want less form filling, access to exactly the right data, and more focus on patients.
  - Patients want access to their data and want to engage with their care teams and communities. They also want to be able to shop for the best products and services.
  - Software developers want access to customers, and want documented, comprehensive APIs and sandboxes to help them.

> "There's a lot of value outside the doors banging to get in. I think we're all aligned to try to actually open up that marketplace to create it and make it real."
>
> — TONY CONFREY

athena is a multi-tenant, single-hosted application where all data is in one place in the cloud. athena is all about open standards and APIs. athena has opened up its system with a set of Rest APIs and launched an app marketplace. Today a developer can find the APIs, build an application, test it in the sandbox, submit it, and get it in front of 100,000 users in the athena network. There are about 150 app developers

using athena APIs, and 30% of athena customers use one or more apps for patient care. This month alone, there are expected to be more than 500 million transactions, proving that athena's business model for apps is working. A team within athena is chartered to build FHIR APIs, however it does not seem to be the main priority.

DISCUSSION

- **Apps vs. the role of the EHR.** A provider might be interested in an app if it provides a distinct capability not offered in an EHR, fits into the workflow, and integrates into the UI. David McCallie commented that app developers must decide whether to use proprietary APIs, which may offer additional capabilities but are locked into a particular vendor, or use open FHIR standards. Cerner hopes that more app developers will choose to use FHIR because it simplifies life for the app developers and the vendors. But, there are limits as to what can be done with non-proprietary APIs.
- **Letting the market decide.** The vendors shared the view that by creating app marketplaces, customers can decide on apps to adopt based on the features, usability, patient safety, security, legal issues, and more. Tony Confrey said that athena sees it as a relationship between the app vendor and the provider who purchases the app; athena does not vet apps. athena creates the marketplace, services it, and shares revenue.
- **Patient portal.** Most of the vendors have a patient-facing portal on their roadmap.
- **CDS Hooks.** All of the vendors are either piloting CDS Hooks or have it on their roadmap.
- **Passing data.** In response to a question about assurances to institutions that vendors will allow data to pass to another vendor, all panelists assured that "yes" they will allow data to pass.

Tools and Services for Marshalling Data at Scale

Andy Palmer, Koa Labs, Tamr (Moderator)
William Crawford, Senior Advisor, Enterprise and Digital Health Group, Fitbit (formerly)
Len D'Avolio, PhD, Co-founder, Cyft
Shawn Murphy, MD, PhD, Corporate Director of Research Computing and Information, Partners Healthcare
Jason O'Meara, Quest Diagnostics
John Shon, AB, MD, VP of Bioinformatics and Data Sciences, Illumina

OVERVIEW

The main opportunity in marshalling data at scale is improving clinician decisions at the point of care. Other opportunities include leveraging data to personalize care and providing patient-facing information that uses data to give patients more insights and control.

Data-related challenges that must be overcome involve dealing with the massive volume and variety of data, being able to pull together data from disparate sources, and being able to find the data that really matters.

CONTEXT

This session focused on data, both the challenges related to data in healthcare and the opportunities.

KEY TAKEAWAYS

HEALTHCARE IS NOT CURRENTLY AGGREGATING OR EFFECTIVELY LEVERAGING DATA AT THE POINT OF CARE.

The challenges discussed include:

- **Dealing with the massive volume and data and the many different varieties of data.** The amount of data in the EHR is already overwhelming, but with the addition of genomic data, imaging data, diagnostics, prescriptions, monitoring data, and enormous potential data from personal devices (like Fitbit), the data becomes truly massive. Managing this data takes computation power and expertise to determine what data really matters.

> "These [wearable devices] generate a lot of data. Depending on which device you are wearing and how active you are . . . there might be 10,000, 20,000, up to 100,000 data points a day for an individual. That's obviously a lot more data than 99% of applications are going to find useful. One big challenge is how do you wrap that up into much smaller indications that can drive some kind of whole decision making."
>
> — WILLIAM CRAWFORD

In addition, there is an endless amount of supporting information available from medical journals, clinical trials, changing clinical guidelines, etc. This amount of data and information cannot be effectively analyzed and applied as is.

- **Historically, the data in healthcare has not been used effectively.** Despite having an abundance of data, this data has not been used in healthcare at the point of care, has not been used to personalize treatment, and has not been leveraged to answer fundamental questions.

  One reason why data has not been effectively used is because of its form. The data in healthcare tends to be unstructured free text, is distributed, and is messy.

- **The incentives in healthcare have not pushed the industry to better utilize its data.** With the vast majority of healthcare still delivered through a fee-for-service payment model, there has not been a great demand to use data to improve quality of care.

THE OPPORTUNITIES FOR AGGREGATING AND USING DATA ARE SIGNIFICANT.

Opportunities mentioned by panelists include:

- **Uniting data.** Panelists are excited to use technology to aggregate data from multiple sources to provide a single view. This includes EHR data as well as multiple non-EHR sources such as separate niche databases, registries, images, monitoring data, genome data, data from personal health devices, and more. While much of the data produced by wearable devices like Fitbits may be of marginal value, data such as resting heart rate and sleep data—in combination with other data—may have some clinical value.

> "Being able to unite the data into a single view is in some ways the lowest-hanging fruit and is a most important, primary purpose for our app."
>
> — SHAWN MURPHY

Once data is united, intelligence can be layered on top and visual tools can enhance the presentation of the data. Data can then be used to make better diagnostic and treatment decisions.

> "Ultimately, it's about driving decisions at the point of care."
>
> — JASON O'MEARA

- **Analyzing healthcare's messy data.** A key reason that the data in healthcare has not been used effectively is because of how messy the data is. But technologies like machine learning and natural language processing change that. These technologies produce new types of analysis that improve healthcare.

> "After years of researching whether or not these technologies—machine learning and natural language processing—can be used to improve healthcare, the answer is definitely yes."
>
> — LEN D'AVOLIO

- **Personalizing healthcare.** Historically treatments in healthcare have been based on "average patients," even though there is no such thing as an average patient. By aggregating extensive data from multiple sources and using new technologies, treatments can become highly personalized.

> "It's incredibly important that we try to aggregate and leverage the data. There's going to be incredible insight learned from every individual patient, but also across large subsets of patients."
>
> — JOHN SHON

Open or Shut Case? Open Standards in Commercial Systems

John Wilbanks, Chief Commons Officer, Sage Bionetworks (Moderator)
Gil Alterovitz, Director of Biomedical Cybernetics Laboratory, Boston Children's Hospital
Deborah Estrin, Professor of Computer Science, Cornell Tech
Adrian Gropper, MD, Patient Privacy Rights
Andy Palmer, Koa Labs Tamr
Jon White, MD, ONC

OVERVIEW

There was strong agreement among the panelists that open standards and modularity are critical to enable innovation, and open standards provide multiple benefits to patients, clinicians, and researchers. The process for determining standards needs to have a sense of urgency and emphasize creating running code, as opposed to traditional consensus-driven standards committees, which are slow and bureaucratic.

CONTEXT

The panelists described the benefits of open standards, offered different reasons why open standards are so important, assessed the process for creating standards, and discussed moving forward.

KEY TAKEAWAYS

OPEN STANDARDS MADE THE INTERNET POSSIBLE, ARE THE LAW IN HEALTHCARE, AND DELIVER MULTIPLE BENEFITS.

Deborah Estrin observed that we've all experienced the success of openness, as without the open modularity of the Internet we wouldn't have the Internet that we know, and wouldn't have the proliferation of commercial services that exist.

> "It all happened [the Internet] that it could grow from a research platform to this commercial juggernaut because of those standard interfaces, and because of modularity built into the architecture. This allowed advances in a completely decentralized way."
>
> — DEBORAH ESTRIN

ONC's Jon White summarized several benefits of open standards in a series of tweets.

Tweet
Access to your health information is a legal right. Closed systems infringe that right by creating unnecessary barriers.
Open standards enable competition and innovation in health IT and healthcare.
Open standards reduce friction for science, research, new treatments, safety surveillance, and other national interests.
Open standards improve cybersecurity and system reliability.

He also said that certification of health IT improves API transparency. He directed everyone to the Certified Health IT product list on the ONC's website, which provides detailed information about each product, the developer, the version, the ID, and API documentation.

OPEN STANDARDS ARE A PREREQUISITE FOR API ALIGNMENT. ONCE APIS ARE ALIGNED, DATA QUALITY IS AN ISSUE.

Andy Palmer believes that sharing data and integrating systems in healthcare requires alignment of the APIs, which can't happen without open standards. Thus, open standards are essential and are urgently needed.

However, once APIs are aligned, what will become obvious almost immediately are poor data quality and semantic irregularities between the various systems. Cleaning up the data sounds easy but is not, and is not solved through standardization or aggregation. The key is using probabilistic techniques and models.

OPEN STANDARDS CAN SERVE PATIENTS.

Adrian Gropper described the moving story of a researcher who was diagnosed with ovarian cancer in 2013, with a prediction of 44 months to live. She used tumor genomics to navigate her treatment with a handful of oncologists and data scientists all over the country, and to help make very difficult treatment decisions. Her conclusions were: 1) when your tumor is sequenced, take the information away on a flash drive; and 2) share that sequence as broadly as possible with many machine learning algorithms, start-ups, and any other sources that could be helpful.

This is how open standards can serve patients, because a patient's genomic information becomes available and shareable. The patient could share their data with IBM Watson, which could review relevant articles. This patient published an article about her treatment and outcome, adding to the knowledge base.

> "This loop of patient/oncologist and machine learning demands open standards and patient-directed choice of the artificial intelligence system. It's just obvious."
>
> — ADRIAN GROPPER

In this story, there was no EHR mentioned. It was about the standards around managing the access to patient information. A model to consider—using FHIR and SMART APIs—is a patient-centered FHIR EHR using an authorization server controlled by the patient.

OPEN STANDARDS AND MODULARITY ARE IMPORTANT IN THE DIGITAL BIOMARKER SPACE.

Standards and modularity allow development, validation, and use of digital biomarkers. Digital biomarkers are derived interpretations of diverse data sources generated outside of the clinical setting. Examples include a test for Parkinson's that involves tapping a mobile phone touch screen. There are also cognitive shifts that can be detected through facial responses or interactions with voice bots, like an Alexa, as well as mobility traces and measures of activities of daily living.

Modularity and standardized interfaces to the raw data sources are important. Standardization ensures consistency in interpreting data. Analysis of digital biomarkers is needed in an end-to-end context over time.

> "End-to-end clinical translation of digital biomarkers can now happen given SMART on FHIR, CDS, and the platforms that are allowing us to validate these measures."
>
> — DEBORAH ESTRIN

OPEN STANDARDS WILL HELP PROPEL GENOMICS.

Per Gil Alterovitz, it is a critical time for genomics and for standardizing genomics to avoid different stakeholders having different pressures and information. A great deal of information can be gathered from different sources, which needs to be communicated in a standard way.

Working with FHIR Genomics, a team has built an open standard that can be incrementally adopted from different angles. Five use cases have been selected and will be tested to make sure the standard works.

ALL OF THE PANELISTS TOUCHED ON MODULARITY IN SOME WAY.

John Wilbanks highlighted ways in which benefits of modularity were mentioned. These included:

- Letting some standards emerge as bottom-up aspects of machine learning
- Having a goal of regulating pieces of the standards that come out
- Separating the security and the data layers
- Incremental adoption

Deborah Estrin sees end-to-end solutions as too much for most startups, which should focus more narrowly on developing one outstanding component.

OPEN STANDARDS NEED TO CONTINUE TO BE DEVELOPED WITH GREAT URGENCY.

Standards are often developed by groups that come together, negotiate, and try to forge consensus. This can be long and slow. There is also the creation of "open specifications" that are open processes that look like standards, but there is a company in charge.

Some participants feel that if the EHR vendors and the EHR ecosystem don't act with urgency to create open standards around data, some party—probably a company—will come along and build a better information asset, making the group trying to develop standards obsolete. For example, Google didn't wait around for standards committees to build maps; they just built them and the navigation companies and standards groups were left behind.

Thus, the sense of urgency is not necessarily to develop standards but to develop running code that companies adopt.

Others shared this sense of urgency but now that it has only been three years since SMART on FHIR began, it is part of legislation, and all vendor products must have an open API. So, the community has acted with urgency, has not been bound by a traditional standards model, and has made significant progress.

The Role of Consensus, Law and Regulation

Ken Mandl, MD, MPH, Director, Computational Health Informatics Program, Boston Children's Hospital (Moderator)
Aneesh Chopra, President, NavHealth
Natalie Kates, Product Manager, Digital Health Service
Donald Rucker, MD, National Coordinator for Health Information Technology, ONC
John Wilbanks, Chief Commons Officer, Sage Bionetworks

OVERVIEW

The 21st Century Cures Act mandates open APIs, and prohibits information blocking, to steer the industry toward interoperability. However, there is still confusion in the marketplace. Third-party developers need to know that there will be a market for their apps in order to have the confidence to move forward.

In developing regulation, panelists and participants do not want a traditional slow, bureaucratic process, which is unlikely to succeed. They prefer a collaborative process with a great sense of urgency.

CONTEXT

The panelists shared their thoughts on the role of regulation, standards, and how to move forward with a sense of urgency. Participants offered their perspectives on regulations, standards, challenges, and moving forward.

KEY TAKEAWAYS

THERE IS A ROLE FOR REGULATION AND THE PRIVATE SECTOR.

The panelists offered their views on the role of government, though John Wilbanks noted that outside of ONC, it's not easy to find people in government who understand how the speed and scale of technology have changed in the past 10 years.

Aneesh Chopra

- As Secretary of Commerce, Herbert Hoover saw government as being able to convene, invest in R&D, and motivate industries to scale up. That nation of government is applicable today.
- Acting on that idea, with funds from the Recovery Act, the federal government invested about $15 million to support what has become the SMART platform and SMART on FHIR.
- The path forward is to take advantage of public, private, and collaborative models where there is a clear direction.

Donald Rucker

While Steve Jobs changed multiple industries without consensus, the collective decision of the country is that we will have consensus. There are some areas, like usability, where there is no real role for the government, but other areas where the government will have a larger role. Specifically, the 21st Century Cures Act mandates:

- There shall be interoperability.
- There shall be no information blocking.
- There shall be open APIs.

There are three broad use cases for interoperability:

1. Patient access to their data. Legally patients own their data, but practically this has not been operationalized.
2. Bulk access to data. Large employers are demanding this.
3. Open APIs and SMART on FHIR. These allow market competition.

> "As we look at open standards, the three use cases are individual ownership [of data], bulk accountability, and open APIs allowing market competition."
>
> — DONALD RUCKER

John Wilbanks

Because of the lack of knowledge about technology in the government there aren't many conversations looking at standards systems and regulatory systems, and assessing when they work and don't work. An illustration of a typical process is the struggle in making progress on standards for digital rights management, which has taken at least four years. Meanwhile, iPhone and Android software contain native DRM, making the standards being worked on pointless.

Another example is Wikipedia, which is an open system, with a governance process. SMART has the potential to be like Wikipedia, in regulating access, control, and standardization. SMART doesn't affect the apps themselves, but it makes it possible for lots of people to take lots of shots on goal. Some apps will fail and others will succeed.

However, a traditional approach to standards and regulation that is legislatively based is not likely to succeed. In contrast, now that there is regulation about an open API, SMART on FHIR provides the beginnings of an ecosystem.

The real question is how to accelerate the entire process without having a corporate group try to create a proprietary version of SMART on FHIR, which wouldn't be healthy. Key questions surround governing SMART on FHIR to make it responsive over the next five years, and ensure openness and access (which is a political issue), without impinging on development of technology standards (which is not a subject for the political process.)

> "If you've got the text of regulations, the rough consensus on writing code in SMART, and the pool of individuals who've gotten access to their data . . . then I think we have a shot at something that can evolve at the same speeds that the technology business infrastructure evolves."
>
> — JOHN WILBANKS

Natalie Kates

Natalie Kates offered brief remarks about her work implementing an API-first strategy in the government.

GROUP DISCUSSION

Participants weighed in with additional thoughts on standards and regulation.

- **EHR vendors are restricting access to apps.** One participant relayed a story where the CIO of a health system that uses an EHR from a major vendor, and where the health system paid for the API component, was informed by the vendor that it couldn't hook up to an application because it had not been developed as a project by employees of the hospital. This participant said this is not an isolated incident, but is happening more broadly.
- **It's the customer's choice.** A panelist responded that when an EHR customer (i.e. a health system) purchases an EHR and has an API, it is the health system's right to choose how to use it.
- **It's the law.** The 21st Century Cures Act is very specific that this kind of behavior is not where the country wants to go, and there are significant penalties for such behavior.
- **It's the perception.** Even if vendors can't restrict a health system, many health system CIOs perceive that they are prohibited from using an API and apps. A participant said it would be helpful if ONC could issue an opinion that could be taken to customers clearly stating that they are allowed to connect their EHR to APIs and to use apps. This would help clarify the reality to users.
- **It's the key to innovation.** Forcing open APIs that make apps available to anyone to implement is not necessarily in the interest of major EHR vendors, but it is a key to unlocking innovation in healthcare.
- **Letting people experiment.** At times, regulators try to impose standards and rules to impose control and minimize failure. However, sometimes in new markets it is okay to let people try things, run amok, and fail—this is how progress is made.
- **Maintaining proprietary data models.** Aneesh Chopra commented that one of the reasons he likes the work related to the FHIR server is that the endpoint is abstracted. As a result, no EHR vendor is exposing their proprietary data model to any patient-facing app.
- **Model RFP.** Chopra also referenced a draft model RFP developed in 2014 that provides language where all parties agree that there will be an abstract layer between the vendor's data model and apps, there will be agreement on

how the appliance is installed, but all IP from the appliance out is owned by the author of the app, not the data source. However, this model RFP has not been broadly adopted. (A participant said that not only are health systems not using this model RFP, but many provider systems have signed contracts that give complete ownership and rights over the data to the EHR vendor, even though the law is clear on patient ownership of their data.)

- **Making the value case.** Even if APIs and apps are legal and allowable, for providers to begin using apps there must be a clear value case for doing so. To many providers this value case isn't clear. Chopra shared examples of how health systems are wasting money today accessing data for various purposes and argued that an API and apps could provide enormous savings. He believes a strong value case can be made.

Hooks for Decision Support. Can We Get There Fast?

Josh Mandel, MD, Harvard Medical School; Health IT Ecosystem Lead, Verily (Moderator)
Blackford Middleton, MD, MPH, MS, Chief Informatics and Innovation Officer, Apervita, Inc.
Kevin Shekleton, Vice President & Distinguished Engineer, Cerner
Gajen Sunartha, MS, Direct of Innovation R&D, Boston Children's Hospital
Micky Tripathi, PhD, AB, President and CEO, Massachusetts eHealth Collaborative (MAeHC) & Argonaut Project

OVERVIEW

General excitement is high around the potential for CDS Hooks, which today is perhaps where the SMART project was four years ago. Session participants support continuing to pursue CDS Hooks somewhat separately from HL7 to allow for greater flexibility and to proceed more rapidly. Initial applications show signs of the possibilities and benefits for CDS Hooks.

CONTEXT

Panelists discussed the process of getting feedback on CDS Hooks and early CDS Hooks implementations.

KEY TAKEAWAYS

CDS HOOKS IS STILL EARLY IN DEFINING HOW THINGS WORK.

There is a great deal of excitement about CDS Hooks, which can make it easier to plug services into an EHR at the point of care. Yet the spec is early and work is still underway to define how everything is supposed to work, whether it is the security model, the way to launch apps, or other details.

This project started outside of the standards world. Stakeholders came together, wrote down the specification, tried it, and got some feedback. Over time, the group is trying to bring this back into HL7 and work with some decision support work groups, while continuing the development of CDS Hooks.

Perspectives on this approach included:

- CDS Hooks is an open source project similar to SMART and FHIR in that regard. There is a standard within HL7 that competes to some degree with CDS Hooks, so the two groups had to figure out a collaborative path forward in order to provide the greatest benefit to the community. Despite some major differences in the tools and methodologies, there is optimism that SMART, CDS Hooks, and other open source projects will all be under the same umbrella so that organizations will have a standard they can adopt.
- Argonaut and CDS Hooks are not ready to unmoor themselves from HL7. It is necessary to strike a balance between remaining open to two-way conversations with the standard development organizations, and not being encumbered by their structure and processes.
- Having some friction is natural because the groups are composed of people from different backgrounds. People who work on open source projects tend to be more technically focused whereas those in standards groups tend to be more domain experts.

UNDERSTANDING ARGONAUT PROVIDES GOOD PERSPECTIVE FOR CDS HOOKS.

Meaningful use laid a good foundation for electronic health records and caused providers to begin thinking about interoperability. Argonaut began in 2014 as the private sector decided to "take back interoperability." Argonaut is a group of volunteers from vendors and other organizations who care deeply about outcomes and about making FHIR more usable as quickly as possible.

Argonaut embarked on creating implementation guides which straddle between standards and an open spec. Argonaut doesn't leave the standards world completely, but doesn't strictly adhere to it either. Argonaut tries to give implementation feedback into the standards process faster

than would otherwise happen. Argonaut worked to accelerate creation of implementation guides and has now published some of these guides.

All of Argonaut's vendor sponsors are using the implementation guides as the base for their FHIR API implementations, to increase consistency early in the implementation process, and decrease the amount of variation. The goal is to get greater consistency early in the implementation process to decrease the amount of variation. Argonaut is now focused on getting CDS Hooks up and running.

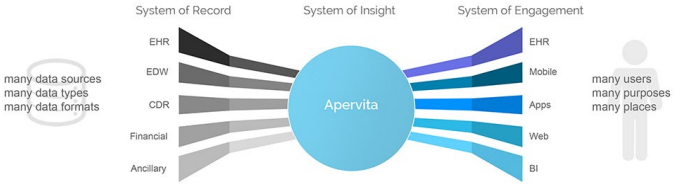
Argonaut is interested in the EHR as a platform, able to invoke CDS services, as well as any outside tool wrapped in a SMART container.

APERVITA IS CREATING A NEW TYPE OF OPEN PLATFORM AND IS IMPLEMENTING REAL-TIME CDS.

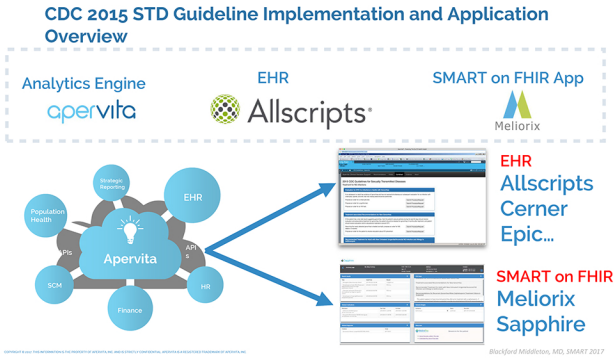
Apervita builds on ONC funding and on the work of the CDS Consortium, which is an instance of cloud-based CDS. Apervita has taken previous ideas and is trying to build an industry scale platform to deliver any number of knowledge assets, knowledge artifacts, data services, or data assets in real time to any EMR or endpoint.

Apervita's concept is based on the premise that health enterprises will be flooded with data and analytics. The complexity of point-to-point solutions is not going to work. What is necessary is a "system of insight," scaled architecture and scaled solutions.

Already, EHRs are a system of record, with high adoption and significant data. Other tools can serve as a system of engagement. Ideally, one analytic tool can leverage the data from multiple EHRs or data sources and provide insight to multiple endpoints. That's where Apervita comes in. It has a mapping layer that takes data in from the system of record and the system of engagement.



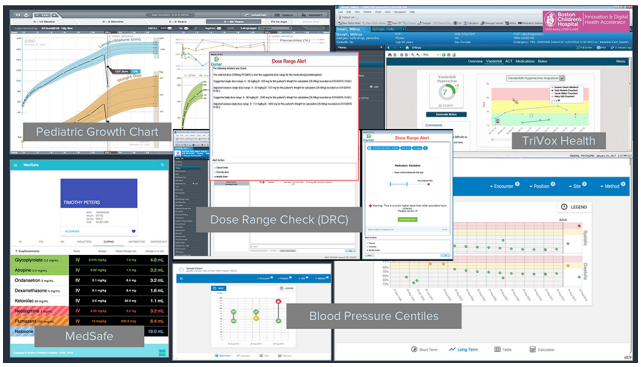
The knowledge extraction process consists of several steps, and is implemented in real-time CDS on Apervita. The outcome is a platform that can deliver as a service a SMART on FHIR container. The workflow uses CDS Hooks.



BOSTON CHILDREN'S PLANS TO USE CDS HOOKS FOR MULTIPLE APPLICATIONS.

CDS Hooks, while very early, can help solve several problems. Within a hospital, the IT function is incredibly busy and can't take on innovation work, making it hard to get new apps into production. Clinicians often ignore and override frequent, text-based alerts, which can create patient safety issues. Also, hospitals often have multiple EHR systems, illustrated by Boston Children's, which has Epic and Cerner.

Boston Children's is using FHIR to access data in the Cerner system, and using the CDS standard. Information is visually provided to clinicians showing them how they compare to other physicians. This meets clinicians halfway in their workflow. It is an early use of CDS.



DISCUSSION

- **Adoption of decision support.** An audience member wondered whether a greater evidence base of clinical results, including publication of randomized clinical trials, would help spur greater adoption of clinical decision support. Attendees, including a representative from Intermountain Health, said there is a wealth of evidence about the benefits of decision support. However, John White from ONC said that randomized control trials are not the key to changing clinical practice in the United States. To get clinicians to adopt decision support it needs to be awesome, and we don't have awesome decision support today.

Preparing the Enterprise

Arnaub Chatterjee, MHA, MPA, Senior Expert, Pharmaceutical and Medical Products Group, McKinsey & Company (Moderator)
Charles Bach, Data Architect, Kaiser Permanente
James Buntrock, Vice President of Information Technology, Mayo Clinic
Alistair Erskine, MD, Chief Informatics Officer, Geisinger Health System
William Gregg, MD, MS, MPH, Vice President, Clinical Informatics, HCA
Adam Landman, Partners Healthcare
Hiten Patel, Head of Product Management for Enterprise Analytics, Advisory Board Company

OVERVIEW

Representatives from several of America's largest, most prominent health systems are focused on interoperability, aggregating and analyzing data to develop insights, and adding apps to EHRs when appropriate. Some are developing and implementing their own apps. There was significant enthusiasm for integration through an open standard, and the SMART on FHIR standards were mentioned repeatedly. The fact that the largest health systems in the country are looking at APIs and apps shows that the potential opportunity is massive.

CONTEXT

Technology leaders from some of America's most prominent health systems—Kaiser, Mayo, Partners, Geisinger, and HCA—described their priorities and challenges in implementing technological solutions.

KEY TAKEAWAYS

INTEREST IN APIS AND APPS AMONG HEALTH SYSTEMS IS HIGH.

Each panelist described their situation, shared opportunities and challenges, and described their organization's approach to improve the value of their EHR through open APIs and apps.

- **Kaiser.** Kaiser has 39 hospitals and 670 medical offices, and serves about 12 million members with 200,000 employees. A priority is to navigate the organization's oceans of data to draw insights. Important organizational design principles are:
  - Pick modern architecture that can scale and has industrial-strength processing power.
  - Think about solutions from a Kaiser perspective. All solutions are championed by a physician lead and have an end-to-end delivery team.
  - Collaboration is key.
- **Mayo Clinic.** Mayo Clinic is embarking on the largest technology investment in the organization's history and is converging EHRs. In conjunction with this investment, innovation has been tempered and there is pent-up demand. About three years ago the organization decided to focus heavily on data and API investments to keep data fluid. Mayo built enterprise APIs, including FHIR endpoints, and SMART on FHIR apps. One app provides access to historic data that is not loaded into Mayo's EHR, and another app makes recommendations to clinicians about clinical care, initially focused on six conditions. Mayo has also created a Center for Innovation that is wrestling with the challenge of translating innovation into practice.
- **Geisinger.** Geisinger prides itself on being an open system, with open notes, open results that are immediately made available to patients, and open data. Geisinger was involved early in trying to build and then commercialize SMART on FHIR apps. Their typical approach is to develop a functionality and roll it out across all systems. At times important data doesn't reside within EHRs, making it necessary to incorporate data from outside the clinical record into the workflow.

  In creating apps, Geisinger is focused on:
  - Patient-facing apps. This includes an app that provides patients with refunds if they aren't satisfied with their care and an app that deals with providing food to diabetic patients instead of pills.

— Provider-facing apps which include identifying patients where recommended care was not provided.

A challenge includes tension in dealing with the organization's EHR vendors, which are focused on supporting their products and protecting their trade secrets, while app developers are trying to distribute their software broadly.

- **Partners.** Brigham & Women's Hospital, part of Partners, has had service-oriented architecture for over 20 years. This has enabled Brigham to develop innovative internal applications, including specialty-specific applications, and enable them to talk to each other.

  What's new are patient-facing APIs, which are logical and appropriate. But getting organizational buy-in can be difficult. Challenges include privacy and patient understanding, as patients don't necessarily understand that they are releasing their data and are responsible for what happens to their data.

- **HCA.** HCA has 72 hospitals across the United States, 121 surgery centers, and about 27 million patient encounters per year. HCA has been building a service-oriented architecture and is trying to leverage the power of its data.

  Two key areas of focus for HCA are:

  1. *The front end.* Within its system, HCA has every imaginable front end, which presents problems. HCA has been moving toward a standard central platform enabled by SMART on FHIR that relegates the existing EHR to more of an operating system. This will enable HCA to be more flexible and nimble. HCA has demonstrated SMART on FHIR within that platform and is in the process of rolling it out.
  2. *A common notification platform.* HCA has tens of thousands of unique interfaces across the enterprise. (Just the maintenance of these is significant.) The organization wants to be able to route a signal to a clinician, wherever they are. To be able to deliver the right information at the right time, HCA has built a common notification platform over enterprise service specs. Whenever data is at rest or in flight, data will be translated and made available. HCA has used about 10 FHIR resources and the starting point for developers is to use FHIR. When dealing with a new vendor, wanting to use a proprietary standard is a nonstarter.

  Benefits of this approach are:

  — It fosters innovation throughout the company as everyone is working on a common platform, talking a common language. All parties can now come up with SMART on FHIR apps that can be used by HCA internally.

  — It lowers maintenance costs by eliminating wasted work.

  — It helps achieve the vision of a learning healthcare system by enabling quick implementation and learning.

Also on the panel was Hiten Patel from Advisory Board, a research firm focused on best practices. Advisory Board also has a software business and a consulting practice. The firm has observed that hospital CIOs, having completed implementation of EHRs, see analytics as their primary focus. Advisory Board has not seen open standards as a top CIO priority.

Main themes Advisory Board has heard from CIOs are:

- The focus is on time to value. A CIO's budget is seen as a cost center that doesn't drive revenue and is a tax on the organization.
- Central analytics teams are tapped out as demand for their services exceeds supply.
- Data governance is a huge challenge. The EHRs will be the central source of truth, but other data needs to be pulled in to drive the right decisions.

Open standards don't make the top of the list, but a question is whether open standards can help with time to value and ROI.

HEALTH SYSTEMS ARE FOCUSED ON THE BEST SOLUTIONS, REGARDLESS OF WHETHER THEY ARE INTERNALLY OR EXTERNALLY DEVELOPED.

There was general agreement that health systems are seeking the best solutions, without a bias for whether they are internally or externally developed. If a solution is developed internally it is likely because there isn't an existing external solution for a problem and because the organization has internal expertise. When pursuing an external solution, most health systems are focused on working collaboratively with vendors.

Keynote

Atul Gawande, MD, MPH, Surgeon, Author, Professor, Public Health Researcher

OVERVIEW

The greatest value comes from generalist physicians, not specialists, who deliver sustained incremental care over years. Generalists develop long-term relationships with patients and treat the whole patient. To improve the treatment of patients over time and make the best decisions, it is important to integrate as much data as possible including medical data, behavioral data, data about patients' living conditions, and data about the quality of care available. It is also important to align policy with the goal of creating value.

CONTEXT

Best-selling author Atul Gawande discussed creating value in healthcare by looking at which type of clinicians deliver the greatest value and where data can help improve the value delivered.

KEY TAKEAWAYS

PCPS CREATE GREATER VALUE THAN SPECIALISTS.

Going back to the 1940s and 50s, when diseases appeared, physicians provided heroic treatment and delivered miraculous cures, creating a system focused on short-term, intensive episodic interventions. But over time it was discovered that health could be dramatically improved by treating and monitoring chronic diseases such as hypertension, increasing the importance of ongoing, incremental care.

This raises the question, which type of physicians provide more value, generalists or specialists?

Specialists have more depth of knowledge and expertise, are guideline driven, and provide better care for any specific procedure or disease. And specialists often become frustrated with PCPs and question their value, wondering if patients should just go straight to specialists instead of first seeing the PCP.

However, the data shows that generalists produce better health results along all long-term measures of health. A study in the UK shows that when poor populations receive increased primary care, their life expectancy increases dramatically.

In looking at this question, Dr. Gawande found several differences between specialists and generalists.

	Specialists	Generalists
Types of Physicians	Surgeons Radiologists Cardiologists Dermatologists	Internists Geriatricians Pediatricians Rheumatologists Allergists Headache specialists
Compensation	Higher	Lower
Types of interaction	Episodic, short term	Holistic, long term
Care approach	Look at specific disease, procedure; look to rule out absolute worst case	Look holistically at the entire patient; look at entirety of symptoms, health issues, and context of patient's life
Timing of value creation	In the short term	Over the long term

Specialists add high value in short bursts. Generalists add value over the entire life of the patient. Specialists are somewhat transactional, while generalists build important long-term relationships with patients. In fact, highlighting the importance of relationships is research from the UK showing that patients who have the same primary care physician for years have a 12% lower hospitalization rate. This is because patients who have a relationship with their physician are more likely to communicate symptoms and seek treatment earlier, preempting the need to be hospitalized.

While in past decades the value of short-term episodic treatments was higher, now the value of long-term incremental care delivers greater value, and this is only increasing. Incrementalists add value by:

- Monitoring patients over time
- Seeing patterns
- Continually adjusting care
- Acting in advance

> "The value of incremental care has passed heroic interventions. . . . Today, the value of incrementalists is adding more value [than specialists]."
>
> — ATUL GAWANDE

Dr. Gawande illustrated the importance of both specialists and generalists with a story about his son, who experienced a life-threatening health issue at birth. Through the intensive surgical efforts of specialists over a few hours, and then over a few weeks, his life was preserved. These specialists had significant resources, tools, and technology—and were extremely well compensated. But, it was the efforts of incrementalist physicians over the next 21 years that enabled his son to grow and thrive. These incrementalists tend to be undervalued and not receive the same compensation or resources, though they were critically important in his son's life.

DATA CAN BE USED TO IMPROVE THE INCREMENTAL CARE THAT IS PROVIDED.

Four types of data can be continually gathered and integrated to improve the care delivered:

1. **Information about the body.** This is the most common type of healthcare data available and used today, such as data in the EHR. It will grow over time to include genomic data. Data about the patient's body is extremely important, but just provides one set of information about the patient.
2. **Information about patients' living conditions.** This is data about how and where patients live and work, which is important data that impacts health. Today this data is rarely gathered, integrated with other data, and put to use.
3. **Information about the quality of care that is available.** Knowing about the patient's body and living conditions is only part of the equation. It is also important to know what care is available to the patient and the quality of this care.
4. **Information about the patient's behavior.** What are the patient's circumstances and their ability to adhere to the instructions given?

Collectively this data will inform providers and enable them to provide better, more holistic care. However, the data needs to be made usable. Today the technology that is generating data is evolving faster than the ability to enable humans to use the data.

POLICY NEEDS TO SUPPORT INCREMENTAL, HOLISTIC CARE THAT DELIVERS THE GREATEST VALUE.

Data has now shown that incremental care is the greatest source of value. Now, policy needs to be aligned with this reality. A few salient facts:

- Pre-ACA 27% of people would have been uninsurable due to preexisting conditions. Now that percentage would be even higher.
- If a person has insurance coverage they are much more likely to get incremental care; if they don't have coverage they are more likely to avoid incremental care.
- When people who have not had insurance coverage get insurance, there are not big changes in their health in the first 1-2 years, but there are significant improvements in their health 4-5 years after they get coverage. The biggest improvements are for those with chronic conditions.
- Many politicians are focused on providing narrow catastrophic insurance coverage. However, health problems are not just catastrophic in nature; they accumulate from a series of chronic conditions over time. Health improves when there is incremental care provided over time.
- When patients have a high deductible, such as $6,000, they will avoid getting primary care. The payoff for primary care is not immediate; it happens over years.

> "People will lose value when they have $6,000 deductibles."
>
> — ATUL GAWANDE

DISCUSSION

- **Attracting the best and brightest.** An attendee asked what it takes to attract the best and brightest young doctors to go into primary care. The answer: money. Today, primary care physicians get paid half of what specialists do, and have less prestige and fewer resources. To attract the best and brightest, reverse this.
- **Rethinking the time value of care and payment.** Today, people think about healthcare and insurance over one year. Perhaps it makes senses to think about healthcare similar to a mortgage, over 10 or 20 years. This would result in investments and results over a long time horizon.