

Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT



JASON Report Task Force

David McCallie, co-chair

Micky Tripathi, co-chair

September 3, 2014



- Review of JTF Charge
- Members, process, and timeline
- Listening session description
- Assumptions and caveats
- Recommendation framework and preliminary recommendations
- Next steps



- Analyze and synthesize feedback on the JASON report
 - Discuss the implications of the report and its impact on HHS, other Federal agencies and their strategies
 - Assess the feasibility and impact of the JASON report on HHS and the broader HIT ecosystem
 - Identify use cases and lessons learned from current experience
 - Establish specific recommendations that can be integrated into the Federal Health IT Strategic Plan and the ONC interoperability roadmap
 - Provide a high-level mapping of the PCAST 2010 report with the JASON report (added subsequent to initial charge)



- Review of JTF Charge
- Members, process, and timeline
- Listening session description
- Assumptions and caveats
- Recommendation framework and preliminary recommendations
- Next steps

Task Force Members



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Member Name	Organization	Role
David McCallie	Cerner	Chair
Micky Tripathi	Massachusetts eHealth Collaborative	Chair
Deven McGraw	Manatt	Member
Gayle Harrell	Florida State Legislator	Member
Larry Wolf	Kindred Healthcare	Member
Troy Seagondollar	Kaiser	Member
Andy Wiesenthal	Deloitte	Member
Arien Malec	RelayHealth	Member
Keith Figlioli	Premier, Inc.	Member
Wes Rishel		Member
Larry Garber	Reliant Medical Group	Member
Josh Mandel	Children's Hospital Boston	Member
Landen Bain	CDISC	Member
Nancy J. Orvis	FHA/DoD	Ex Officio
Tracy Meyer	FHA/ONC	Ex Officio
Jon White	HHS	Ex Officio

Updated Meeting Schedule



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Meetings	Task
Wednesday, June 18th 9:00-10:30am ET	<ul style="list-style-type: none"> Review charges Identify action steps
Tuesday, July 1st 3:30-5:00pm ET	<ul style="list-style-type: none"> Review discussion questions Listening session planning
Thursday, July 31st 2:00-5:00pm ET	<ul style="list-style-type: none"> Listening session
Tuesday, August 5th 11:00am-12:30pm ET	<ul style="list-style-type: none"> Listening session
Tuesday, August 19th 11:00am-12:30pm ET	<ul style="list-style-type: none"> Listening session debrief Develop recommendations
Tuesday, September 2nd 11:00am-12:30pm ET	<ul style="list-style-type: none"> draft recommendations
<i>Tuesday, September 3rd -HITPC</i>	<ul style="list-style-type: none"> <i>Draft recommendations to HITPC</i>
<i>Wednesday, September 10th-HITSC</i>	<ul style="list-style-type: none"> <i>Draft recommendations to HITSC</i>
Tuesday, September 16 th 11:00am-12:30pm ET	<ul style="list-style-type: none"> Refine recommendations
Friday, September 19 th 1:00-3:00pm ET	<ul style="list-style-type: none"> Refine recommendations
Wednesday, October 1 st 11:00am-1:00pm ET	<ul style="list-style-type: none"> Refine recommendations
Wednesday, October 8 th 9:00-11:00am ET	<ul style="list-style-type: none"> Finalize recommendations
<i>Wednesday, October 15th – Joint HITPC/HITSC meeting</i>	<ul style="list-style-type: none"> <i>Final recommendations</i>



- Review of JTF Charge
- Members, process, and timeline
- Listening session description
- Assumptions and caveats
- Recommendation framework and preliminary recommendations
- Next steps



- The Task Force held two listening sessions to gather input from a variety of stakeholders.
- Panels focused on:
 - Exchange service providers
 - Research
 - Standards
 - Consumer facing ecosystem
 - Vendor APIs
 - App Providers
- Detailed findings from the listening sessions are contained in the appendix. These findings have informed our deliberations and recommendations.



Day One (Jul 31, 2014)

Exchange Service Providers

- David Horrocks, Chesapeake Regional Information System for our Patients (CRISP)
- Ted Kremer, Rochester RHIO
- Jitin Asnaani, CommonWell Health Alliance
- Eric Heflin, Healthway

Research

- William Tierney, Regenstrief Institute
- Sarah Greene, Patient-Centered Outcomes Research Institute (PCORI)
- Landen Bain, CDISC
- Gwen Darien, Cancer Support Community

Standards

- Grahame Grieve, Fast Healthcare Interoperability Resources (FHIR)
- Thomas Beal, openEHR
- Steve Emrick, National Library of Medicine (NLM)
- Stan Huff, Healthcare Services Platform Consortium

Day Two (Aug 5, 2014)

Consumer-facing ecosystems

- Ali Emami, HealthVault
- John Mattison, Kaiser
- Kevin Riddleberger and Patrick Leonard, iTriage
- Gordon Raup, Datuit
- Anil Sethi, Gliimpse

Vendor APIs

- Charles Parisot, EHRA
- George Cole, Allscripts
- Carl Dvorak, EPIC
- Ryan Hamilton, Cerner

App Providers

- Dave Vockell, Lyfechannel
- Tim Michalski, Point of Care Decision Support
- Nate Weiner, Avhanahealth
- Chris Burrow and Steve Mickelsen, Humetrix
- Denis Coleman, AppMedicine
- Jonathan Baran, healthfinch



- Review of JTF Charge
- Members, process, and timeline
- Listening session description
- Assumptions and caveats
- Recommendation framework and preliminary recommendations
- Next steps

A One-Slide Summary of the JASON Report by the Jason Task Force



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

The JASON report concludes that MU Stages 1 and 2 have not achieved meaningful interoperability “in any practical sense” for clinical care, research, or patient access due to the lack of a comprehensive nationwide architecture for health information exchange.

They point to the lack of an architecture supporting standardized APIs, as well as EHR vendor technology and business practices, as structural impediments to achieving interoperability.

They recommend an urgent focus on creating a “unifying software architecture” to “migrate” data from these legacy systems to a new centrally orchestrated architecture to better serve clinical care, research, and patient uses.

This architecture would be based on the use of “public” APIs for access to clinical documents and discrete data from EHRs, coupled with enablement of increased consumer control of how data is used.



1. **JASON process.** Though the JASON report is well-written and concise, there are many issues that can be interpreted in different ways. The JASON process does not allow engagement with JASON authors. We have tried to reasonably infer what is not clear, though we may have misinterpreted in some cases.
2. **JASON recommendations.** The JASON report covers more ground than listed in its specific recommendations. Our review thus covers some areas that are not necessarily listed in the formal recommendations.
3. **Timing of JASON report.** There has been a long time lag since the JASON report was conducted. Investigation was conducted in early 2013, but much has changed in the industry in the last 18 months, such as market deployment of Direct-enabled functions, and beginning of MU2 attestations using C-CDA.
4. **JASON Scope.** JASON explicitly focused on high-level technical architecture considerations. They noted that several other challenges to interoperability – such as legal/policy, federation/jurisdiction, and business model – were not in the scope of their report.
5. **JTF consideration of security issues.** JASON recommended encryption of data and transactions as a critical security feature, but did not propose any new technologies or measures than are already in use today. We thus have not focused on that aspect of the report.
6. **JTF consideration of patient identification issues.** JASON refers to the need for resolving patient identities across implementations as a key barrier to data aggregation. However, they do not propose any new technologies or approaches. We thus have not focused on that aspect of the report.
7. **Limitations of JTF preliminary recommendations.** Due to the tight timetables, our preliminary recommendations are fairly high level and will need further exploration and broader discussion



- Review of JTF Charge
- Members, process, and timeline
- Listening session description
- Assumptions and caveats
- Recommendation framework and preliminary recommendations
- Next steps



- 1. Current State of HIE**
- 2. Architecture**
- 3. Core clinical and financial systems**
- 4. APIs**
- 5. Consumer access and control of data**
- 6. Research and HIE**
- 7. Accelerating interoperability**

1. Current State of HIE: Background



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Background

- **JASON report finds that “meaningful interoperability” is virtually non-existent**
 - Conclude that interoperability is hampered by the lack of published APIs to enable automated data and document exchange across systems
 - Little patient access
 - No “rational access” between organizations for clinical care or research
 - *“[I]f this is the highest level of adoption of health information exchange the vendors will agree to, then adoption of more meaningful information exchange appears to be very challenging.”*

JTF Preliminary Recommendations

- **ONC should take into account the current state of interoperability as well as current trends before incorporating JASON findings in any decisions on HIE plans, policies, and programs.**
 - We believe that JASON did not adequately characterize the progress made in interoperability, though we agree that there is considerable room for improvement as will be outlined in these recommendations.

1. Current State of HIE: Recommendations and Discussion



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Discussion

- **As noted earlier, the JASON findings were reached 18 months ago, some 6 months before the beginning of MU Stage 2. While there has been some change in the capabilities available in the market, there has been an even larger positive change in the trajectory of interoperability progress.**
 - Meanwhile, demand for interoperability has grown dramatically in the last 18 months, driven by MU Stage 2 and the growth of value-based purchasing, Population Health services, and ACOs. The supply-side is responding to meet this demand.
- **JASON expresses concern that Direct and CCDAs could become interoperability dead-ends, however, this concern may be somewhat misplaced**
 - MU was structured intentionally to stage interoperability over time to allow for market adjustment to new technologies and workflows
 - JASON correctly identifies that interoperability does not yet enable standardized API mechanisms for accessing clinical documents and data
 - We agree (see later recommendations) that immediate attention should be focused on improving interoperability for document-based and data-based exchange through standardized APIs, which would include a mechanism for market coordination that does not yet exist today

2. Architecture: Background



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Background

- **JASON appears to be recommending a centrally orchestrated, nationwide architecture to resolve incompatibility of individual implementations that exists today.**
 - *“Interoperability issues can be resolved only by establishing a comprehensive, transparent, and overarching software architecture for health information.”*
 - *“The architecture should provide a logical organization of functions that allow interoperability, protect patient privacy, and facilitate access for clinical care and biomedical research. JASON has provided an example of what such an architecture might look like.”*
 - *The architecture should identify the small set of necessary interfaces between functions, recognizing that the purpose of a software architecture is to provide structure, while avoiding having “everything talking to everything.”*
- **They do note that their proposed software architecture could have heterogeneous implementation modes, including a mix of centralized and federated approaches.**
 - *“The architecture that JASON proposes allows for various specific implementations, including as possibilities integrated software suites that run on a single box, a cloud implementation, or a widely federated system of systems with shared responsibilities across different organizations.”*
- **JASON recommends that ONC define the nationwide “overarching software architecture”, and direct the development of its requirements and technical specifications**
 - *An immediate goal...should be for ONC to define an overarching software architecture for the health data infrastructure*
 - *ONC should create (or redirect) appropriate committees to carry out...the detailed development of requirements for the functions and interfaces that comprise the architecture.*

2. Architecture: Recommendation



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

JTF Preliminary Recommendations

- **The industry should accelerate the current path of loosely coupled architecture based on iteratively proven, standards-based APIs and data model standards that support both document and discrete data access**
- **ONC should help to shape and accelerate this process by assisting with convening industry stakeholders to define the minimum components necessary to loosely couple market-based implementations**
- **ONC should not attempt to impose detailed architectures on the market**
- **ONC should help to shape and accelerate this process by aligning and leveraging federal infrastructure and programs to support rapid development and adoption of such minimal components, once they are defined**

2. Architecture: Discussion



Discussion

- **A monolithic software architecture is unlikely to be feasible in the US market**
 - Would require “top-down” direction and implementation from HHS that would require considerably more resources and legal authority than currently exists, even with MU Stage 3 and 2017 Edition certification
- **The JASON “architecture” is really more of an “architecture pattern” which will require a rich ecosystem of specific implementations to become useful**
 - The proposed JASON architecture allows for loose coupling of multiple compatible-but-distinct implementations, which is much more consistent with the way that the US market is organized
 - These distinct implementations will have to be market-based (i.e., not determined or sanctioned through regulatory processes) in order to be sustainable and relevant
- **The JASON goal of an operational “virtual repository in the cloud” would require some type of strong centralized coordination backed by legal authority and/or strong incentives**
 - Need for legal alignment, policy development, business/organizational model development, and technical design, deployment, and operations
 - Loose coupling based on high-value use cases is more feasible in current industry landscape
- **The current direction of interoperability is aligned with many if not all of the components of the JASON architecture and follows closely on the JASON-proposed migration path (see JASON figures 3-5)**
 - JASON says it is acceptable to start without atomic data, intrinsic encryption, semantic translation, and middleware applications and building these over time
 - Some current implementations enable meaningful exchange by compromising on these same capabilities

3. Core clinical and financial systems



Background

- **JASON concludes that current EHR and financial systems need to be replaced in order to meet the goals of the proposed software architecture**
 - *“Today’s EHR systems are already legacy systems, many of which are built on the MUMPS database technology first developed in the 1960s. Unfortunately, these systems are likely to dominate the HIT landscape for years to come.”*
 - *“The architecture incorporates a migration pathway from the current legacy software used to store and process EHRs to the future system of broad interoperability.”*
- **JASON focused on only documentation and storage of clinical notes and data, and largely ignored other currently available EHR functions such as CPOE, CDS, and workflow orchestration.**
 - Current generation EHRs and financial systems are denoted as “stovepipe legacy systems”
- **JASON also assumes that the current structure of the market suffocates innovation**
 - *“Current approaches for structuring EHRs and achieving interoperability have largely failed to open up new opportunities for entrepreneurship and innovation that can lead to products and services that enhance health care provider workflow and strengthen the connection between the patient and the health care system”*
 - Suggests that the current market is not open to entrepreneurs and new entrants, AND that current EHR and financial system vendors are not innovating themselves

3. Core clinical and financial systems



JTF Preliminary Recommendations

- The industry should accelerate the parallel paths of improving current document-level encoding standards (CCDA) while introducing discrete data access APIs and associated data element standards in EHRs
- **ONC should immediately seek guidance from the HIT Standards Committee on:**
 - The maturity of development of standards to enable document- and data-level APIs
 - The foundational API requirements for document- and data-level access that can reasonably be included in 2017 Edition Certification to help to launch an ecosystem for more robust API development and implementation in the future
- **ONC certification should leverage standards-based APIs where possible to expand opportunities for modular certification**

3. Core clinical and financial systems



Discussion

- **Current EHR systems are more functionally sophisticated and technologically dynamic than JASON gives them credit for**
 - Many of the functions highlighted in the JASON software architecture are performed by EHR systems today (e.g., UI applications, Semantics and Language Translation, Search and Index Functionality, open APIs)
 - Many vendors already support APIs, and have numerous third-party “apps” integrated into workflows
 - However, current APIs are vendor-proprietary and thus reduce the market opportunity for entrepreneurial developers, and could lead to “vendor lock in” without external market coordination
- **Market demand for interoperability is growing rapidly and the supply-side is beginning to respond through rapid innovation by existing vendors and the influx of new entrants**
 - Technical barriers, though challenging, are eclipsed by the policy, legal, business, and socio-technical barriers to greater interoperability
 - More formalized structures and processes for market coordination of technical, policy, legal, business, and socio-technical need to evolve to catalyze more rapid progress
- **Innovation and entrepreneurialism are best promoted by focusing on functional interoperability goals and open architecture through standardized APIs, rather than on the internal software design of core clinical and financial systems**

4. APIs Background



Background

- **JASON urges moving beyond CCDAs to data-level “public” APIs to support the goals of exposing discrete data for improved clinical and research uses.**
 - *“[S]imply moving to a common mark-up language will not suffice. It is equally necessary that there be published application program interfaces (APIs) that allow third-party programmers (and hence, users) to bridge from existing systems to a future software ecosystem that will be built on top of the stored data.”*
 - *“At present, large-scale interoperability amounts to little more than replacing fax machines with the electronic delivery of page-formatted medical records”*
- **They propose accelerating this development through regulatory requirements, primarily MU Stage 3**
 - *“EHR software vendors should be required to develop and publish APIs for medical records data, search and indexing, semantic harmonization and vocabulary translation, and user interface applications. In addition, they should be required to demonstrate that data from their EHRs can be exchanged through the use of these APIs and used in a meaningful way by third-party software developers.”*
 - *The APIs should be certified through vetting by multiple third-party developers in regularly scheduled “code-a-thons.”*
- **They are highly concerned that the industry will not move beyond Direct and CCDAs**
 - *“[I]f this is the highest level of adoption of health information exchange the vendors will agree to, then adoption of more meaningful information exchange appears to be very challenging.”*

4. APIs Recommendations



JTF Preliminary Recommendations

- **ONC and the industry should support and pursue the JASON call for development and adoption of published, standards-based APIs and data models for documents and atomic data in a framework of legal, policy, and business “rules of the road”**
- **To this end, CCDAs refinement (document-encoding standards) and FHIR (for data-level standards and standards-based APIs) should be targeted and accelerated through ONC contracting with existing initiatives and SDOs for development of tight specifications and implementation guides focused on high-value use cases and licensed for public use**
 - ONC should encourage rapid public/private experimentation and iterative improvement processes with these emerging APIs to ensure that they work as intended.
 - These experiments should include uses targeting clinical care, research, population data, as well as exposure to consumers via EHR Portals.
- **Standards development and certification should leverage existing industry and HITECH structures**



Discussion

- **Open APIs are typically based on accepted standards, and are published and documented at a sufficient level of detail that they can be implemented without intervention by the source system hosting the API**
 - The JASON notion of “public API” may need additional clarification. For example, does “public” imply an obligation by the EHR to provide access to the API?
 - We note that without external mechanisms for validating trust and appropriate use specific to health care, there will still be a need for coordination between connecting parties, as well as normal business coordination regarding licensing, responsibilities, etc that exists in all industries
 - The development of an industry ecosystem to coordinate such mechanisms could take as long, or longer, than the development of the technical standards
- **The growing industry adoption of standards-based API work such as HL7 FHIR, focused on high-value use cases, is the most appropriate and sustainable path to accelerated use of standardized data-level APIs across the industry**
 - FHIR Profiles offer a promising approach to meeting the demand for “semantic interoperability” and thus minimizing the need for “metadata translation services” denoted by JASON
 - However, there is much work to be done before FHIR can become a standard mature enough for large-scale deployment
- **In parallel, need to further refine document-level CCDAs to enhance their usability in an open API architecture**
 - Data-level APIs are not a replacement for structured document-level CCDAs, which capture encounter-level context that is critical for clinical care, as well as the narrative details that cannot be captured in structure.
 - Thus, there is an ongoing need to aggressively improve existing CCDAs standards while working in parallel towards complementary data-level APIs.



Discussion (continued)

- **A published open API framework can partially offset the need for strict standardization of APIs**
 - Some discussion considered that if well-documented APIs and API support structures are made available by EHR vendors, there may be less need for the APIs to be identical, as long as they meet core elements of high-value use cases
 - This could protect against an unintended consequence that JASON-like robust APIs among highly circumscribed functional components could lead to overly constrained APIs that are not flexible to emerging data access needs
- **Standards development and certification should leverage existing industry and HITECH structures, at least through the first couple of years of MU Stage 3 attestation (and 2017 Edition Certification)**
 - Creation of new standards-deeming or certification bodies at this point in time will likely greatly hinder progress toward a public API approach by creating market confusion
 - Existing SDOs are already curating API development – need to catalyze and focus these efforts rather than introducing intermediary structures or processes that will take time to mature and gain market acceptance
 - Streamlining current ONC certification for end-to-end testing through public-private iterative, agile processes is the best approach for testing and validation through the 2017 Edition Certification time period, after which an assessment should be made as to how to best coordinate market-based approaches to sustain standards coordination and validation

5. Consumer access and control of data : Background



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Background

- **The JASON report initially asserted that patients “own” their healthcare data. Subsequent clarification modified this proposition to “patients participate in the management of his or her data”**
- **JASON calls for granting “fine grained” consumer (patient) control over uses of health data**
 - “Privacy bundles” would capture common access patterns that fit most patient needs
 - Undergirding these “privacy bundles” would be a requirement for a fine-grained level of data tagging and segmentation to allow such “privacy bundles” to apply to a wide variety of use cases and legal/policy situations
- **JASON calls for providing consumer access to healthcare data via the same discrete data APIs that would address clinician and research data access needs.**

5. Consumer access and control of data: Recommendations



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

JTF Preliminary Recommendations

- **Patient-facing EHR functions should expose similar discrete-data APIs as discussed for clinical care and research needs**
 - The Blue Button Plus (Pull) project offers a logical starting point – by expanding the current use of FHIR and OAuth2 to include a richer set of APIs
 - Consider models that leverage the SMART Platform as an open specification for “app” developers to explore
- **HHS (OCR) should help clarify the degree to which patients and consumers can control access and usage of their personal health data. Much confusion exists, even among HIT experts.**



Discussion

- **The Task Force has not yet spent enough time on the JASON “privacy bundle” concept**
- **Standards-based, data-level APIs accessible to patient could become a major source of innovation for the industry.**
 - There is strong interest from the “mHealth” app industry in gaining direct data access to patient data, probably via consumer-granted access to their provider’s portal.
- **The technical availability of APIs would need to be accompanied by business processes to support health-care specific concerns (privacy, appropriate use of data) as well as general business concerns (data rights, liability, etc)**
- **Confusion exists about the degree to which data access rights are “carved out” under existing regulations versus the consumer’s right to a copy of their data and subsequent control of access to their copy.**

6. Research and HIE: Background



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Background

- **JASON assumes that clinical, research, and consumer access use cases can all be supported by the same architecture**
- **JASON assumes that existing clinical data could be used for large-scale research purposes.**
 - *“A new software architecture will make aggregated health care data available to all biomedical researchers... The federated database will provide large effective sample sizes ... in what amounts to an ongoing clinical trial with over 300 million potential enrollees.”*
- **JASON concludes that the lack of EHR support for a consistent data-level API creates a fragmented research environment that grossly underutilizes existing clinical data**
 - *“At present, access to health data is limited to proprietary datasets of selected patients.”*

6. Research and HIE: Recommendations



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

JTF Preliminary Recommendations

- **Standards-based, discrete data APIs to improve researchers' access to routine clinical data should be strongly supported through technical and policy development**
 - Agree with JASON recommendation to convene the research community to identify use cases, technical requirements, alignment with existing data collection/analysis structures and processes, and legal/policy barriers and opportunities
 - Research community should participate in decisions about where structured APIs can best support research use cases
 - This should include representation from current initiatives where research is leveraging routine clinical data, such as Kaiser Permanente and i2b2
- **Policy work to address the regulatory, governance, and business barriers to greater research access to routine clinical data should begin immediately, in parallel with API development**
 - Additional research and regulatory refinement will be necessary to balance the needs of the research community with the need to protect patient privacy.

6. Research and HIE: Discussion



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Discussion

- **Standards-based, discrete data APIs would improve researchers' access to routine clinical data, with powerful consequences for observational research, but perhaps more limited benefit for other types of biomedical research**
 - JASON vision for research access to clinical data is most appropriate for large scale clinical and health services “observational” (exploratory, hypothesis-generation) studies
 - Benefits for biomedical research would be somewhat limited since most routine clinical data is not captured under the rigorous control needed by clinical trials.
- **Additional work will be necessary to reconcile the JASON vision of a common data-level API with existing approaches to clinical research.**
 - Different types of research (controlled trials, outcome studies, etc) have their own approaches and infrastructures, and in many cases have existing standards in common use (CDISC, RFD, etc.)
- **Potential inconsistencies in the JASON report about balancing the need for consumer control of non-clinical data usage versus the research community's need for unfiltered, un-edited raw data**
- **JASON also calls for additional work on standards for de-identification of research data, and on potential changes in regulatory approach to dealing with attempts at re-identifying research data**
- **The challenges of protecting patient privacy will grow as more and more and more data is captured digitally.**

7. Accelerating Interoperability: Background



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Background

- **JASON advocates using MU Stage 3 as the primary lever for provoking the industry changes that it would like to see**
 - *“CMS should embrace Stage 3 Meaningful Use as an opportunity to break free from the status quo and embark upon the creation of a truly interoperable health data infrastructure.”*
 - *“This pathway could be provided by published APIs mandated through the CMS Stage 3 Meaningful Use program”*
 - *“JASON believes that now is time to define such an architecture, leveraging the opportunity to specify CMS Stage 3 Meaningful Use requirements to drive implementation”*
- **JASON began its work in late 2012**
 - Did not have benefit of lessons learned from implementation of the C-CDA for MU Stage 2
 - Assumed much more time to define, gain consensus, and prepare for MU Stage 3

7. Accelerating Interoperability: Recommendation



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

JTF Recommendation

- **ONC and CMS should consider MU Stage 3 as one of many levers to promote advancement toward JASON goals.**
 - Especially because the 2017 Edition Certification timetable does not appear to allow sufficient time for widespread adoption of the standards-based discrete data APIs at the core of the JASON architecture
- **The federal government should align and leverage the many other means at its disposal to promote advancement of JASON goals.**
- **ONC should immediately assess and implement where possible streamlined approaches for incorporating new standards into federal certification**
 - ONC should seek HIT Standards Committee guidance on this topic

7. Accelerating Interoperability: Discussion



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Discussion

- **MU Stage 3 and 2017 Edition Certification is not as powerful a lever as presumed by JASON**
 - Timelines are too short to require revolutionary changes in software and API design
 - Declining incremental incentives and competing industry priorities have partially diminished the market influence of the MU program
 - Vendors will still have to meet certification requirements, so there is still power in MU's market orchestration influence
- **A barrier to maximizing the power of MU Stage 3 is the long cycle required to get a technical standard included as part of federal certification**
 - For example, MU Stage 3 begins in approximately 24 months, yet that may not be enough time to get any standards-based data-level APIs incorporated under current processes
- **Market demand for interoperability is growing rapidly**
 - Growth of value-based purchasing (ACOs, hospital readmission penalties, etc), rising consumer expectations, rising standards of care
- **As the MU program ramps down, the importance of effectively orchestrating other federal levers will be critical success factors in providing some channels for standardization**
 - Purchasing of health IT systems (DoD, VA, IHS, other), interoperability with Federal health care providers, creating publicly accessible HIE infrastructure components (e.g., nationwide provider directory), Medicare and Medicaid value-based purchasing initiatives, NIH intramural and extramural research, FDA and pharmaceutical and medical device regulation, public health infrastructure, LTPAC regulation, CLIA lab accreditation, advanced imaging facilities accreditation



- Review of JTF Charge
- Members, process, and timeline
- Listening session description
- Assumptions and caveats
- Recommendation framework and preliminary recommendations
- Next steps



- Gather directional inputs from the HITPC and HITSC
- Further specify recommendations in four remaining Task Force meetings (add more if necessary)
- Cross-reference to PCAST report
- Cross-reference to ONC Interoperability Road Map

Appendix



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT



- The Task Force held two listening to gather input from a variety of stakeholders. Panels focused on:
 - Exchange service providers
 - Research
 - Standards
 - Consumer facing ecosystem
 - Vendor APIs
 - App Providers



- Many reactions point out that the JASON report underestimates progress being made in sharing discrete patient data. (Beyond “digital fax machine.”)
- Many felt that while the vision of discrete data APIs was a reasonable path the necessary standards are not ready, and the time frame proposed by the JASONS was too fast. Several panelists recommended incrementally improving upon current CDA document-centric standards.
- Many panelists expressed a tension between improving the current state vs moving towards a new state and urged an incremental path be taken in any approach.
- Many panelists felt the implementation timelines in the JASON Report were not realistic and felt 6-10 years was a more reasonable timeline for a complete shift to discrete data API (e.g. FHIR).
- Many panelists thought focus on discrete APIs would advance interoperability. Numerous panelists considered FHIR to be the likely emerging candidate, though other options exist. A majority of opinions felt that FHIR itself, and implementation by vendors, would not be possible under current 2017 Edition timetable.
- Technical architecture alone will not enable seamless exchange of health information the policy, business and legal aspects of exchange need to be addressed in tandem. Building a “network” will be as challenging as implementing standard APIs over “stovepipe” legacy EHRs.
 - Business incentives for exchange need to be aligned. No elegant architecture will overcome an economic disincentive to share patient data.
 - Governance is key, need to take the time to get it right.



APIs

- Many stakeholders thought additional focus on standards-based, discrete data APIs could be helpful to advance interoperability.
- But other stakeholders had varying opinions of the role of APIs in solving interoperability issues:
 - JASON like platforms and their robust APIs misdirect us down a maze of tightly coupled integrations that are costly, fragile and brittle, not at all based on the loosely coupled data exchanges [Who said this?]
 - Specific API requirements as part of ONC certification are neither realistic nor necessary; the growing industry adoption of standards-based API work such as FHIR, if focused on high- value use cases, is the more appropriate and sustainable path to accelerated use of APIs across the industry.
- There were differing opinions among app developers on the need to standardize EHR APIs. Some app developers felt it was important to have standard APIs across EHR vendors. Other app developers felt it wasn't necessary to standardize vendor APIs if EHR vendors were required to create APIs that were well documented and could read and write information. Examples of industries where multiple APIs exist were cited.
- Several EHR vendors pointed out that they already expose (proprietary) discrete data APIs, and have many third-party users of their APIs.
- Current API approaches are either document-centric (XDS, XCA) or discrete-data centric (FHIR, OpenEHR.) Numerous groups are working on developing FHIR and FHIR Profiles, including S&I's DAF, SMART Platform, HSPC, and IHE.) Document-centric APIs were de-valued by the JASONS, but several panelists pointed out that CCDAs documents typically include embedded discrete data elements.
- The existence of a "public" API does not automatically imply that any entity has a right to use the API. Additional licensing, certification, and business arrangements (among other steps) are usually required before access to the API is granted to third parties.



APIs (continued)

- Suggested artifacts necessary for a public API:
 - Complete documentation (Developer Resources) for each level of the API
 - Ideally, a “test bed” will accompany the API where the API can be tested, in a non---destructive manner, without exposing any patient identifying information.
 - Many public APIs will also include sample applications that provide a framework for proper use of the API.
 - Support mechanisms to assist developers in resolving issues
 - Licensing mechanisms to promote adoption and deployment to a client base.
 - Ability to communicate when a change to the API will be made
- There was sparse discussion of the JASON’s recommendations about cryptography, metadata translation, and indexing services. Some panelists pointed to the need for a National Patient Identifier or equivalent national scale MPI service (including linked patient consent tracking) in order to realize the full JASON vision.
- There was relatively little discussion of the JASON’s “privacy bundle” concept.

Timeline

- Panelists had differing opinions on if the timing of including an API requirement in Meaningful Use Stage 3 was achievable.
- Many panelists felt that the timelines outlined in the JASON Report were not achievable. The transformation discussed would take more on the order of 6-10 years for the ecosystem to fully implement and operationalize the entire JASON architecture.



Standards: Current and Future:

- A number of panelists felt that while the vision in the JASON Report was a reasonable path it would be difficult to implement and that more would be gained through following an approach of incrementally improving upon the standards/infrastructure in existence today.
- Many sources have described the problems with currently deployed C-CDA and its implementations – However, several of our panelists believed that C-CDA usage was getting better over time and has significant value for a variety of use cases. There was agreement that improvements to C-CDA should be made as quickly as possible (MU2 issues)
- Patient identify management came up repeatedly as a central problem that will have to be better addressed to achieve the vision outlined in JASON or any other approach to improving interoperability.
- FHIR was viewed by panelists as the most likely path towards the JASON vision though many felt FHIR would not be ready in time for inclusion in Stage 3 of Meaningful Use. One specific example of necessary work to be completed was the development the ability to query for a “complete” patient record.
- Some panelists raised concerns that the JASON Report didn’t focus sufficient attention to the challenges around semantic translation though the FHIR testimony described how FHIR Profiles could alleviate most of the need for semantic translation services.



Patient controlled data use

- Patient at the center may make it easier to manage some aspects of exchange of health information– including some types of secondary use.
 - Methods for patients to directly control who has access to their data
 - Methods for patients to contribute to, view, and when necessary correct their data
 - Mechanisms for patients to authorize the use of their data for research
 - Of note, the JASONs have updated their original notion that patients “own” their data, and have acknowledged that patients “participate in the management” of their data.
 - There is confusion about rights associated with primary clinical data versus the copy that patients have a right to obtain.
- The research community has a different set of data and standards needs versus providing clinical care. The research community has its own set of standards development organizations and while at times leverage standards utilized for clinical care (such as the C-CDA) they also have other unique needs not covered by standards/infrastructure development for clinical care purposes.

