

Question Response  
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**1. Please describe your standard initiative? How could it support the implementation of a JASON like infrastructure? What if any modifications to your standard initiative would be required to better align your work with a JASON like infrastructure**

NLM supports three major vocabularies -- SNOMED CT<sup>1</sup>, RxNorm<sup>2</sup> and LOINC<sup>3</sup> -- which are major underpinnings of Meaningful Use.<sup>4,5</sup> SNOMED CT provided standard codes and names for medical conditions, organisms, procedures and many other aspects of clinical care. NLM is the US Member Representative to the International Health Terminology Standards Development Organisation (IHTSDO), which owns and maintains the International Edition of SNOMED CT. NLM creates US Extensions concepts based on user requests, and releases the US Edition of SNOMED CT two times per year. RxNorm provides codes and names for prescribed drugs and their ingredients and is published monthly. And LOINC provides codes and names of tests, measurements, clinical reports and survey instruments. NLM also participates in the development of many HL7 message standards, and UCUM, which is a standard for developing computable units of measure codes. All of these vocabularies and standards are essential for efficient exchange and use of electronic clinical data, and Meaningful Use regulations require all of them for use to some degree. NLM also developed and launched the Value Set Authority Center,<sup>6</sup> considered the 'source of truth' for value sets required to compute meaningful use quality measures. In addition, NLM publishes a very large vocabulary system called the Unified Medical Language System (UMLS), which helps EHR systems understand clinical meaning by showing linkages and relationships, and in some cases mappings, between disparate vocabulary standards such as ICD10-CM, CPT, SNOMED CT, and others.

- **How could it support ...?**

The above standards are essential for any electronic medical record usage across institutions, and JASON could only succeed if the systems containing the data it addressees used these vocabulary standards.

- **What modifications would be needed...?**

These standards are like air to combustion motors in that they are independent of the architecture, and would be needed by JASON or any other architecture. No special modifications would be needed for a JASON architecture, but the content of these standard vocabularies is constantly being refined and these vocabularies will continue to expand to accommodate clinical needs, new medical tests, treatments, technologies and approaches to care.

**2. What is the timeline for integration of emerging standards into the ecosystem?**

The HL7 message standard alluded to above has been under development for more than a quarter century and has been embedded in many parts of the medical ecosystem for more than a decade. All but the smallest hospitals have been using HL7, admission discharge and transfer, and test reports, for years. Commercial laboratories and free standing radiology systems have also been using HL7 messages for reporting results to office practices for years. Considering only hospitals use, we estimate that at

least 40 billion HL7 tests result messages (called ORU's in HL7) are transmitted in the US each year. However most of this transmission is within care institutions.

DICOM for radiology images and NCPDP for community pharmacy and prescription messages are also in almost universal use. The US e-Prescribing requirements are based on the NCPDP SCRIPT prescribing standard and have deep penetration, carrying almost every electronic prescription being sent to a pharmacy.

LOINC and SNOMED do have wide international use: LOINC has been translated into a total of 12 different languages ranging from Chinese to Portuguese, and SNOMED CT has been adopted by nearly 30 countries. Most commercial laboratories offer LOINC codes to identify the kind of tests they report. Meaningful use regulations requires LOINC, RxNorm, SNOMED CT, and UCUM to be used in some portion of the electronic medical record and in some HL7 messages delivered by hospitals and offices, specifically in HL7's CDA patient summaries, some laboratory reporting, and tumor registry messages. But present requirements are limited: they only require that LOINC (for the test name) and SNOMED (for answer codes) be applied to a modest percentage of reported tests and require no standard codes for Radiology, or other kinds of non-laboratory tests.

These three vocabulary standards have been incorporated into clinical systems, but not as consistently as the message standards, which more often carry locally-invented institutional codes rather than the universal codes provided by LOINC, RxNorm and SNOMED CT, and this lack is the greatest barrier to communication from hospitals to office practices and HIE's, and from one health care institution to another. Big costs for mapping one institution's codes to another, or from a source institution to a Health information exchange, are high barriers to the goal of integrated health data. If MU3 required use of universal code systems, including standard UCUM units in all clinical reporting, it would facilitate the transport and availability of clinical data for research and care.

**If time permits, please consider answering as many of the additional general questions below.**

- **Given currently implemented information technology (IT) architectures and enterprises, what challenges will the industry face with respect to transitioning to a JASON like architecture? What challenges will your organization face?**

The JASON report seems to be unaware of many of the important realities of the current health informatics scene. It did not mention a single vocabulary standard nor did it mention the deep penetration of some existing message standards such as HL7, X12, and DICOM in the clinical world. Finally it did not mention important new developments like HL7 Fast Health Interoperable Resource (FHIR),<sup>7</sup> SMART Apps<sup>8</sup>, and Blue Button<sup>9</sup>. The only messaging standard mentioned was DICOM, and that in somewhat disparaging terms, though DICOM has penetrated every radiology service and many other image services and has made radiology images available on disk to any patient who asks for them.

The JASON architecture has just appeared on the scene. No reference implementation or experience with it exists, and much of it was described in vague, hand waving terms. So this question and many of those that follow, begs the question as to whether the JASON architecture is the one true answer to the problems of health care IT (though it contains some good ideas), and whether an expanded examination of alternatives with a clear understanding of current directions is warranted.

- **Do you see an evolutionary path for the industry to move from currently implemented approaches to a JASON like architecture?**

See answer above

- **What policy and technology developments would be necessary to assure the privacy and security of information in a JASON like architecture?**

With recent legislation and regulation, privacy and security requirements of single organizations have been extensively reviewed and discussed, and recommendations made and implemented. The risk from hacking is a different problem that applies to all information systems. We don't see it being anything specific to the health industry, or that JASON offers special solutions to hacking, which is getting intense attention from the IT industry. The health system should adopt any industry wide standards that emerge to solve the problem.

We don't see how fine grained privacy and security standards would achieve any of the goals of availability of clinical information for care and research, because they could constrain the availability of clinical data for these purposes. Allowing individual patients to specify what test results, observations and notes were made available to what kind of individuals, and at the individual test level basis, could make it very difficult to know when one had complete information in either the research or clinical practice environment. We would also like to understand how this would improve practice efficiency, when clinicians would be obliged to explain to their patients how to use the system and the pros and cons at many detailed levels, and why it makes sense to jump to a fine-grained system, when even simpler, coarse-grained systems have not yet been implemented or tested in real world use.

- **What existing efforts (standards, initiatives, pilots etc.) in the marketplace are advancing a JASON like infrastructure?**

As mentioned in the introductory questions there are many efforts that would solve some of the problem for which JASON is proposed as a solution. FHIR is one of the most comprehensive and elegant HL7 initiatives. It proposes a set of mechanisms based on named resources that that can implement most the functions and content of HL7 version 2 (v2), which is already the basis of most clinical data communication in health care institutions today. However, FHIR goes well beyond HL7 v2. It serves as both a document and a message delivering system, is independent of the particular representation system, (at present supports both XML and JSON) and is being widely taken up.

Another important initiative is SMART -- a standard for developing APPs that could be applied to any EMR. More about this effort below.

- **A key recommendation of the JASON Report is that EHR vendors should be required to a) develop and publish APIs for medical records data) searching and indexing, c) semantic harmonization and vocabulary translation, and d) user interface applications. What existing efforts are underway in health care that could inform the implementation of this recommendation?**

- a) The idea that EMR vendors should support APIs for accessing an searching their medical record systems is a good one that pre-dates the JASON Report. One approach is specified by the SMART Platform,<sup>10,11</sup> which has gotten industry support and is now aligned with, and being implemented in, the FHIR framework.
- b) The goal for searching and indexing is more complicated and will likely be constrained by the kinds of platforms and the computer power available to the host systems. What should be

indexed will depend strongly on the use case and the applications, which tend to vary and evolve. NoSQL databases<sup>12</sup> have a quite different approach to indexing than conventional relational databases, and to the extent they are adopted by the healthcare industry, will require different approaches. Regardless, we would recommend giving attention to system-wide indexing with text indexers like SOLR/Lucene,<sup>13</sup> an Apache project. It is blazing fast, open source, and easy to implement for text documents and some structured databases

- c) Research in this area would of course be useful. If this reflects an interest in the primary sources of clinical data to report it using the complementary sets of standard vocabularies listed above, it is a good idea.

So, we should require that data producers use LOINC to code the test name of diagnostic studies, measurements and clinical reports. Data producers should use RxNorm to code all drug prescription, dispensing records and related content (such as allergies). For coded answers to diagnostic studies, as well as other important fields with categorical answers, data producers should use SNOMED CT. We should also require that reports of results with numeric values have units coded in UCUM, which would enable receiving systems to understand the numbers and interconvert results that are reported by different producers with different, but commensurate units of measure.

- d) Interface

The problems of the time costs clinicians and nurses are facing with the use of EMRs are not due solely to conventional interfacing issues.<sup>14</sup> These problems are being caused by: 1) increasing requirements to enter more structured data at each visit, 2) billing and payment system problems which care providers believe adds work without helping patient care, and 3) at times slow performance.

The increased time to work with EMRs is also caused by implementation philosophies: such as always forcing a pre-specified choice from a menu selection and forbidding free text. There are also problems with response time in overloaded systems that hurt the usability of even good interfaces.

There are of course non-optimal human interfaces, and these should be improved.

- **What standards, implementation specifications, certification criteria, and certification processes for electronic health record (EHR) technology and other HIT would be required to implement the JASON reports' recommendation that ONC require open published APIs through Stage 3 of Meaningful Use?**
- **What processes and approaches would facilitate the rapid development and use of these standards, implementation specifications, certification criteria and certification processes?**

Three important actions that could lead to widespread and economical exchange of health care data or all of the purposes envisioned would be;

- 1) More universal use of the federally mandated vocabulary standards by the producers of clinical data, laboratories, radiology departments, EKG machines, Spirometry, Dictation services, etc., as mentioned above
- 2) Some equivalent to a universal patient identifier so that health systems, personal health records (PHRs), and health information exchanges (HIEs) could reliably aggregate data about one patient from multiple sources. This is a difficult problem that is now “solved” by the matching of various keys, but here solutions which are not always perfect, could lead to misfiling of data about patient A in the field of Patient B with dangerous consequences.
- 3) Make it easy to send clinical data in email safely. DIRECT is a proposal that uses email technology to push clinical data and has real benefit, but the need for a central organization to create a special infrastructure has slowed its adoption. Larger scale solutions, such as CONNECT<sup>15</sup> have even more infrastructure impediments and overhead costs (as could occur with some of the JASON mechanisms). What is really needed is a simple system for pushing encrypted packages in email, and there are a few promising industry developments underway.

- **How might ONC and other Federal agencies best integrate the changes envisioned by the JASON report into their future work?**

We would like to understand better how JASON is the answer to the existing problem before pushing toward any mass federal agency backing.

- **What actions would you recommend ONC take to help the industry advance towards a JASON like architecture that supports interoperability for primary and secondary uses of health information?**

See above response

Some parts of the JASON report seemed to suggest starting all over with a top down approach. If this is the intent, it is a wrong position. Experience with large (top down) software development has largely been a disaster in this and in other countries, especially with health care related information technology projects. The evidence is well documented in a book titled Dangerous Enthusiasms.<sup>16</sup> Development works best when it is gradual, organic, and grows from smaller beginnings – as has occurred in health care IT standards which are just now closing in on a breakthrough point. The major thing holding them back is insufficient regulatory requirements to use standard coding systems in the message content.

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<sup>1</sup> <http://www.ihtsdo.org/snomed-ct/>

<sup>2</sup> <http://www.nlm.nih.gov/research/umls/rxnorm/>

<sup>3</sup> <http://loinc.org/>

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<sup>4</sup> Final Rule: Centers for Medicare and Medicaid Services (CMS), HHS. Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2, 77(171) Fed. Reg. 53968 (Sept. 4, 2012) (amending 42 C.F.R. § 412, 413, and 495).

<sup>5</sup> Final Rule: Office of the National Coordinator (ONC) for Health Information Technology, Department of Health and Human Services. Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, 77(171) Fed. Reg. 54163 (Sept. 4, 2012) (amending 45 C.F.R. § 170).

<sup>6</sup> <https://vsac.nlm.nih.gov/>

<sup>7</sup> <http://www.hl7.org/implementation/standards/fhir/>

<sup>8</sup> SMART Apps. Intelligent Health Laboratory, Boston Children's Hospital; Informatics Program at Harvard-MIT Health Sciences and Technology. <http://smartplatforms.org/>

<sup>9</sup> Office of the National Coordinator for Health IT (ONC), US Department of Health and Human Services. Blue Button. <http://bluebuttonplus.org/>

<sup>10</sup> Mandl KD1, Mandel JC, Murphy SN, Bernstam EV, Ramoni RL, Kreda DA, McCoy JM, Adida B, Kohane IS. The SMART Platform: early experience enabling substitutable applications for electronic health records. J Am Med Inform Assoc. 2012 Jul-Aug; 19(4):597-603. doi: 10.1136/amiainl-2011-000622. Epub 2012 Mar 17.

<sup>11</sup> <http://docs.smartplatforms.org/>

<sup>12</sup> <http://nosql-database.org/>

<sup>13</sup> Apache. Solr. <http://lucene.apache.org/solr/> Copyright © 2011-2012 The Apache Software Foundation, Licensed under the Apache License, Version 2.0 <http://lucene.apache.org/> Apache and the Apache feather logo are trademarks of The Apache Software Foundation.

<sup>14</sup> McDonald CJ, McDonald MH. Electronic medical records and preserving primary care physicians' time: comment on "electronic health record-based messages to primary care providers". Arch Intern Med. 2012 Feb 13;172(3):285-7

<sup>15</sup> <http://www.healthit.gov/policy-researchers-implementers/connect-gateway-nationwide-health-information-network>

<sup>16</sup> Gauld R, Goldfinch S. Dangerous Enthusiasms - E-Government, Computer Failure and Information System Development. 2006 Otago University Press ISBN-13: 978-1877372346