Comments from Kforce Government Solutions (KGS)

1   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?

The Meaningful Use program includes any meaningful health information exchange requirements and significant gaps to achieve interoperability itself. Today, the widespread adoption of electronic health record (EHR) systems that providers use are difficult to use and lack the ability to exchange information without costly upgrades. We are well into the next level of the Meaningful Use program and providers are struggling to meet even modest Health Information Exchange (HIE) requirements that need to be addressed as an action, which is less emphasized as a practical approach.

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

The roadmap focuses heavily on technology specifics that vendors and providers need when developing IT products. It is less focused on actual interoperability on how it needs to be addressed.

3. Is the timing of specific actions appropriate?

Although there are high-level time-lines proposed, there are not enough details about how to implement the milestones to ensure success. KGS recommends providing enough guidelines for a successful implementation.

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

This document identified various stakeholders across the guideline. It will be beneficial to combine the overall roadmap, along with implementation timelines with stakeholder mappings, to provide a snapshot about who owns what. The actions are not targeted towards the interoperability across the areas.

2   Priority Use Cases

1. Appendix H 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 submit 3 priority use cases from this list that should inform priorities for the development of technical standards, policies and implementation specifications.

The top three priority use cases that need to be addressed are:

- 39 – Primary care providers share a basic set of patient information with specialists during referrals; specialists "close the information loop" by sending updated basic information back to the primary care provider
- 21 – Patients have access to, and can conveniently manage, all relevant consents to access or use their data.
- 35 – Individuals have electronic access to an aggregated view of their health information including their immunization history.

Although the full priority list is lengthy, use cases should be categorized into three to four groups. By developing these groups, the ONC can strategically address use cases.

Direct Patient Care –Patient-centric Use Cases (15)

- 4, 7, 9, 11, 12, 13, 14, 18, 20, 35, 36, 37, 48, 52, 56
- Top 3

  - 35 – Individuals have electronic access to an aggregated view of their health information including their immunization history.
  - 36 – Individuals integrate data from their health records into apps and tools that enable them to better set and meet their own health goals.
  - 37 – Individuals regularly contribute information to their electronic health records for use by members of their care team.

Bi-Directional Communication Use Cases (13)

- 1, 2, 3, 5, 6, 8, 10, 23, 27, 39, 40, 41, 43
- Top 2

  - 39 – Primary care providers share a basic set of patient information with specialists during referrals; specialists "close the information loop" by sending updated basic information back to the primary care provider.
  - 40 – Hospitals automatically send an electronic notification and care summary to primary care providers when their patients are discharged.

Administrative, Research, & Statistical Use Cases (18)

- 15, 16, 19, 21, 24, 28, 32, 34, 38, 42, 44, 45, 46, 47, 49, 50, 51, 55, 29
- Top 2

  - 21 – Patients have access to and can conveniently manage all relevant consents to access or use their data.
  - 49 – While managing chronically ill patients after a disaster, emergency medical providers have the ability to query data from other sources regardless of geography or which network houses the data.

Financial – Payer and Care Giver Billing Use Cases (7)

- 22, 25, 30, 31, 38, 53, 54

3 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?*

The ONCs challenge is to ensure that governance is developed that encourages continued innovation and improvements in health information exchange, while safeguarding personal and patient health information. The ONC needs to be a stakeholder that focuses on safeguarding patient data.

To achieve the goals of nationwide interoperability, there needs to be a high level of Public Trust. Our nation's data is constantly under attack and cyber terrorism is a part of every

American's life that can negatively impact the number of patients that can benefit from healthcare interoperability. The ONC must challenge the healthcare industry to invest in security innovations that results in a high level of patient and care provider confidence.

The Department of Veterans Affairs (VA) MyHealth*e*Vet and the Virtual Lifetime Electronic Record Health (VLER) program provided the ability for VA health care providers to share health information with non-VA providers, when authorized by the patient. Recently, the VA provided additional security controls to further secure patient information and VA systems. This was achieved through cloud innovations and published Federal security standards.

It will benefit the ONC in being the champion for open source interoperability. To achieve nationwide interoperability, all organizations need to invest in solutions that provide the ability to communicate within and outside their organization. This can be a larger financial challenge for some organizations and regions. Continuous review and promotion of open-source solutions will promote discussions and development of new and innovative open-source solutions.

To recognize and support the industry-led governance effort, KGS suggests the ONC adopt an approach that focuses in on patient confidence and open source development. By grouping the use cases submitted to public comment, listening sessions, and Federal agency discussions into four major categories, the ONC can prioritize current and future use cases, as well as lead IT stakeholders to introduce governance that meets the needs of patients and organizations.

4   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? Should they align with Federal policies that reinforce adoption of standards and certification?*

Financial incentives will be driven by two primary forces: private health plans wanting to decrease costs while attracting more insurers and consumers wanting better value for their healthcare dollars. Private health plans will make the business case for savings across its network. Savings obtained from insurer's using multiple providers across its network would be one component of that business case. Private health plans could use co-marketing dollars, and/or pass along administrative cost savings, and/or savings from signing-up new companies, to their network providers to help defray interoperability investments. This would be done in concert with private health plans marketing efforts to attract new customers by touting the value of their network's interoperability.

End-consumers (patients) will choose the value that makes the most sense for their stage in life and their financial capacity. This will lead to market differentiation and levels of service enabled by basic interoperability. For example, in a healthcare world that is patient-centric where an individual's health record is universally portable, then data analytics specific to the patient's demographics, genetic-profile, history, etc. would be a value-add. Of even greater value-add would be analytics based on ongoing clinical data, the patient's illness-profile, and their treatment regimen. In these examples, it is easy to imagine private health plans increasing their data analytics capabilities as a profit center or service.

If the private health plans business case is substantial enough, they could use existing Consumer Groups to market the value of interoperability to their consumer members. Together, the private health plans and consumer groups could lobby Congress for interoperability policy or regulations. The Federal Government could also accelerate adoption and ultimate value-add to

everyone by increasing the cost of non-compliance. This might be an area where the Federal Government can lead by example.

For example, VA could provide Veterans with a consolidated view of their health records across VA Medical Centers (VAMCs) and outside Purchased Care providers. VA could then market it as a value that everyone should have (e.g., have access to a consolidated health record and clinical data across all healthcare providers. This could be done with specific Consumer Groups, which in-turn, become patient advocates. Ultimately, consumers' behavior will drive the financial incentive by choosing health plans and providers that provide the greatest value.

KGS believes that the Federal Government can only effectively incentivize and ultimately enforce adoption through Federal policy. The concrete example that we can provide as part of our past performance is the migration of X12-formatted electronic healthcare transactions from version 4010 to 5010, and National Council for Prescription Drug Programs, (NCPDP)-formatted electronic pharmacy transactions to version 5.1 to D.0. Both 5010 and D.0 are Health Insurance Portability and Accountability Act (HIPAA) mandated Electronic Data Interchange (EDI) formats. As such, the migration was Federally mandated. The 5010/D.0 migration project was an over two-year project requiring changes to VistA and its enabling EDI systems. This project was also a systems prerequisite for the eventual migration from International Classification of Diseases (ICD)-9 to ICD-10. Highlights include:

- VA was ready and compliant as per the Federal mandate, on time and ahead of widespread industry compliance
- The VA FSC ensured VA's readiness by developing dual 4010/5010 transaction processing capabilities (in case required changes to VistA were delayed)
- The dual 4010/5010 processing capability also enabled VA to continue to transact with non-compliant trading partners and to automatically switch once the outside trading partners were compliant

As stated, VA was ahead of the industry and its solution enabled the industry to catch up. CMS extended the compliance date for the industry but imposed fines for any entity not meeting the new date. This is a valid and KGS-unique example of how the Federal Government can use policy, existing legislation (HIPAA), and the sheer size of its healthcare operations, to enforce adoption of interoperability standards. Financial incentives will be obtained by industry by those who figure out how to sell their interoperability capabilities to anyone doing healthcare business with the Federal Government.

5 Privacy and Security Protections for Health Information

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

REST is simple, scalable, and more consistent with Internet protocols (e.g., GET, PUT, POST and Delete). REST does not have predefined security methods, which causes developers to negate security implementation details. This leads to web services with serious vulnerabilities, including injection attacks, cross-site scripting (XSS), and broken authentication and cross site request forgery (CSRF).

Security aspects of RESTful services that need to be addressed are ***authentication and authorization***. There are standard practices that can be used to implement RESTful services in a more secure manner. KGS would like to follow security guidelines set by National Security

Agency (NSA), Enterprise Applications Division of the Systems and Network Analysis Center (SNAC): https://www.nsa.gov/ia/_files/support/guidelines_implementation_rest.pdf

6   Core Technical Standards and Functions

The common clinical data set and individual data matching approaches both have sufficient information for current and future needs.

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

KGS agrees and strongly support to standardize common clinical data set to improve consistently and reliably of data shared during transitions of care (and with individuals and their caregivers) to achieve a foundation of interoperability. KGS also supports decision of expanding common data set vitals details to include body height; body weight measured; diastolic and systolic blood pressure; heart rate; respiratory rate; body temperature; oxygen saturation in arterial blood by pulse oximetry; body mass index (ratio); and date and time of vital sign measurement.

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

KGS supports the proposed approaches for accurate individual data matching by establishing standards for required sets of data elements for individual identity query and record linking transactions, as well as establishing best practices for patient registration, patient updates, and correction to information. We also agree to include at least two technical profiles when requesting patient records from HER systems for Individual Data matching and Patient Identifier Cross Referencing (PIX)/Patient Demographics Query (PDQ) for internal system use and Cross-Community Patient Discovery (XCPD) for external use.

7   Certification and Testing

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

Semantic interoperability can be viewed as the ability for data shared by systems to be understood at the level of fully defined domain concepts. We endorse the operational definition of semantic interoperability as "the ability to import utterances from another computer without prior negotiation, and have your decision support, data queries and business rules continue to work reliably against these utterances," with an understanding that interoperability improves incrementally.

Challenges to today's semantic interoperability include ambiguities, lack of complete expressivity, redundant representations that cannot be computationally converted into a common canonical form, implicit semantics, and misunderstanding of context. Testing semantic interoperability between two computer systems means measuring whether information exchanged can be automatically interpreted by the receiving system accurately enough (with reliable sensitivity and specificity under the same decision support rules) to produce useful results, as defined by the end users of both systems.

Health IT requires models of sufficient generality to bridge multiple uses, and this requires an overarching approach to interoperability that is both general and capable of specificity to address new use cases. Such a strategy is being developed within Health Level 7 (HL7) and exchange

protocols, including the HL7 version 2 messaging standards; the HL7 version 3 messaging standards; and the HL7 Clinical Document Architecture (CDA) family of clinical document standards. HL7 version 3 messages and CDA documents are richly expressive, in that they can formally represent a significant breadth and depth of clinical content, including professional recommendations, national clinical practice guidelines, and standardized data sets as templates or constraints.

Perhaps the best known example of a templated CDA specification is the HL7 Continuity of Care Document specification, where the standardized data set defined by the American Society for Testing and Materials (ASTM) Continuity of Care Record is used to guide the construction of templates that constrain CDA specifically for summary documents. Other CDA Implementation Guides built on this templated CDA strategy include Consult Note; Diagnostic Imaging Report; Discharge Summary; History and Physical Note; Operative Note; Procedure Note; Personal Health Monitoring Report; Public Health Case Report; Neonatal Care Report, and others.

To best test or certify semantic interoperability using HL7 CDA, a single logical data storage model is important because received communications could be parsed and imported, and semantics would be explicit so that, given guidelines for safe querying, a complete understanding of data – regardless of the sender or interoperability profile – would be possible. Decision support and business rules would trigger and execute as expected, and data from multiple sources would be safely and reliably aggregated. Data from one source could be safely and reliably used in another context. The many silos and data pockets of today would be collapsible into a single meaningful resource. The following technical steps can facilitate the testing and certification process:

- Create a reference physical database for storing imported expressions – A Reference Information Model (RIM)-based physical database capable of storing CDA documents would meet this requirement.
- Develop a library of database queries – Database queries can identify patients for whom a decision-support rule should fire, or patients that should be included in a quality measurement population. A community library would allow for contributions from a wide variety of stakeholders.
- Submit sample instances into the database – HL7 CDA instances are submitted into the database where they are parsed and stored.
- Measure query sensitivity and specificity against imported utterances – Measuring sensitivity and specificity can serve as a gold standard of knowing whether or not an imported utterance provides data that ideally should be detected by a set of database queries.

8   Measurement

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

Yes, the framework covers how health information will be shared, exchanged, transferred, used, and evaluated across various health system components and stakeholders well.

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

Information flow and usage are the most important concepts to measure. As this process evolves, it would be valuable to establish a set of granular measures on syntactic, semantic, and process interoperability and methods to evaluate a particular interoperability process that takes place locally, regionally, or nationally.

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

As a major national initiative, it is practical to select certain domains and priority populations to focus on first. Organizations with more advanced HIE infrastructure and policies in place are more suitable for pilot rollouts. To date, health information between providers and patients has been inherently asymmetrical, where providers have more advantages over patients in terms of data collection, management, standards, and integration. Assuming this information imbalance continues, providers should initiate the interoperability efforts with standardized EHR structure for patients across the care continuum to follow.

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?*

Lack of unified, well-specified standards has been a main impediment to achieving interoperability, which kept many providers from electronically sharing information. HIE organizations have been actively pursuing the goal of unified standards and made some progress. For example, the eHealth Exchange, which was formerly known as Nationwide Health Information Network (NwHIN), has successfully demonstrated its ability to link participating healthcare provider and consumer groups through CONNECT software at a regional and national level.

More emphasis should be placed on unified standards as a part of the EHR certification process. Given historically a lack of established interoperability standards has resulted in vendors using vastly different terms, methods, and approaches to designing their health IT systems, stakeholders are more likely to be willing to propose novel metrics and provide "test beds" to assess the potential for nationwide use. This will significantly reduce variation and increase the likelihood that these systems will be unable to talk to and understand one another.

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

The following measurement gaps/key characteristics/metrics have high priorities and need to be assessed, tested, and addressed both locally and nationally for scalability: 1) independence of technical architecture and exchange modality, and 2) health data can be aggregated to report up at the population level.

An organization can form or join a quality and data analytics team in order to become familiar with the types of information being requested and where it fits into the standards realm. It is important to create a matrix to track what types of data are transmitted, how it is transmitted, and what standards are used.

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

Because ONC presently is largely reliant on self-reported data from national surveys and program participants, it is important to include data-driven reports to monitor progress more

objectively (e.g., reports on how reliable and successful the transitions of information exchanged among hospitals or medical centers, supported by logs, calculated success rates, summaries of exchange failures, documentation on exceptions) followed by mediation solutions or standards.

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

ONC plans to leverage partnerships with Federal agencies on reporting and tracking and use nationwide surveys of health information organizations to monitor infrastructure to support exchange and exchange activity. However, to effectively monitor eligible providers and hospitals and avoid self-attestation of meeting the requirements, there needs to be a more rigid mechanism to address gaps identified.

An interoperability governance committee can play a critical role in overseeing program integrity by reviewing documents submitted from providers and hospitals and analyzing the data to ensure they truly meet interoperability requirements. It is essential that proper and continuous oversight is in place not only to ensure meaningful use of EHRs through the three stages, but also to prevent fraud and abuse vulnerabilities in EHRs and HIEs.

In order to move this to an implementation level, the financial incentives for each stakeholders – either direct incentives or indirect incentives – need to be thoroughly communicated and tracked so they will gain confidence and momentum for adoption. Publishing the metrics about implementation success will be added factor for adoption or to get enough details to push for the adoption.

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

First, data holders should refer to the best available standards and implementation specifications published by the interoperability standard advisory to categorize and structure their local health data by clinical purposes and code sets. Various data holders then could share information through Service Oriented Architecture (SOA) that enables different systems to interoperate together.

For known, trusted recipients, an unsolicited "push" method can be used to send health information directly to the destination. Query can also be conducted among data holders within and outside a specific health information exchange domain to solicit and retrieve data. With advanced cloud technologies, it is also possible to store and aggregate standardized health data from multiple data holders in a centralized data repository, where large-scale data can be maintained and protected in a systematic manner and each participating HIE member can access the repository regardless of its region. This way, data holders can easily share updates to further support ONC to report on nationwide progress.

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?

In the short term, reports or surveys conducted on providers, hospitals, and health information organizations will remain essential to track and measure interoperability impact. For example, comparative reports from Agency for Healthcare Research and Quality (AHRQ) on how many duplicative tests, harmful drug interactions, and readmissions were there before and after interoperability implementation within an organization.

In the long run, with progress on personal health records and advanced telehealth and mHealth technologies, consumers (patients) can play an important role on monitoring the impact of health information exchange and interoperability. Not only can they measure and report the number and success rate of interoperable transactions, but also the quality of syntactic, semantic, organizational, conceptual, and technological interoperability between patients and care delivery organizations.

Presently, the experience and progress made through eHealth Exchange can facilitate a good start on testing and measuring interoperability impact. Over the past few years, Federal agencies, including VA and DoD, have exchanged millions of patient records, and their interagency health exchange results can serve as a good starting point to measure interoperability impact. In addition, Health Information Service Providers (HISPs) have supported eHealth Exchange participants by providing them with operational and technical health exchange services necessary to fully qualify to connect to eHealth Exchange. With an open source software supported architecture, more participants may be able to join the network and provide more adequate data sources to measure interoperability impact.