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A Shared Nationwide Interoperability Roadmap

Request for Comment Response

April 3, 2015

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Introduction

Accenture strongly supports ONC's goals of furthering interoperability, outlined in the *Connecting Health and Care for the Nation - A Shared Nationwide Interoperability Roadmap*. From Accenture's leadership role in Health IT and our long-standing support of ONC programs, including the Standards and Interoperability Framework, we appreciate the value a comprehensive health IT roadmap can provide to the government, healthcare industry, and citizens. As a global consulting company with more than 600 clients from leading healthcare providers, payers, public health, and life sciences organizations, Accenture feels that interoperability is an important business priority for our high performing clients and will help them ultimately provide better healthcare and services to their customers. We applaud ONC for providing the healthcare industry with a strategic direction and forum to collaborate on how to best accomplish critical interoperability tasks.

Accenture commits to helping ONC in their mission of advancing healthcare through interoperability. We can act as a conduit between ONC and our healthcare clients. Accenture can serve as a trusted sounding board for ONC regarding how policy decisions might impact the healthcare industry, leveraging our understanding of our clients and their challenges in the current healthcare system. We can also inform our healthcare clients of the Interoperability Roadmap and the objectives set forth by ONC, and of nationally recommended standards that should be considered for the implementation of health IT. We are also committed to connecting ONC with our relevant healthcare clients, to help strengthen collaboration. Additionally, as an employer for more than 323,000 Accenture staff globally and therefore a private purchaser of healthcare, we strive to provide our employees with modern, effective benefit plans to provide our employees with the best possible care. Our U.S. based benefit plans are with payers who are openly supportive of healthcare interoperability and participate in collaborative discussions with other payers regarding data exchange.

Accenture appreciates the opportunity to provide this commentary to the Nationwide Interoperability Roadmap. We recognize the significant impact the plan will have for both the private and public health sectors as well as citizens. In addition, we would welcome the opportunity to discuss the plan with you in further detail.

Accenture’s Answers to Questions Posed in a Shared Nationwide Interoperability Roadmap

General

1. *Are the actions proposed in the draft interoperability Roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?*

   Of the four critical actions for near term wins, we strongly support advancing incentives for sharing health information according to common technical standards, starting with a common clinical data set. Providers should be financially incentivized to share data, and to take advantage of available data from other sources, such as using previous test results in lieu of ordering a new test. Bill codes could specify that existing data was used instead of ordering new tests, ensuring there was a record of reuse. Leveraging alternative data sources in patient care will directly enable interoperability, lowering costs and providing better care.

   We also recommend that ONC consider actions that enable mobile access to administrative and financial data. The Roadmap places an emphasis on expanding consumer and mobile access to clinical data, but ignores administrative and financial data by ruling it out of scope. This exclusion conflicts with the changes going on in healthcare delivery systems and payment reform, and we encourage ONC to include considerations for administrative and financial data while determining near term solutions for interoperability.

2. *What, if any, gaps need to be addressed?*

   - <u>Common Clinical Data Set.</u> Additional focus and standardization is needed for a defined common clinical data set. It is widely understood that a common data set is essential for interoperability, yet there are still gaps between organizations using the same EHR vendors (e.g. Cerner, Epic) because the “local code sets” are not compatible. This is only magnified when the sharing of data is attempted between competing vendors.

   - <u>Varying speeds of EHR adoption and interoperability</u>. The roadmap should account for the fact that different providers and different consumers will “adopt” technology at varying paces based on many factors, not just the four critical actions for near term wins. Different stakeholders will have different incentives and drivers. The different rates of adoption can be improved through the existence of intermediaries that can help absorb the differences. The roadmap should consider alternative routes that offer different paces.

3. *Is the timing of specific actions appropriate?*

   Yes, with two considerations:

   - Consider gradual level of participation. It will be difficult for all organizations to adopt consistent standards at the same time due to a variety of reasons, such as budget limitations, variations in workflows and practices, available resources, etc. Invariably there will be some who come on board sooner and others later. A graduated level of participation in a national system needs to be considered as opposed to an organization being all in or not able to participate at all.

   - Maturity of standards as a key factor in interoperability. The timing for the adoption of standards should take into account the time required for successful testing and piloting of the standards. It is counterproductive for the industry to implement untested standards to only find out later that they need to be amended. Accenture encourages ONC to fully assess standards maturity before including them in future rule making. We will also provide our comments to ONC's "2015 Interoperability Standards Advisory" paper.

4. *Are the right actors/stakeholders associated with critical actions?*

   Yes, especially with the emphasis and focus on the user-friendliness of the system for the healthcare workers and patients. The learning health system must always be focused on the needs of the primary users – health care professionals and their patients. Feedback about data and its associated workflow from participating members of both of these groups is key to developing and implementing a successful system. It would be unfortunate to create a technically superb system only to find out that the users find it awkward or cumbersome in its everyday use. Representative input from patients and professional medical organizations is essential as the system is developed and implemented.

Priority Use Cases

1. *Appendix H (shown below) lists the priority use cases submitted to ONC through public comment, listening sessions, and federal agency discussions. The list is too lengthy and needs further prioritization.* ***Please select 3 priority use cases*** *from this list that should inform priorities for the development of technical standards, policies and implementation specifications.*

   Based on the request to select 3 priority use cases, #3, 18 and 33 should be included.
   3. The status of transitions of care should be available to sending and receiving providers to enable effective transitions and closure of all referral loops.

33. Providers have the ability to query data from other sources in support of care coordination (patient generated, other providers, etc.) regardless of geography or what network it resides in.
39. Primary care providers share a basic set of patient information with specialist during referrals; specialists “close the information loop” by sending updated basic information back to the primary care provider

The roadmap acknowledges the importance of giving patients access to their data, and including them as a significant player in the learning health system. In order for patient access and coordinated care to function properly, all providers will need to have effective EHRs, interoperable with other providers. ONC should prioritize use cases to support and automate the basic care process, and follow later with patient specific use cases.

Governance

1. *The draft interoperability roadmap includes a call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. ONC would like to recognize and support this process once it is established. How can ONC best recognize and support the industry-led governance effort?*

   ONC can best recognize the industry-led governance effort by appreciating how the industry currently views the role of the US government in healthcare and what they believe the role should be. There is a need for creating the rules that allow for a level “playing field” and which incorporates the input of all stakeholders (patients, providers, vendors, and federal agencies). At the same time, it is important that consumer demand and provider profitability influence the outcomes. There is a strong need for ONC to develop a fair governance model and then make modifications as time goes by to “rebalance” the model as dictated by the market. ONC should remain actively engaged in the governance process to help ensure that patients/individuals are represented. They also need to be actively engaged to ensure that appropriate communication is taking place between different stakeholders. ONC should also be involved in the identification of national priorities as part of the overall governance process. Additionally, in its role as coordinator, ONC should help promote and communicate business incentives in order to encourage organizations to align with common practices and standards.

Supportive Business, Cultural, Clinical and Regulatory

1. *How can private health plans and purchasers support providers to send, find or receive common clinical data across the care continuum through financial incentives?*

   Private health plans and purchasers can support providers by driving the payment arrangements and then allowing the standards and technology stakeholders to come up with solutions. That would serve as a call from the purchasers, in a collective way, to the industry to provide approaches to address the need for standardization. These alternative proposals could be assessed based on defined criteria to select a preferred approach for the payers to adopt. The appropriate stakeholders would need to be involved in selecting the approach, including CMS and states, as well as vendors and providers.

2. *Should they align with federal policies that reinforce adoption of standards and certification?*

   Yes, private health plans and purchasers should align with federal policies to reinforce adoption of standards and certification. It is important that the private payers and government align on what they want from data exchange. Right now there is a disconnect in the quality measurement space and this is a significant burden on vendors and providers. A collaborative process like the one described in the question above could help move towards alignment. The process should not be the government making decisions and the payers falling into line.

Privacy and Security Protections for Health Information

1. *What security aspects of RESTful services need to be addressed in a standardized manner?*

   Currently for SOAP based health related web services, there are specifications that prescribe Authentication, Identity Proofing, Authorization and Consent Management. However, there are no such specifications currently defined for RESTful Services.

   RESTful services typically depend on the security provided by HTTP layer (or HTTPS). Developers will need to build security in their software design. There are best practices provided by OWASP (The Open Web Application Security Project) to consume, develop and use RESTful web services.

   https://www.owasp.org/index.php/REST_Security_Cheat_Sheet#Authentication_and_session_management

   Testing and verification of the services to ensure that they have been implemented in a secure fashion will be essential. For example, how do the consumers know real-time that the services they are consuming are secure/authentic? There needs to be a standard form of mutual remote attestation, so the consumer and service provider can interoperate in a secure and confident manner. This goes above-and-beyond typical authentication/authorization as a way to verify the integrity of each party in the transaction.

Core Technical Standards and Functions

1. *Which data elements in the proposed common clinical data set list need to be further standardized? And in what way?*

In general, clinical data objects need an underlying information model that supports clinical care, quality measures/clinical decision support, and research. The model must consider that initial data capture most likely depends on front line care givers. Data captured at the point of care is likely to be the best and most precise that will be available downstream; this doesn't necessarily align with the precise granular needs of downstream secondary users. In our experience, successful implementation is unlikely without a standard underlying model.

Standardizing the definition of the common clinical data set does not solve interoperability without addressing how context, provenance, and security flags are established for the data. Documents, messages, and even queries provide context to data, but once consumed by a system, one must decide what context must always be attached to the data. There is a need to distinguish standardizing the coding of the data element from the representation of the data element. For some there are nearly universally accepted coding sets, but even in these cases there are deviations. "Sex" would seem like a simple coding problem, but there are coding variations dependent on purpose of use, e.g., physiological, sexual identity. The concept of patient name can be different across countries, where naming has different components and meanings. Our opinion is that if all the data elements are standardized, interoperability is more likely to be effective, leading to increased abilities to conduct effectiveness research or measure population health.

The Interoperability Roadmap's proposed common clinical data set includes Medication Allergies, with RxNorm being the advised standard. However, significant complexity still remains in handling allergies of drug classes, and the transformation and mapping required for drug classes between medication terminologies is an ongoing and complex endeavor. Food/substance allergens are also critical, and although SNOMED-CT or UNII have been discussed, many EHRs are not conformant to this and utilize free text fields. Because the content and structure standards (particularly legacy HL7 v2.x) and source systems do not commonly include the ability to represent the patient's allergy list and structure with multiple terminologies, it is still nearly impossible for several different health systems to store, represent, and synchronize an accurate full list of allergies (symptoms, severity) with each other as a patient's health evolves.

As health systems absorb multiple specialties, Procedures are also represented in Current Dental Terminology (CDT). This was supported by Meaningful Use Stage 2 as an optional route for recording dental procedures. However, as it is optional, some EHRs have opted not to incorporate this yet, jeopardizing the interoperability and loss of specificity. In addition, dental procedures are commonly stored and communicated by tooth – with past procedures, current procedures, and 'care plan of future procedures' all associated by the tooth involved. Since these are organized in different documentation areas (Procedures, Care Plan) for other health fields, in C-CDA templates and even in newer FHIR resources, we find that flexibility for this area may be needed.

2. *Do you believe the approach proposed for Accurate Individual Data Matching will sufficiently address the industry needs and address current barriers?*

   We do not believe the approach is sufficient. The proposed approach is primarily around enhancing data quality by identifying and standardizing data elements that need to be used in patient matching. The approach then suggests testing other voluntary data elements and, upon analyses of results, making these data elements part of the required set. What's not being elaborated upon is the actual matching itself. This approach will improve the matching results, as data quality and sufficiency is the primary driver that causes mismatches or false negatives, but only up to a point, and it probably will not sufficiently address industry needs. The desire for exchanging and linking patient information across facilities still outweighs the ability for each provider, facility or data-holder to perform the necessary data quality updates and IT capabilities to synchronize more standard matching algorithms and capabilities across platforms.

   Measuring the matching capabilities will be complex. Chances are that this will be most difficult to measure at the sites that likely have the worst issues with data quality and current patient matching capabilities. Additional fields, such as previous name and previous address, could be considered, but this addition in the typical 5-point matching algorithms, platforms, exchanges and patient query service profiles seems excessive. Until HHS can create policy around a unique identifier to support HIPAA's original requirement, this issue will continue.

Certification and Testing

1. *In what ways can semantic interoperability be best tested? (e.g., C-CDA content and semantics)*

   Semantic interoperability requires both a consistent understanding of the data itself and tight binding to terminology. Testing must address both of these areas. For the data model, testing must validate that the data is interpretable against an agreed upon reference model. The desired outcome is that the system receiving or using the data can reliably interpret it without creating mappings for each data source and that the data itself can be reliably interpreted and not produce medical errors.

   Tests for semantic interoperability can include a set of end-to-end use cases that include a receipt of a patient summary record (C-CDA) and the ingest of this record, which includes a problem list, medications and allergies. The test would be a set of clinical actions prescribed for this patient that demonstrate that the information was ingested, displayed, and used properly for procedures, such as prescribing medications and identifying specific drug-drug interactions from the summary care record information.

Testing of the semantic binding may be simpler because the reference model should provide the binding, so if you know the data element that you are representing, the binding should be easy to validate.

A potential barrier is the need for a robust and clinically validated reference model. Without the reference model, the testing and certification will have limited scope and value.

Measurement

1. *Does the measurement and evaluation framework cover key areas? What concepts are missing?*

Yes. The framework groups the measurements into three key areas of: capability to exchange; information flow and usage; and impacts. We agree that those are the appropriate key areas to focus on. However, we feel further clarification is needed on how much information sharing is done by provider in the "Information Flow and Usage" focus area. The focus seems to be on "ability to search, access, ingest, and use external data," which is important, but the outbound aspect of "rate of sharing and informing external participants of patient activity" is also critical. How well is that provider coaching its practice to inform fellow providers or associated specialists? A measure of "closing the loop" would be helpful to understand how many clinical events requiring a closed loop response are achieved. This measure could potentially be completed with other e-Prescribing, Lab and CPOE measures. In addition, we believe additional consults, referrals, and information returned or published to related care team is also important.

2. *Which concepts from the framework are the most important to measure? What types of measures should be included in a "core" measure set?*

In the near term, we suggest that ONC consider including the following types of measures:

1. The percentage of possible users that have the infrastructure in place to enable exchange of EHR data. Identify and remove the barriers that prevent non-participants from exchanging data.
2. Among those that have appropriate access, measuring the uptake and usage among different populations/segments and types of data being exchanged/requested and under what scenarios.
3. The type of information most desired for exchange among care givers and between care givers and patients/consumers/their families and focus on those areas that will have most impact.

We recommend monitoring the "Outbound" % of discharge summaries / summary care documents and the % of clinical information shared to the system that adheres to standard terminologies. Conversely the "Inbound" % of discharge summaries /summary care documents that are accessed based on the number of requests attempted, % successfully received, etc.

We also recommend that ONC consider the following measurement issues:

1. The level(s) at which nationwide measurement should occur (e.g., encounters or patients; users; organizations; or health care system or network-wide) and
2. The inclusion of a subset of nationwide core measures should focus on certain subpopulations or use cases where the value of exchanging data using interoperable health IT is considered a priority within the Roadmap.

3. *Should measurement focus on certain use cases, priority populations or at certain levels of the ecosystem (e.g., encounter, patient, provider, organization)?*

Yes, focusing measures on priority populations such as the chronically ill would demonstrate more precise usage and impact where 80% of care is being spent. A chronically ill patient will likely have multiple specialists involved and require information sharing to different care team members. Measuring the information received, processed and utilized for chronically ill patients should be higher level of exchange activity, and higher and more measurable impact than an entire population. The measurement of information shared 'outbound' and notified 'inbound' for this patient population could result in a good measured balance of that provider's role in the care team.

4. *What other types of metrics have been successfully used at the local or regional level that might be considered for nationwide use? Would stakeholders be willing to propose novel metrics and provide "test beds" to assess the potential for nationwide use?*

From our work at the Social Security Administration, we know that SSA measures the number of medical records received from interoperable partners and identifies the number of disability cases that can be adjudicated with the interoperable data. In addition, VA, CMS, or other government agencies that adjudicate claims could potentially measure the number of claims that can be fully adjudicated with the information received from interoperable parties. However it is unlikely that these federal stakeholders would provide "test beds" to assess potential for broader/nationwide use due to PII concerns.

5. *What measurement gaps should be prioritized and addressed quickly?*

One of the program goals is to reduce health care costs by leveraging existing data, but yet there is no measure that addresses this goal. Because a small portion of the population has interoperable medical data, there needs to be a methodology for aggregating this data to measure how widespread interoperability is at the population level. ONC needs to define the scope of interoperability. From our experience, one way to accomplish this is by measuring rates of access. This data should be available via Audit Trail and Node

Authentication (ATNA) audit logs of exchanges. Events should be logged for every read/inquiry detailing the requesting organization and provider.

6. *What other available data sources at the national level could be leveraged to monitor progress?*

   NIH, CMS and SSA may have data that could be leveraged to monitor progress, and we recommend that ONC work closely with other agencies to assess where they can leverage and share data to monitor progress of interoperability.

   For prescriptions, some e-Prescribing networks have advanced capabilities to track prescriptions filled, and communicate this back to the provider. However, the closed loop of sending a response back to the prescriber to understand whether medications were filled is an important part of medication adherence and should be considered. These e-Prescribing networks do track providers that have integrated this capability and those who have not.

   Private sector organizations often conduct surveys and may provide information on EHR adoption and plans to implement that could be used to determine “capability to exchange”. There are likely state and local groups that have members that are participating in health data exchanges as well. Perhaps these groups could serve as a mechanism to collect the information. There may also be transactional data that is available to track usage. For example, there are ways to track web and mobile app usage among end users. To the extent that we focus on specific Web based and mobile health applications, we could get a view on absolute adoption and usage rates. There are API platforms and web/mobile analytics tools that can help us track activity.

7. *Are the potential mechanisms for addressing gaps adequate? What are other suggestions?*

   There are still significant barriers to measuring the impact of learning health system ‘research’ aspects, and the ability for organizations to achieve the optimal capabilities of de-identified data sharing (outbound and inbound) and enabling data usage for research purposes. Until a measure is set that establishes a visible outward progression towards more open de-identified data sharing for research purposes, organizations have very little incentive to share ‘outbound’ and require significant investment to access other ‘inbound’ data sources as well.

8. *How should data holders share information to support reporting on nationwide progress?*

   From our experience, we believe it would be helpful to have a required reporting process to provide insight into adoption, barriers, usage and value. Data holders could start with self-reporting at first. This would provide insight into the state of the market. To promote more accurate reporting and adhere to privacy regulation, the data may need to be kept confidential.

9. *What are appropriate, even if imperfect, sources of data for measuring impact in the short term? In the long term? Is there adequate data presently to start some measurement of impact?*

   We believe there needs to be an explanation regarding the return on investment and value of interoperability across different use cases using an accepted set of metrics for costing. Once it is understood how people use the data from external sources to support diagnosis, treatment, and referrals, the value could be better quantified. While this may be imperfect, it would provide a rule of thumb for quantifying benefits.

   We also recommend quantifying the extent to which getting medical history and early warning signals or knowing adverse reactions is helpful in preventing deaths, injury, unnecessary hospital stays, and costs. There is a need to model impacts so the industry knows a tangible value of interoperability. For example, there is a huge initiative in hospitals around hand washing and things like the checklist manifesto around sound business processes in hospitals. They have proven a strong ROI from this, which has led to greater adoption of these processes. The more we can show a cause and effect relationship, the more likely the industry will take actions to implement and track the measurements of impact.

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