



Regenstrief Institute

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Ré: JASON Report, “A Robust Health Data Infrastructure”

Dear Members of ONC’s Health Information Policy Committee:

I am pleased to offer the following testimony concerning the JASON report that was commissioned by ONC and the Agency for Healthcare Research and Quality. I represent the Regenstrief Institute, Inc. as its current President and CEO. The Regenstrief Institute was established in 1969 and, at 45 years of age, is the oldest research institution in the country dedicated to improving health systems. Its Center for Biomedical Informatics has been a pioneer in building electronic health record (EHR) systems and health information exchange (HIE). I am also a member of the EHR 2020 Task Force of the American Medical Informatics Association. Although my testimony does not necessarily represent the opinions of AMIA or its EHR Task Force, I have discussed the JASON report with them and have included selected responses in my final testimony. That said, my testimony reflects my own opinions and do not necessarily reflect the opinions of the Regenstrief Institute, AMIA, or the Indiana University School of Medicine, for which I serve as Associate Dean for Clinical Effectiveness Research.

On the following pages, my comments are divided into three parts: (1) general comments, (2) responses to specific questions posed to the Research Panel, and (3) responses to additional questions.

General Comments

Overall, I found the JASON report to be surprisingly naïve, outdated, unrealistic, and not responding to its charge to recommend how to collate data from disparate health information systems for analysis. Instead, it recommends a radically different broad architecture for EHRs and their interchange of data in the U.S. that is impractical and unworkable at this time. Smaller increments using current systems and standards would have been more helpful.

Section 3.1 lists 15 problems with the current state of EHRs and HIEs in the U.S. I agree with all of them, and they are the main reasons why what JASON recommends can't happen in the near future. They are all very thorny issues that are deeply embedded in our national fragmented health care (non)system that must be overcome before making radical changes to the EHR and HIE infrastructure. Overcoming them all right now in one fell swoop is simply not possible. Each needs substantial work, and overcoming them is outside of JASON’s charge. JASON should have provided a practical way of moving the needle forward now to enhance the creation of analyzable datasets of clinical data in the near term. The increasing number of EHR implementations are coming from a decreasing number of large vendors such as Epic and Cerner which creates opportunities for dialog and movement. JASON suggests that ONC and CMS can solve these problems by forcing the EHR industry to accept common EHR standards and APIs on which vendors can build their systems and communicate data between systems. That is

simply not going to happen anytime soon, so this report as it stands provides little practical advice. And again, it doesn't respond to JASON's charge by ONC and AHRQ on pages 11 and 12, specifically:

- *How can complex data handling techniques and Internet-based technologies be applied to health care to promote the development of real-time integrated datasets at a scale seen in other industries?*
- *How can the various users of health data in the clinical research and public health communities be presented with tailored and highly specific data views in near real time based on routinely collected health data?*
- *As health data grows from megabits to gigabits per individual, what fine-grained analytics should be made available to patients and health care providers to guide health care decisions?*
- *What fundamental data management capabilities are needed to support potential future requirements in an open-ended manner?*

[The entire JASON report seems to respond to this one bullet item, but it does so by starting over with a new national EHR/HIE infrastructure.]

- *What are the national security consequences of not addressing comprehensive health data opportunities in clinical research and public health?*

Our experience with the Indiana Network for Patient Care (INPC) has shown that collating data from dozens of commercial EHRs can be done with today's technology.^{1,2} It is difficult to be sure—interfaces change constantly, standards evolve, and interpretations and implementations vary. But JASON could have made recommendations on how ONC and CMS might expand and support existing HIEs and encourage their use of existing technologies to capture discrete data for clinical care and research. JASON decided that the U.S. health information infrastructure needed a complete reboot with a new conceptual model. I don't disagree that a more standardized and open model would provide robustness, but retooling hundreds of health systems' EHR implementations just won't happen in the near term.

JASON naively thinks that if HIT is using the standard architecture it suggests, the data will just come together:

- *A new software architecture will make aggregated health care data available to all biomedical researchers, not just those who happen to work at a large academic center with strength in a particular specialty. The federated database will provide large*

¹ Biondich PG, Grannis SJ. The Indiana network for patient care: an integrated clinical information system informed by over thirty years of experience. *J Public Health Manag Pract* 2004;Suppl:S81-6.

² McDonald CJ, Overhage JM, Barnes M, et al. The Indiana network for patient care: a working local health information infrastructure. An example of a working infrastructure collaboration that links data from five health systems and hundreds of millions of entries. *Health Aff (Millwood)* 2005, 24:1214–1220.

effective sample sizes, both to support statistical significance and to identify statistical outliers.

Establishing a federation of data providers is hard work—it took the Mini-Sentinel initiative years to develop the organizational infrastructure to share data in a federated manner, and it is highly entropy-prone. The sociological and organizational barriers to maintaining such federations are much higher than the technical ones.

JASON also seems to make the assumption that notes and encoded data being entered into EHRs are accurate and worthy of extraction for secondary use, including research. Currently this is not a safe assumption: many notes containing history, physical exam findings, assessments, and plans are inaccurate because of copy/paste, template use, time pressure and weakness of EHR functionality. Encoded data are often entered by busy providers thinking about something else, or they are entered before complete information is available. For example, a recent study by Regenstrief investigators showed that the diagnosis of heart failure from two different health systems was proven wrong by imaging data (mainly from echocardiograms) 57% of the time.³ Physicians entered heart failure as the most likely diagnosis for a set of non-specific symptoms and findings, and more often than not subsequent studies showed that the patient was suffering from something else, most often chronic obstructive pulmonary disease, which presents with shortness of breath, abnormal lung sounds, and a large heart shadow on chest xray, similar to heart failure.

Hence JASON's assumption that problem lists, medication lists, pain scores, and other codified data would be highly valuable to a learning healthcare system may be inaccurate. Knowing what data are useful—separating the signal from the noise—is an ongoing, active area of developmental research within clinical database epidemiology community and critical to JASON's charge. (For example, adding prescriptions for ACE inhibitors or beta-blockers to the diagnosis of heart failure lowers the false-positive rate significantly.) Yet it is not discussed.

Moreover, JASON spends a lot of time describing a radical approach to EHR and HIE architecture but little or no effort describing the functions of such architecture and their attendant policies, procedures, and expectations. Such functions include basic operations (entering and retrieving notes, orders, and other information) and enhancements to health care delivery, such as e-prescribing and clinical decision support. These things don't happen and won't if the architecture and its attendant policies and procedures don't support them.

JASON makes two fundamental “findings”:

- *The current lack of interoperability among data resources for EHRs is a major impediment to the unencumbered exchange of health information and the development of a robust health data infrastructure. Interoperability issues can be resolved only by establishing a comprehensive, transparent, and overarching software architecture for health information.*

³ Rosenman M, He J, Martin J, Nutakki K, Eckert G, Lane K, Gradus-Pizlo I, Hui SL. Database queries for hospitalizations for acute congestive heart failure: flexible methods and validation based on set theory. J Am Med Inform Assoc. 2014 Mar-Apr;21(2):345-52.

- *The twin goals of improved health care and lowered health care costs will be realized only if health-related data can be explored and exploited in the public interest, for both clinical practice and biomedical research. That will require implementing technical solutions that both protect patient privacy and enable data integration across patients.*

I disagree with the first finding: as described below, the Indiana Network for Patient Care and other HIEs have been able to acquire and merge data from a variety of existing health care information systems using existing mature health information standards for data coding and transmission. Other HIEs and research networks have also had success. Therefore linking health information systems and data to perform clinical operations or research is not impossible. It is simply extremely challenging and success has been limited to a few places. This more informed finding suggests that there exist workarounds and opportunities to incrementally improve how systems interoperate to achieve the goal of collating disparate data for analysis in a learning health system.

Today's lack of interoperability between EHRs not a problem of lacking interoperability standards. It's the lack of fully implementing them mainly due to the reticence of health systems and EHR vendors to share data. Lack of EHR data sharing is therefore more a problem of sociology than technology. JASON's prescription for a standard architecture and APIs may work in countries with strong central ministries of health and without pre-existing electronic health record systems, such as Rwanda, Kenya, and the Philippines (where the open-source systems OpenMRS and OpenHIE are being implemented nationwide), but it can't work in short order in the U.S., in my opinion.

I wholly agree with and support the second finding.

JASON states that "*Interoperability is best achieved through the development of a comprehensive, open architecture.*" I agree with this statement, but it is naïve to think that this will happen without dramatic changes in federal regulations and subsequent overhauls of existing EHRs and interface technologies, which would take 5-10 years. This report is "pie in the sky" and does not give practical advice in the current reality. JASON repeatedly states that merging data from disparate EHR systems will require APIs and semantic interoperability standards without any mention of the enormous challenges of establishing these latter, as recently outlined by D'Amore et al.⁴

JASON also asserts: "*This lack of evidence [that EHRs and HIEs improve quality, safety, or efficiency of care] is partly attributable to slower-than-anticipated adoption rates of computerized HIT systems, especially among small health care organizations and individual providers [2,3].*" These references are woefully out of date (2006 and 2009). ONC's own website provides information showing that by 2012, 80% of non-federal hospitals⁵ and half of

⁴ D'Amore JD, Mandel JC, Kreda DA, Swain A, Koromia GA, Sundareswaran S, Alschuler L, Dolin RH, Mandl KD, Kohane IS, Ramoni RB. Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative. J Am Med Inform Assoc 2014 (in press).

⁵ National Coordinator for Health Information Technology. Adoption of electronic health record systems among U.S. non-federal acute care hospitals: 2008-2012 (ONC Data Brief No. 9). Available at: <http://www.healthit.gov/sites/default/files/oncdatabrief9final.pdf>, accessed April 17, 2014.

physician practices in the U.S.⁶ have either implemented a certified EHR or have contracted to do so. Furthermore, a recent survey of HIE initiatives⁷ found that 61% more HIEs were actively exchanging clinical data in 2012 when compared to an earlier survey in 2010. And a very recent data brief from ONC reveals that the ability to electronically report laboratory results to public health departments grew dramatically from 8 states in 2005 to 48 states in 2014.⁸

“Even with the emerging evidence of benefit, implementing the useful exchange of EHRs across the entirety of the US presents an enormous challenge.” Agreed, so don’t try to do it all at once! Support large demonstration HIE projects like the Indiana Network for Patient Care^{1,2} and New York’s State Health Information Exchange³ to show what can be done and improve on current interoperability policies and procedures for health information exchange (HIE) and the organizational constructs and business models to support HIE along with the evidence that HIE works and is cost-effective. Then support other HIEs to implement these technologies.

JASON states that, *“Evidence that the widespread use of EHRs and HIEs actually improves the quality, safety, or efficiency of health care in the US has been slow to accumulate.”* It appears that the authors of the JASON report accepted this statement and did not attempt a relevant literature review. Yet in Indiana alone, use of INPC data has been shown to improve diabetes care and colorectal cancer screening,⁹ increase HIV testing among emergency department patients,¹⁰ lower the costs of emergency department care,¹¹ and enhance reporting of notifiable conditions to the State Department of Health.¹² Many similar studies from other HIEs have been reported in the peer-reviewed literature.

In summary, JASON fails to meet its original charge by ONC and AHRQ and instead proposes a radically different national EHR architecture. The latter is needed, but in the meantime there are important uses to which EHR data can be carefully applied. NIH recently created and generously funded the BD2K (Big Knowledge to Data) Initiative to develop tools, approaches, and methods to doing just that.¹³ Perhaps the results if the BD2K Initiative will provide ONC with the guidance towards the collation and use of EHR data that JASON failed to provide.

⁶ National Coordinator for Health Information Technology. Physician adoption of electronic health record technology to meet meaningful use objectives: 2009-2012. Available at:

<http://www.healthit.gov/sites/default/files/onc-data-brief-7-december-2012.pdf>, accessed April 17, 2014.

⁷ Adler-Milstein J, Bates DW, Jha AK. Operational health information exchanges show substantial growth, but long-term funding remains a concern. *Health affairs (Project Hope)*. 2013;32(8):1486-92.

⁸ Wu L, Abbey R, Daniel J, et al. ONC Issue Brief: Health IT for Public Health Reporting and Information Systems. Washington, DC: Office of the National Coordinator for Health Information Technology; 2014 [cited 2014 May 5]; Available from: <http://www.healthit.gov/sites/default/files/phissuebrief04-24-14.pdf>. Accessed August 1, 2014.

⁹ Central Indiana Beacon Community Fact Sheet. Available at: http://mpcms.blob.core.windows.net/bd985247-f489-435f-a7b4-49df92ec868e/docs/1224405a-2518-4a36-bf9b-4fc16ffce10e/default_57_1135785195.pdf. Accessed July 30, 2014.

¹⁰ Wilbur L, Huffman G, Lofton S, Finnell JT. The use of a computer reminder system in an emergency department universal HIV screening program. *Ann Emerg Med*. 2011 Jul;58(1 Suppl 1):S71-3.e1.

¹¹ Overhage JM, Dexter PR, Perkins SM, Cordell WH, McGoff J, McGrath R, McDonald CJ. A randomized, controlled trial of clinical information shared from another institution. *Ann Emerg Med*. 2002 Jan;39(1):14-23.

¹² Overhage JM, Grannis S, McDonald CJ. A comparison of the completeness and timeliness of automated electronic laboratory reporting and spontaneous reporting of notifiable conditions. *Am J Public Health*. 2008 Feb;98(2):344-50.

¹³ National Institutes of Health. Big knowledge to data (BD2K). Available at: <http://http://bd2k.nih.gov>, accessed February 24, 2014.

Research Panel Questions

1. Could you address the tension in the JASON report around consumer control of data sharing versus unfiltered data?

In 2011, the Regenstrief Institute received an ONC Challenge Grant (with me as the Principal Investigator) to design a system that would (a) capture patients' preferences for granular control over access to their EHRs and then (b) allow patients' preferences to determine what INPC data would be displayed to different categories of users. The goal of this project was to work through the technical and organizational challenges of creating and implementing a patient-controlled data segmentation system. This project included a demonstration study where this data segmentation program was fully implemented in one primary care clinic affiliated with Eskenazi Health, Indianapolis' urban public teaching health system affiliated with the Regenstrief Institute and the Indiana University School of Medicine. At the end of this six month demonstration study, we surveyed patients and providers opinions of data segmentation and its effects on patient care and communication. The comments below reflect what we learned as part of this three-year project for which a series of articles will be published in a special dedicated supplement to the *Journal of General Internal Medicine* in late 2014.

In our study, we tagged individual data items as being in selected categories of "highly sensitive" data as defined by the National Committee on Vital and Health Statistics.¹⁴ Although meta-data tagging was not difficult for discrete data (with numeric or coded results), it was not possible for information embedded in free-text notes and reports, where a lot of patient information is recorded. For example, a primary care physician's note could say, "The patient had an abortion at age 18 and post-partum depression after her first child at age 23." This sentence contains two categories of sensitive data—mental health and reproductive health—and yet the note would be tagged as "primary care" based on who wrote it or where it was written. Granular control of EHR data will not be possible until natural language processing (NLP) can tag every important concept within a free-text note and then redact text based on patients preferences.¹⁵ Currently, this is not possible, but we are working on it.¹⁶

Even discrete data can cause problems. For example, tricyclic antidepressant medications are often used for treating neuropathic pain and preventing headaches, making it difficult to know how to tag them. Similarly, some antipsychotic medications are also used to treat pain and nausea as well as schizophrenia. Until NLP matures and is widely implemented to extract data from free-text to clarify conditions for which drugs are prescribed or electronic prescribing systems force physicians to say what conditions they are treating with each prescription, classifying and controlling access to medication information will prove difficult. Yet JASON makes no mention of these difficulties in meta-data tagging. I believe this is an important area of

¹⁴ Carr JM. National Committee on Vital and Health Statistics Recommendations Regarding Sensitive Health Information. Available at: <http://www.ncvhs.hhs.gov/101110lt.pdf>. Accessed March 28, 2014.

¹⁵ Leventhal JC, Cummins JA, Schwartz PH, Martin DK, Tierney WM. Patient control of provider access to their electronic health records: Technical and organizational challenges. *J Gen Intern Med* 2014 (in press).

¹⁶ Were MC, Gorbachev S, Cadwallader J, Kesterson J, Li X, Overhage JM, Friedlin J. Natural language processing to extract follow-up provider information from hospital discharge summaries. *AMIA Annu Symp Proc*. 2010 Nov 13;2010:872-6.

development, and ONC should liberally support research and development of NLP as a core technology for EHRs and health information exchange.

Our research suggests that patients have widely different opinions of what data they would like visible to which type of health care provider and others who might have access to information in their EHRs.^{17,18} The JASON report overlooks patients' desires to provide very different levels of access to different types of health care providers and non-provider users of EHR information. For example, Caine et al. found that virtually 100% of patients would allow full access to their EHR data for their primary care physicians while only 15% would provide full access to researchers.¹⁷

Moreover, our research showed that health care providers were highly concerned with the adverse effects on the quality of care and provider-patient relationships if patients were allowed to restrict access to their EHRs.¹⁹ Yet the JASON report is silent on this issue. For example, on page 33, JASON states, "*It is anticipated that different patients would opt for different levels of assumed risk associated with sharing their personal data, in return for different perceived benefits that may accrue from that sharing, both for themselves and for society.*" This statement and the entire JASON report completely ignore the risks associated with patients hiding their health care data from their clinicians. Health care is an information-intensive business: most of the business of health care involves the collection, storage, reading, processing, and transmitting of information. Restricting provider access to patient information will undoubtedly pose risks to patient safety, resulting in errors of omission and commission, and could increase costs through duplicate testing and treatment.

Moreover, health care providers have a solemn responsibility to deliver the highest quality of care, often in the face of life-threatening conditions. Would it be fair to expect them to do so without the full complement of patient data? Balanced solutions that would give patients granular control over access to data in their EHRs must weigh their interests in controlling EHR access and how their data are used ("nothing about me without me") against their health care providers' responsibility to deliver the highest quality, most efficient care. JASON completely ignores this issue.

In summary, allowing patients to have effective granular control over access to data in their EHRs—determining what information they would hide from whom—requires a level of NLP that is currently lacking. Hiding and redacting data from health care providers could have adverse effects on the quality, safety, costs, and outcomes of care and on provider-patient relationships.

¹⁷ Caine K, Hanania R. Patients want granular privacy control over health information in electronic health records. *J Am Inform Assoc* 2013; 20:7-15.

¹⁸ Caine K, Kohn S, Lawrence C, Hanania R, Tierney WM. Access, understanding, control and notification: Implications for the design of a patient-centered tool to allow individual choice in the disclosure of EHR data. *J Gen Intern Med* 2014 (in press).

¹⁹ Tierney WM, Alpert SA, Byrket A, Caine K, Leventhal JC, Meslin EM, Schwartz PH. Provider responses to patients controlling access to their electronic health records: A prospective cohort study in primary care. *J Gen Intern Med* 2014 (in press).

2. What do you need in terms of unbiased participation?

Biased data yields biased results that cannot be relied upon to tell the truth about the topic being studied. Truly unbiased studies must have full access to all available data, and only unbiased results should be used for clinical decision-making.

3. How you feel about opt in or opt out option (for patients)?

The question about opting in and opting out can be asked of both data segmentation and access to data for research. I will discuss each of these separately.

In our ONC-funded data segmentation study, we took an opt-out approach. We did this for two reasons. First, our qualitative research with patients showed that patients expected health care providers to have access to their EHRs unless the patient desires otherwise. And in health care, providers have had such access throughout history. Hence, both patients and providers believe the status quo is opting out. Suddenly changing to an opt-in approach would be much more difficult to implement from both cultural and technical reasons. Moreover, the INPC uses an opt-out approach to capturing patient data into the HIE, and it has functioned well for 25 years.

As for opting in and out of using data for research, first we have to define research. Generally, there are two categories of investigations that use patients' EHR data: little 'r' research (where analyses are performed, usually by provider organizations, to improve quality and safety and to manage practices more efficiently) and big 'R' research (where analyses attempt to generate new knowledge, usually by academic investigators). I believe health systems should have full access to patient data for quality improvement research unless patients opt out. Such studies are necessary and patients directly benefit. Academic researchers using identified data should be required to get consent (opting in). Researchers should be able to use de-identified data unless patients opt-out. In both cases, Institutional Review Board review and approval is required.

Let's talk about de-identification. On page 50, JASON states that de-identification is impossible. That is patently false, and JASON provides no references. I have found no case where data completely lacking any of the 18 HIPAA personal health identifiers could be linked back to individual patients unless one has access to the health system's data in the first place. All individuals who have such EHR access are governed by enforceable data use agreements. If they are going to breach patient confidentiality, they don't need de-identified data to do it.

Because truly de-identified data as defined by HIPAA cannot be traced back to individual patients, patients are at very low (if any) risk of harm from their de-identified data being used for big 'R' research aimed at generating new knowledge. For patients whose data are being analyzed, such research could be of direct benefit to them. Hence, an opt-out approach to research using de-identified data is appropriate and will generate unfiltered, complete data since our experience has shown that very few Eskenazi Health patients choose to opt out of having their data used for research (and during each encounter with Eskenazi Health, patients are given the option of opting out).

4. What is your position on consent? JASON report argues that de-identification techniques are not robust for ensuring privacy so they advocate the need for informed consent. Federal research rules does include a form of consent via professional committees- IRBs Consent may cause relevant data to be filtered.

I discussed these issues above in response to Question #3.

5. What challenges and successes have you had to date collecting and utilizing data from EHRs and other health IT systems? Would a JASON like architecture help address the challenges you encountered?

For more than 25 years, I and my colleagues have worked with data from the Indiana Network for Patient Care (INPC), one of the country's oldest, largest, and most comprehensive health information exchanges.^{1,2} The INPC uses a standard data transmission format (HL7) to download data in real time from health information subsystems (lab, pharmacy, registration) in 103 of Indiana's approximately 120 hospitals into a single cloud-based data repository. The INPC also captures and merges identified patient data from health insurers, Indiana Medicaid, and the Indiana State Department of Health. Through a document delivery system that sends most of the laboratory and imaging reports in Indiana to more than 20,000 subscribing physicians,^{2,20} the INPC captures most laboratory test results in Indiana as numeric or coded results, when available, or text reports. As a result, since it was established in 1987, the INPC has captured more than 5 billion observations for more than 14 million individual patients, including more than 11 million in 2012 alone.

The INPC data use standard codes such as ICD9-CM, CPT-4, and LOINC for diagnoses, procedures, and diagnostic tests and clinical observations, respectively. A core of code mappers maintains the integrity of the coding scheme and deals with exceptions that don't automatically match the INPC's concept dictionary. The INPC also provides data to its 103 hospitals and affiliated outpatient practices via a standard messaging format, the continuity of care document (CCD).

The architecture JASON recommends would not help the INPC, as it has been able to maintain analyzable data across 103 institutions using the current interoperability and coding standards. In fact, moving to new an entirely new architecture as recommended by the JASON report would place a substantial burden on the INPC and all other existing HIEs and data sharing within multi-hospital health systems. The INPC's developers have shown that current technologies and coding schemes are sufficient to deal with the vast majority of health information systems (and subsystems) and data types. Scrapping these for a different set of standards would create a lot of work with minimal benefit. Although it has been difficult to establish and maintain health information exchanges in the U.S., this has not been due to technical barriers but rather sociological, political, and economic barriers to the sharing of information between health care provider organizations. Certainly the current technologies can be improved: for example, Fast Healthcare Interoperability Resources (FHIR), an improved health care messaging standard.²¹

²⁰ Barnes M. Lessons learned from the implementation of clinical messaging systems. AMIA Annu Symp Proc. 2007 Oct 11:36-40.

²¹ FHIR. Available at <http://www.hl7.org/implement/standards/fhir/>. Accessed July 28, 2014.

All of that being said, I have also had experience developing and implementing electronic health records in developing countries. I led a group of Kenyan and American informaticists that deployed sub-Saharan Africa's first outpatient electronic health record system in 2001²² which became the platform for a comprehensive HIV/AIDS information system²³ that, in turn, was transformed into OpenMRS.²⁴ Closely following the architecture outlined by JASON, OpenMRS is an open-source platform for EHR development that has been implemented in more than 40 countries, most in sub-Saharan Africa and Asia. We have shown the system to be interoperable transnationally in sub-Saharan Africa²⁵ where analyses have included data for tens of thousands of patients from dozens of HIV/AIDS clinics.²⁶ Because these countries had centrally controlled health care delivery systems and no pre-existing EHRs, they were able to establish a single open-source standard that could be implemented. In fact, five countries are currently in the process of implementing OpenMRS in all national health clinics: Rwanda,²⁷ Kenya, Tanzania, Mozambique, Bangladesh, and the Philippines.

So based on this experience, I agree with JASON that in countries other than the U.S. that have a centrally controlled national health system, especially where there are no pre-existing EHRs, an open-source platform with common interoperability APIs and open-source development can more easily yield interoperable electronic health information. I just don't believe it is possible to force such an architecture at one time in the U.S. where we have no national health system and the majority of hospitals and physicians' practices already have EHRs or have contracted to install them.^{5,6} An incremental approach is warranted.

²² Rotich JK, Hannan TJ, Smith FE, Bii J, Odero WW, Vu N, Mamlin BW, Mamlin JJ, Einterz RM, Tierney WM. Installing and implementing a computer-based patient record system in sub-Saharan Africa: The Mosoriot Medical Record System. *J Am Med Informat Assoc* 2003; 10:293-303.

²³ Siika AM, Rotich JK, Simiyu CJ, Kigotho EM, Smith FE, Sidle JE, Wools-Kaloustian K, Kimaiyo SN, Nyandiko WN, Hannan TJ, Tierney WM. An electronic medical record system for ambulatory care of HIV-infected patients in Kenya. *Int J Med Informat* 2005; 74:345-355.

²⁴ OpenMRS. Available at <http://www.openmrs.org/>. Accessed July 28, 2014.

²⁵ Tierney WM, Achieng M, Baker E, Bell A, Biondich P, Braitstein P, Kayiwa D, Kimaiyo S, Mamlin B, McKown B, Musinguzi N, Nyandiko W, Rotich J, Sidle J, Siika A, Were M, Wolfe B, Wools-Kaloustian K, Yeung A, Yiannoutsos C, the Tanzania-Uganda OpenMRS Consortium. Experience implementing electronic health records in three East African countries. *Stud Health Technol Inform* 2010; 160:371-375).

²⁶ Ciaranello A, Lu Z, Ayaya S, Losina E, Musick B, Vreeman R, Freedberg KA, Abrams EJ, Dillabaugh L, Doherty K, Ssali J, Yiannoutsos CT, Wools-Kaloustian K. Incidence of World Health Organization stage 3 and 4 events, tuberculosis and mortality in untreated, HIV-infected children enrolling in care before 1 year of age: an IeDEA (International Epidemiologic Databases To Evaluate AIDS) east Africa regional analysis. *Pediatr Infect Dis J*. 2014 Jun;33(6):623-9.

²⁷ Allen C, Jazayeri D, Miranda J, Biondich PG, Mamlin BW, Wolfe BA, Seebregts C, Lesh N, Tierney WM, Fraser HS. Experience in implementing the OpenMRS medical record system to support HIV treatment in Rwanda. *Stud Health Technol Inform*. 2007;129(Pt 1):382-6.

Responses to Additional Questions

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

Implementing the architecture recommended by JASON is not possible in the U.S. at this time or the near future, given the current status of vendor-driven EHR implementation. However, the path to realizing a JASON-like architecture will not be evolutionary—the country will not gravitate in that direction spontaneously, since the main financial commitment to EHRs is through commercial vendors. Moving in that direction will take political action by ONC, CMS, Congress, or some other governmental agency with the power to engage the health care and biomedical informatics communities and wrestle control of the EHR infrastructure from the vendors. Such political actors don't (and won't) make such fundamental changes quickly, especially in a sector of our economy (health care) that generates 18% of GDP.

My organizations (the Regenstrief Institute, the Indiana University School of Medicine, Eskenazi Health, and IU Health) don't face the challenges of implementing a JASON-like architecture because we already have a highly functional HIE, the Indiana Network for Patient Care, that includes most of the citizens of Indiana, effectively uses established messaging and coding standards, has been serving our clinical, managerial, and research needs for decades.^{1,2} Moreover, Regenstrief's Global Health Informatics Program has already implemented a JASON-like architecture in the developing world and is using it to roll out national EHR and HIE systems in Rwanda, Kenya, Tanzania, Mozambique, Bangladesh, and the Philippines.

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

I don't have the expertise to comment usefully on technologies to assure privacy and security of health information.

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

OpenMRS²⁴ and OpenHIE²⁸ follow an organizational structure and function quite similar to what JASON recommends, with a standard open-source platform and APIs supporting EHR development by a community of developers. As shown in the map to the right, OpenMRS has been implemented in more than 40 countries and is being implemented in all Ministry of Health venues in five countries: Rwanda, Kenya, Tanzania, Mozambique, Bangladesh, and the



²⁸ OpenHIE. Available at: www.openhie.org. Accessed July 31, 2014.

Philippines. As mentioned above, this is possible because (a) these countries have a national health system that is centrally funded and governed, and (b) there are very few existing EHRs.

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

There are several serious efforts to develop a standard platform and APIs for data sharing in the U.S. Most HIEs and RHIOs have done so (or are doing so). Mini-Sentinel²⁹ and PCORNet³⁰ are two similar large-scale, multi-institutional efforts. As mentioned above, OpenMRS²⁴ is becoming quite successful with this approach in the developing world.

10. *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?*

I don't have the expertise to make such recommendations.

11. *What processes and approaches would facilitate the rapid development and use of these standards, implementation specifications, certification criteria and certification processes?*

To be frank, I don't think these standards, specifications, and certification policies and processes will be developed rapidly. There are too many large EHR vendors who have their products in place in too many health care institutions to fundamentally change their model of software development and interfacing overnight. I think this requires a national dialogue, led by ONC and perhaps AMIA—the governmental agency in charge of EHR development and rollout and the world's oldest academic society without significant conflicts of interest—that would include health care providers, EHR developers, HIEs, the research community, and patients. The latter should be represented by real patients and not advocates for a particular approach to health care information storage and management. This development process, guided by ONC and CMS, will take 5-10 years to complete.

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

I believe that health information exchange is required for the interchange of health care information. I don't believe an "N by N matrix" of every EHR being connected to, or available for searching to, every other EHR is a realistic model, at least at this point. If one believes that statewide or regional HIEs are a near-term solution, they will require financial support from

²⁹ McClure DL, Raebel MA, Yih WK, Shoaibi A, Mullersman JE, Anderson-Smits C, Glanz JM. Mini-Sentinel methods: framework for assessment of positive results from signal refinement. *Pharmacoepidemiol Drug Saf.* 2014 Jan;23(1):3-8.

³⁰ Florence RL, Curtis LH, Califf RM, Platt R, Selby JV, Brown JS. Launching PCORnet, a national patient-centered clinical research network. *J Am Med Inform Assoc.* 2014 Jul-Aug;21(4):578-82.

ONC which, in turn, can then drive the conversation on evolving the U.S. EHR community to a standard platform, APIs, and interface technologies.

13. 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?

- A. Commit to health information exchange as the near-term solution for wide access to health care information. Generate a plan for financially supporting statewide or regional HIEs, and then implement it. Support should be based, to a significant extent, on the degree to which health systems and providers participate in an HIE and use HIE data for clinical care, care management, improving quality and safety, and research.
- B. Support the use of existing standards and interoperability frameworks and work with their governing bodies to improve them to better serve the needs of EHR data analysts aiming to improve care and generate new knowledge.
- C. Support developmental and implementation research on natural language processing (NLP) and other technologies for identifying and tagging EHR concepts and using the meta-data tags to enhance the usefulness of EHR data to clinicians, clinical managers, quality improvement and safety enhancement coordinators, and researchers.
- D. Engage health systems, clinicians, biomedical informaticists, researchers, EHR vendors, and especially patients in a national dialogue on how best to balance Fair Information Practice principles and patient control over EHR access with providers' need for EHR data to deliver safe, high-quality, cost-effective care.
- E. Convene health system leaders, the vendor industry, academic biomedical informaticists, and patients to develop a set of high-level policies for HIEs and their capture, management, transmission, sharing, and analysis of health care information.
- F. Convene technical experts to design interface technologies and detailed implementation schemes based on the policies developed in E above.
- G. Once the groups in E and F complete their work on HIEs, have them begin working on the next generation architecture of health information infrastructure for the U.S. At that point, the current JASON report, though even more out of date, will provide a decent starting point for the conversation.