[Submitted Electronically to HealthIT.gov]

April 3, 2015

Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Washington, DC

RE: **Draft *Interoperability Roadmap***

Kaiser Permanente offers the following comments on the **draft ONC Interoperability Roadmap ("Roadmap")**, posted January 27, 2015 at the CMS Quality Measures Public Comment page.[1]

The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the U.S., with over 9.5 million members in eight states and the District of Columbia.[2] Kaiser Permanente is committed to providing high-quality, affordable health care services and improving the health of our members and the communities we serve. We recognize that evidence-based quality measures, sound methodology and well-designed quality reporting will help lead to improvements in health care delivery.

We appreciate the opportunity to provide our feedback.

GENERAL COMMENTS

Kaiser Permanente commends ONC for presenting a vision and direction to achieve nationwide interoperability. We strongly support the US health care system becoming a functionally interoperable learning health system.

We agree that interoperable health IT can contribute to improving health outcomes, quality of care, and access to care at a lower cost. As we describe in more detail in this letter, we strongly recommend defining interoperability in broader terms. The Roadmap should focus on identifying, achieving, and measuring the larger goals interoperability is intended to serve (for example, improving population health, or better supporting transitions of care) rather than

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[1] http://www.healthit.gov/policy-researchers-implementers/interoperability-roadmap-public-comments

[2] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 38 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members.

targeting interoperability as an end in itself. Interoperability can help the healthcare system realize the goal of having personal health information available for decision-making at the point of care.

Furthermore, the Roadmap should address how interoperability relates to transformation of health and health care, including payment reform and new care delivery arrangements. These are influential factors in transforming how care is delivered and in advancing the adoption and use of interoperable systems. Beyond increasingly paying for health outcomes, these reforms promote and transform the relationships, expectations, and interactions among providers, consumers, payers, regulators, and other industry stakeholders. With this broader view of changes and trends in healthcare it is should be understood that different models of care delivery and financing can use different models of health information technology and interoperability.

As we discuss in detailed comments in this letter, Kaiser Permanente is also concerned about the establishment of a coordinated governance as presented in the Roadmap.

KAISER PERMANENTE RESPONSES TO ONC GENERAL QUESTIONS ON THE ROADMAP

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?

Some of the near-term (2015 to 2017) critical actions identified in the Roadmap are important steps to take; some of them are achievable. However, other proposed actions are neither the right ones, nor are they achievable in the near-term timeframe. Comments on specific proposed actions are presented in our comments on each section of the Roadmap.

What, if any, gaps need to be addressed?

Business Case. The most significant gap is the lack of a business case for interoperability within the current volume-based payment model. It is crucial to promote and advance the adoption of alternative payment and care delivery models that are based on value and outcomes, not volume and processes. So long as the current fee-for-service payment system is the predominant model, achieving interoperability will be slow at best, or impeded at worst.

Interoperability beyond Technical Levels. The lack of interoperability at other levels beyond technical connectivity (messaging, exchange) is another gap, including semantic, clinical, process and policy interoperability. For example, at the clinical level, current clinical workflows and practices are set up to capture specific data (using specific definitions), and data captured for one purpose may not be used for other purposes due to the lack of semantic interoperability (as an example, the FDA mini-sentinel system currently has 67 different units of measure for blood platelet count).

Interoperable Standards. Another gap is the limited availability of a core set of mature interoperable messaging and content standards for specific common purposes that are

unambiguous, non-situational, ubiquitous, and that avoid or limit interpretation, optionality, and customization.

Unique Identifiers. Progress will be impeded by a lack of valid and unique identifiers for all individuals interacting in health care, including providers, payers and patients, forcing the industry to depend on imperfect, inaccurate, and inconsistent matching methods and approaches.

National Privacy Policy. There is a need for a national privacy policy that applies consistently across states, data, purposes of use, organizations, and individuals, and that is not modifiable or adaptable by states or regions. Such a policy must be flexible and scalable to keep pace with technological innovations.

Data Provenance. The lack of a workable, scalable, data provenance meta-standard that can be used across standards, health IT systems, and data sharing models is another gap ONC should address.

Is the timing of specific actions appropriate?

As we address in more detail later in this letter, we question whether some of the near-term critical actions identified in various sections of the Roadmap are achievable in the proposed timeframe.

We are also concerned that the Roadmap has not fully identified or addressed interdependencies between various critical actions, as well as other factors (e.g., payment and care delivery reform).

Are the right actors/stakeholders associated with critical actions?

In many cases, they are; however, in some cases, not all of the appropriate actors have been identified. As we explain in more detail, below, clinician participation will be necessary to validate usability and the ultimate value of proposed activities.

Please note that all other ONC Questions on the Roadmap from Page 6 are addressed within each of the comment sections below.

COMMENTS ON THE OVERALL GOAL AND DEFINITION OF INTEROPERABILITY

The overall goal of interoperability should be to ensure that the right information about the right person is available at the right time, and also to help patients and clinicians make the best decisions about health and health care. While some ways of achieving the first part of this goal are considered in the Roadmap, the second equally important part is not.

From that perspective, interoperability is a means to achieving the larger end, which is to deliver accurate, reliable, and timely information to improve health care decision-making and ultimately health. Interoperability is not an end in itself. With the patient at the center, achievement of interoperability goals will be measured by the information available, and the ability to act on that information.

We are concerned that the definition of interoperability is insufficient to encompass the goals of patient-centric information availability and care. In this Roadmap, as well as in the Vision document and the Federal Strategic Plan, the definition narrowly focuses on one technical dimension of interoperability, following the definition from IEEE. While we acknowledge the importance of utilizing the IEEE definition, we strongly believe that interoperability, as it applies to health, health care, and health information technology, must be defined in a much more comprehensive way, to include all the following elements:

- Expanded interoperability domains should include consumer engagement, patient narrative, business process, clinical workflow, operational, technical and policy domains
- The technical domain should specify semantic, syntactic, and process interoperability.

Interoperability is much broader than just transactional health information exchange, which is the primary focus of the Roadmap. Achieving the goals of information availability can be met via multiple models, such as shared access, shared systems, or centralized data aggregation; each should be recognized as equally valid approaches to interoperability in addition to the transactional exchange model.

Also, interoperability applies to more than simply electronic health record (EHR) systems; it encompasses health IT more broadly (i.e., IT systems across all health and health care) and to other domains beyond health IT, as noted above.

Interoperability must support healthcare providers that manage a tightly integrated ecosystem, as opposed to fragmented, individual applications simply connected via interfaces. With one of the goals being to support the continuum of care, interoperability must enable healthcare providers to connect all system components that support care delivery in a seamless manner.

COMMENTS ON ROADMAP INTRODUCTION, VISION, SCOPE, PRINCIPLES AND STAKEHOLDERS

Introduction and Relationship to Federal Health IT Strategic Plan

The Federal Health IT Strategic Plan lays out five goals under three overarching themes:
- Collect (Goal 1: Expand Adoption of Health IT);
- Share (Goal 2: Advance Secure and Interoperable Health Information); and
- Use (Goals 3 – Strengthen Health Care Delivery, 4 – Advance Health and Well Being of Individuals and Communities, and 5 – Advance Research Scientific Knowledge and Innovation).

As stated in the document, the Roadmap focuses mainly on defining a path for achieving the advancement of secure and interoperable health information (Goal 2). Realistically, however, all five goals rely on interoperability. The Roadmap fails to explore the key intersections and inter-dependencies between these goals.

Vision

The 2024 vision statement should be more ambitious than having an array of "products and services that support continuous learning and improved health." In addition, interoperable processes and policies should be developed to achieve a true learning health system. While it will be important to 'send, receive, find, and use', the vision must also include 'access.' A key drawback of the Roadmap is its focus on transactional information exchange with little or no regard to other models such as search and access in cloud-based data services environments that may use application program interfaces (APIs) to achieve the same outcome.

We agree that the Roadmap should acknowledge that the term 'health information' includes not just the traditional clinical-based documentation, but also personally maintained and provided information and services.

Scope

As noted above, the proposed definition of interoperability is too narrowly focused on technical capability of a system to exchange health information without special effort from end users. We disagree that the intersection of clinical and administrative electronic health information is out of scope. To achieve true interoperability, both clinical and administrative information domains should be considered because both may be equally important to patient and clinician decision-making. Access to medical records and health plan records together helps to provide a comprehensive picture of the patient.

We believe that other critical elements, such as technology adoption, data quality, documentation and data entry, usability and workflow are within the scope of the Roadmap. These are all critical components for achieving interoperability and should be considered.
The Roadmap notes that it "focuses on decisions, actions and actors required to establish the *best minimum level of interoperability* across the health IT ecosystem, starting with clinical health information, in support of a learning health system." While this is a good, basic start, all the other elements need to also be considered as well. It is important to recognize valid alternatives so as not to drive the entire system to the lowest common denominator.

Guiding Principles

We agree with, and support all ten revised, updated guiding principles. Some comments on specific principles follow.
- "Empower individuals" should be the first principle
- "Focus on value" should be the second principle
- One size does not fit all. The Roadmap says "we will strive for baseline interoperability across health IT infrastructure, while allowing innovators and technologists to vary the usability...." We do not believe that usability per se should vary. The technical design and internal process workflows are elements that should be allowed to vary internally, while always striving to achieve the highest, measurable and meaningful level of usability.
- "Leverage the market." One of the most important market levers, payment and care delivery reform, is not mentioned. The Roadmap should highlight these critical levers.

- "Maintain modularity." The Roadmap should emphasize that independent components must be able to interconnect (interoperate), and conform to specified functional standards.
- The principle of "Universal Access" should be de-coupled from the principle of "Scalability" as it really addresses a different issue: one about Equity in availability and the other about accessibility of technology across the entire ecosystem.
- Lastly, the principle of "Consider current environment and support multiple levels of advancement" should be merged with the principle of "Scalability" under a combined "Scalability and Multiple Levels of Advancement".

Stakeholder Perspectives

The list of stakeholders includes a very wide array of perspectives in health and health care (delivery, payment, public health, government programs, researchers, policymakers, vendors, governing/certification/accreditation bodies, standards organizations). We suggest more detail describing the mechanisms to ensure robust clinical end user input throughout the interconnected activities outlined in the Roadmap.

While it is valuable to consider all of these stakeholder perspectives, the Roadmap is less clear about the roles and responsibilities of each with respect to the critical actions being considered. At the same time, it is not clear how ONC will balance competing or conflicting perspectives in an open and transparent way. To achieve its goals the Roadmap should describe how a balance of stakeholder interests will be maintained for decision-making by public and private stakeholders together without a heavy-handed top down approach.

International Perspectives on Interoperability

With the increased need to exchange health information between countries, it seems important that the Roadmap consider including a discussion on cross-border interoperability and information exchange. Examples of current challenges and issues can be extracted from international projects such as the Trillium Bridge EU-US interoperability project of the European Commission or the EU-US health IT collaboration effort under the S&I Framework. The 10-year Roadmap should lay the foundation to enable information exchange between the US and other countries of individual health information utilizing international interoperable electronic standards.

COMMENTS ON "RULES OF ENGAGEMENT AND GOVERNANCE" SECTION

We are concerned that the Roadmap seems to call for renewed efforts by ONC to define a nationwide governance framework. ONC has tried this in the past, and (as noted in the Roadmap document) failed to gain support from the industry. Given the current status of organized health information exchanges across the country, the need to advance adoption of true interoperable standards, and the significant work needed to transition the industry to alternative payment and delivery models, which are critical enablers of interoperability, we recommend against ONC pursuing another attempt at a top-down, government-centric, federally controlled governance process for health information exchange.

The Roadmap states that governance should address policy, operational and technical standards, and the development of a single set of basic rules to support nationwide interoperability. However, the Roadmap falls short of defining what such common "rules of the road" should be.

The governance principles regarding policy, operations and standards are inconsistent. Some are more like specific requirements; some duplicate existing health information policy (e.g., access to personal health information, or security). Others would tighten controls over health information, beyond existing statutory/regulatory controls (e.g., individual choice). Some overlap the different governance principle domains (e.g., transparency).

Because the domains lack clarity, we recommend eliminating them in favor of listing a set of distinct principles.

Critical Actions

Near Term (2015-2017)

We oppose ONC defining a nationwide governance framework with a common set of rules of the road. We are concerned that developing a common clinical data set for treatment purposes is unrealistic. Different areas of clinical care (clinical specialties, other clinical and health care domains) will not (and possibly should not) systematically collect the same 'common' clinical data set (forcing some clinical specialties to collect information that is not useful or routinely captured in practice). The Meaningful Use program has demonstrated this, by requiring certain providers or specialists to collect data and report measures that are not entirely applicable to them, simply in order to meet the requirements and receive the incentive payments.

The proposed common data set is not well vetted and does not comprise a set of standards. It should not be imposed as a one-size-fits-all solution in varying medical specialties, situations, and care settings. The proposed data set is missing information most frequently requested by clinicians for treatment purposes (e.g. clinical studies like EKG) and it is not well-aligned with common research data sets. Furthermore it is inappropriate to set the same priority for all data elements.

We are also concerned about ONC defining a framework for exchange of patient-generated health data. We agree that a framework is needed for such exchanges. However, the Roadmap calls for establishing a mechanism ONC would use to recognize organizations that comply with common rules of the road. We do not believe that should be a role of ONC. Such recognition is not needed, and could result in harmful, unintended consequences.

Interoperability should be measured by the larger goals: to ensure that the right information about the right person is available at the right time; and to help patients and clinicians to make the best decisions about health and health care. ONC should focus on developing reliable metrics to assess the ability of health IT systems to achieve these

larger goals, through interoperability, rather than attempting to create artificial or arbitrary measures of information exchange to measure interoperability.

COMMENTS ON "SUPPORTIVE BUSINESS, CLINICAL, CULTURAL AND REGULATORY ENVIRONMENT" SECTION

We strongly agree with the Background and Current State section regarding the negative impact of the current fee-for-service payment model on advancing interoperability. We believe the message should be stronger and clearer: Paying for volume is the single greatest disincentive for adopting and advancing interoperability. Until integrated payment models are more widely adopted (moving away from fee-for-service), the ability to move forward on interoperability will be dramatically hampered. Without new payment models, even the best interoperable health IT systems will have limited value because of the lack of financial incentives to use them.

Increased care delivery integration and coordination will also drive increased demands for interoperable systems, another significant factor for transforming how care is delivered and for advancing the adoption and use of interoperable systems. The Roadmap should connect the promised benefits of interoperability, like greater efficiency to those who bear the costs.

We feel it is important to acknowledge the growing geographic mobility and increased consumer choices in the evolving marketplace, resulting in increased numbers of consumer transitions across and between health plans and providers. Thus, interoperability at multiple levels is critical to ensure that data follow individuals across systems.

We support using identified federal and state government policy and procurement levers to advance the adoption and use of interoperable health IT systems. However, we recommend emphasizing the role that federal and state health care programs have in adopting alternative payment models and integrated care delivery models as the most significant lever to advance interoperability.

Role of private payers (health plans) and purchasers

We agree with the areas identified in the Roadmap where payers and purchasers can help advance interoperability, including driving accountable care, adopting value-based payment models, establishing expectations for providers to use interoperable health IT systems, and incentivizing consumers to choose providers that use advanced health IT systems. Payers and purchasers can also help measure the level of care coordination by providers in their networks, as well as adopt next-generation population-based quality measures that support alternative payment models. Payers and purchasers can also align their policies with federal policies that reinforce adoption of standards and use of certified interoperable health IT systems.

Critical Actions

Near Term (2015-2017)

We agree with most near-term critical actions (federal, state, private sector). We question the statement that "ONC will reinforce the ability of individuals and providers across the care continuum to send, receive, find and use a common clinical data set through its funding programs," because there are no details about such funding nor what ONC intends to implement to support these aims.

COMMENTS ON "INDIVIDUALS ARE EMPOWERED, ACTIVE PARTNERS IN THEIR HEALTH AND HEALTH CARE" SECTION

This is another area where the impact of alternative payment models and integrated care delivery reform will have significant impact. Currently, individuals in many health care settings are passive recipients of health services rather than active partners, largely as a consequence of a pay-by-volume (fee-for-service) model.

We strongly agree with the fundamental principle of person-centered health care, and the need to enhance consumer access to and control of their health information.

It is imperative to balance the ability of consumers to control their own health information with the fundamental need of providers to access and use relevant information about a patient to provide the safe and appropriate care. The underlying principle of trust between consumers and providers (patient-provider relationship) should be emphasized.

It is also important to acknowledge the risks when providers make health care decisions based on fragmented information or information that may not be reliable. The Roadmap should address consumer-generated health information, and how it is integrated with all the other clinical health information. Another crucial set of issues involves establishing data provenance standards that can support both the incorporation of patient-generated health information into care delivery, and the inclusion of provenance data when exchanging information with others.

Critical Actions

Near-term (2015-2017)

We suggest that the call to action should be revised to: "All entities that hold health information about an individual should, upon request, provide that information to the individual in an electronic format the individual can use"

We agree that ONC should work with industry to identify best practices for incorporating patient-generated health data in health care delivery. ONC should conduct research and evaluate pilot projects to better understand the value and opportunities of incorporating patient-generated data into care delivery (e.g., how individuals access and use their health information through mechanisms like Blue Button, mobile applications, patient web portals, etc.).

COMMENTS ON "CARE PROVIDERS PARTNER WITH INDIVIDUALS TO DELIVER HIGH VALUE CARE" SECTION

We support the basic statements made in this section and agree it will be important to evolve beyond meaningful use of specific technologies to advancing the learning health system of the future. However, the Roadmap should further explore the value and importance of clinical decision support systems that promote care coordination and continuity of care across organizations.

We recommend greater consideration of transitions of care, long term care, and behavioral health as areas where interoperable systems to support care coordination are critical.

Critical Actions

Near-term (2015-2017)

We agree with all the calls to action.

COMMENTS ON "PRIVACY AND SECURITY PROTECTIONS FOR HEALTH INFORMATION" SECTION

Ubiquitous, Secure Network Infrastructure

We agree that it is important to establish a ubiquitous secure network infrastructure to address concerns that an intrusion in one system could allow intrusions in multiple other systems, and to acknowledge variability in the capabilities and resources across the health care spectrum.

However, we believe that throughout the document, the concepts of "network security" and "data security" seem to be mixed together inappropriately. These are related security sub-domains, but each addresses its own set of issues. We believe a secure network of the learning health system of the future should ensure securing data at rest, in transit, and in use (e.g., in memory/cache), adhering to a common set of data security standards. In addition, it would be helpful to see data security separately discussed in this section, instead of combining it with network security.

The Roadmap should identify and discuss critical components of a secure network infrastructure, including verification and authentication of systems, users, and user identities, authorization of users to access systems and specific data in those systems, defining appropriate access controls, and establishing adequate audit controls. Instead, this section focuses primarily on the importance of encryption, which though a critical element of a secure network, is neither the only nor the most important element in a secure information infrastructure.

Critical Actions

Near-term (2015-2017)

These near-term actions are reasonable and appropriate, including updating the Office for Civil Rights (OCR) Security Risk Assessment tool; establishing a cybersecurity Information Sharing and Analysis Center (which has already happened at nhisac.org);

working with US Commerce Department's National Institute of Standards and Technology (NIST) to publish NIST's Critical Infrastructure Cybersecurity Framework and HIPAA Security Rule crosswalk; and developing a uniform approach to enforcing cybersecurity compliance in health care. However, performance of a deep-root analysis to identify and define most common system vulnerabilities and exploitable risks within the health care industry (including unique health IT systems and needs that create greater risks) is an important component missing from the list. We also believe that, with respect to NHISAC, more maturity and continued process improvement is necessary within the ISAC.

While developing 'at-rest' standards for data encryption and providing technical assistance in this area may be a valuable step, imposing new, stricter requirements about such methods across the entire health care ecosystem would be complex, very costly, and may pose significant patient safety risks if systems do not allow provider access to information for treatment purposes quickly at all times.

Verifiable Identity and Authentication of All Participants

The Roadmap discusses the importance of defining appropriate policies and procedures to identify, verify and authenticate all individuals in the health care ecosystem, yet it should be clearer about the different steps and components of the secure authentication process, including identification, verification, authentication, and access control. It is equally important to highlight the authentication and verification not just of individuals, but also of systems and devices (including clinical technology and mobile devices) that interact with each other and access/exchange health information. While the EHR system serves as the keeper of a patient's record, other ancillary systems including clinical and mobile devices hold pertinent data that must be integrated with the rest of the information in the EHR to ensure all valuable and relevant information is available in a timely manner to providers and patients. An example of the importance of such interoperability is the integration of infusion pumps with the EHR. These devices have grown in complexity to perform dosing and other functions, and programming of the pump through an EHR may result in prevention of adverse events.

Multifactor authentication and higher levels of assurance offer important benefits towards assuring secure, unambiguous authentication of users. However, while multi-factor authentication and higher levels of assurance are becoming technically feasible, their complexity, scalability limitations, and cost can be significant. They apply not only to health care providers and health care organizations, but to every other individual and organization that interacts with the health system. It is also important to note that the level of assurance (LOA) of identity proofing should be consistent with the LOA of authentication, appropriate to the risk level of electronic health information being accessed. For example, it would be inappropriate to use a 2-factor authentication – or LOA 2 or 3 - with a social identity (LOA 1) to access health information that is considered high risk and requires at least LOA 2.

The organizational and operational challenges experienced by the National Strategy for Trusted Identities in Cyberspace (NSTIC) are a reflection of the complexity of these issues. For ongoing authentication, requiring multi-factor authentication for all access to patient portals is market-

premature. Multi-factor authentication is not in wide consumer use, even in the financial services sector. It also poses particular usability problems with some segments of patient populations, including the elderly, poor, and those with learning and intellectual disabilities. We recommend instead offering multi-factor authentication as an option to patients for online access to their clinical information, rather than making it mandatory.

Establishing multi-factor methods for authentication within patient portals, even as a patient-elected service, is complex. Use cases need to address access through web and mobile channels. As such, an implementation date of the end of 2017 is unrealistic for a well-designed, safe, usable system. Before establishing national requirements across the health care spectrum for use of multi-factor authentication and higher levels of assurance, there needs to be analysis and evaluation of the scalable and financially accessible models that includes analysis of the risks that strict authentication methods pose to access of patient information by providers for treatment purposes and related patient safety issues.

A patient portal may provide various information at different risk levels. For example, a patient accessing a doctor's online profile may be a lower risk than retrieving lab results; ordering a prescription of controlled drug substances may pose a higher risk than a general prescription. Multi-factor authentication may be enforced in a certain portion of the patient portal that involves a higher risk of health information by leveraging adaptive authentication technology, instead of mandating multi-factor authentication for the entire patient portal.

Guidelines should be provided regarding on-line identity proofing (e.g., knowledge-based authentication leveraging public / government / financial information), and guidance on LOA for on-line identity proofing by in-person versus remote identity proofing.

Critical Actions

Near-term (2015-2017)

We oppose policies and requirements that adopt mandatory multi-factor authentication for all roles that access health information. We recommend optional implementation. We agree with identifying best practices for identity proofing and think a better approach than national standards would be elective use following the practices in other industries such as financial services. Mandatory use will disadvantage some population segments.

We support proposals to support mobile technologies (such as smart phones) to provide efficient and effective paths for patient and provider identity authentication. Equally important is the use of standards to identify and authenticate mobile devices, as they interact with the health care system. We agree that ONC should conduct pilots to evaluate the use of RESTful approaches to authentication.

With respect to the Standards critical action, the Roadmap should also consider aligning with System for Cross-domain Identity Management (SCIM) that uses RESTful with JSON for identity management across provider organizations. SCIM has become a standard protocol for cloud providers and may be considered for health providers as well, e.g. provision and de-provision affiliate provider's access to patient information.

Consistent Representation of Permission to Collect, Share, Use Identifiable Health Information

Individuals should be able to trust that their health information will be kept private and secure; hence greater emphasis on increasing the level of scrutiny, restrictions, and controls that individuals can exert on their health information, including information providers use for treatment purposes. Striking a balance that ensures consumer trust and safe, effective care will involve addressing various issues of access, use, and disclosure of health information by providers.

The Roadmap should acknowledge that HIPAA provisions for disclosure among entities within an organized health care arrangement (OHCA) promotes care coordination and represents another equally valid approach to interoperability.

We agree that technical advances have improved the ability to collect and manage individual preferences about the use and disclosure of individually identifiable health information. The legislative, regulatory and organizational framework and policies have not yet evolved to address technical capabilities; this is a gap that should be addressed. The cost and value of managing and using these preferences would be important to analyze but have not been well evaluated.

The Roadmap should clearly delineate concepts of consumer preferences regarding privacy and applicable privacy authorization requirements.

Other issues that should be addressed are the scope and level of granularity of consumer choices and preferences. For example, authorization might specify data elements for specific purposes only, define authorized recipient individuals and organizations, specify a timeframe, and/or define the parameters of information exchange. Very granular controls may not be what most consumers want or need to control important aspects of their privacy. Preferences vary from one individual to another and preferences of each individual vary over time, together causing complexity that will be difficult and costly to maintain. Also, these controls would result in a very complex health exchange information ecosystem with slower system response times for accessing or obtaining important patient information at the point of care because of the number of system and authorization rules to be processed for each data element and the multiple control variables in place.

Critical Actions

Near-term (2015-2017)

We agree that OCR should collaborate with ONC on education and outreach to identify areas where additional guidance is needed. While some action items give ONC a leading role in defining privacy policy, OCR as the agency responsible for implementing and enforcing privacy and security regulations should direct these action items.

We are concerned about ONC's proposal to define "basic choice" and adopt technical standards for offering and capturing basic choice electronically. We strongly recommend a national, multi-stakeholder dialogue, facilitated by ONC and OCR, on the various policy options and the value case analysis for consumer choice and consumer preference.

We recommend further consideration of the relationship of data provenance, an important concept of a secure interoperable health information infrastructure, and how or to what extent it relates to consumer choice.

Overall, we believe most of these near-term action items are overly ambitious and unlikely to be achieved within the next 18 months (through 2017).

Consistent Representation of Authorization to Access Health Information

Effective authorization to access health information plays a critical role in a secure interoperable health information infrastructure; establishing a consistent framework and set of standards to assert authorization will be essential.

We oppose establishing rigid, granular standards and requirements for authorization that apply to internal systems within an organization. Each organization should have an ability to define and implement authorization, based on general parameters and guidelines defined through a national standards process.

Critical Actions

Near-term (2015-2017)

ONC and OCR should convene a series of sessions to discuss authorization framework and develop additional guidance on how authorization (and, generally, HIPAA privacy and security) applies to new models of care delivery, such as ACOs.

COMMENTS ON "CERTIFICATION AND TESTING TO SUPPORT ADOPTION AND OPTIMIZATION OF HEALTH IT PRODUCTS AND SERVICES" SECTION

The Roadmap anticipates a new set of diverse and complementary certification and testing programs administered by a variety of different entities to apply to a much larger and encompassing definition of Health IT (not just EHRs but many different health IT systems such as networks, payer systems, population health resources, and systems employed for patient engagement). However, the Roadmap does not establish ONC's authority to regulate (certify) systems beyond EHRs under HITECH. The degree to which the current ONC certification program for EHR technology has met the goals of ensuring interoperable EHRs is uncertain. Testing to enable interoperability and EHR usability should be considered in the Roadmap.

Critical Actions

Near-term (2015-2017)

As noted above, we are concerned about expanding the current certification program beyond EHRs to the entire spectrum of health IT, and the call to industry to provide feedback on additional certification criteria to support ONC's intent to expand the scope of the program. We recommend, as an immediate critical action, a formal, systematic review of the ONC EHR certification program to determine the degree to which the program has met the original goals, the challenges and issues faced by the program as it entered its fourth year of operations, and the effect that its scope and complexity have had in the marketplace.

COMMENTS ON "CORE TECHNICAL STANDARDS AND FUNCTIONS" SECTION

Generally, we agree and support the classification of standards necessary to achieve interoperability into Vocabulary/Terminology, Content/Structure, Transport, Security, and Standards for Services (including APIs).

Consistent Data Formats and Semantics

Common Clinical Data Set
The Roadmap seeks consensus on a standardized common clinical data set (including elements such as name, sex, date of birth, race, ethnicity, preferred language, smoking status, problems, medications, and others), at a minimum. We question the expectation that all providers, regardless of practice/specialty would be required to exchange consistently and each time all predefined common data elements, when these data may not be collected or captured as part of the regular, accepted clinical practice.[3] Thus, for some areas of clinical care, the proposed set might be missing key data elements that most frequently drive implementation of provider-to-provider custom interfaces between and outside EHRs. For other areas the proposed set might go beyond what best clinical practices dictate.

The Roadmap also gives all data elements equal priority. While that approach caters to researchers and others with secondary use requirements, the elements themselves are not well aligned with research data sets and it will dilute the impact for treatment purposes. Achieving improved clinical care through interoperability will remain elusive.

The proposed set does not take advantage of comprehensive existing national standards such as SNOMED CT, and there is no proposed harmonization of these data across federal agencies, as far as we can tell.

Critical Action

Near-term (2015-2017)

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[3] This is one of the issues that the Yosemite Project seeks to address. Using semantic web technologies like RDF and OWL enables the building of translation bridges among the various islands that exist in the larger healthcare system.

The purpose of ONC's standards list is unclear, in particular its relationship to rulemaking.

We do not support the annual publication by ONC of a list of the "best available standards and implementation specifications supporting interoperability". Creating an expectation of changes in standards every year is meaningless and potentially harmful, given that it takes between eighteen months and three years to develop, test, and implement a standard, and to bring a product to market. The negative reaction received from a broad cross section of stakeholders to ONC's 2014 proposed "voluntary" standards and certification criteria provides a persuasive case for not attempting to repeat such an approach.

ONC must recognize that many new standards are strictly additive to cost, complexity, and resource burden. New standards usually do not replace older ones. They are merely layered over the top. Therefore the reality of all standards co-existing in a heterogeneous environment is an important concept for the entire Roadmap.

The realm of existing older standards encompasses a built-in historical maturation process that results in standards better fit for purpose.[4] This undertaking requires performing a systematic evaluation of the standards under consideration to ensure their maturity and adoptability. ONC should use the criteria developed by the HIT Standards Committee in performing such an evaluation.

While we agree with and support the idea of establishing and prioritizing a set of use cases for interoperability, we strongly recommend that use cases should be narrow in scope and standards development organizations should be used to fulfill this use case development function. Priorities and decisions should reflect balanced representation of stakeholder interests in an open and transparent manner.

Secure, Standard Services

The Roadmap promotes the value of Application Programming Interfaces (APIs) in helping achieve interoperability, given their simplified, scalable, modular approach to allow interfacing with health IT systems. While this might be a very promising approach, there still need to be proven, practical use cases that demonstrate the value, benefits, and contributions they make to interoperability across organizational boundaries within healthcare.

Critical Actions

Near-term (2015-2017)

While we support a coordinated approach to developing and standardizing a targeted set of public APIs for nationwide interoperability, this cannot be achieved over the next 18

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[4] For example, the evolution of V2 lab standard messages – orders and results from V2.3.1 to V2.5.1.

months; 3 to 5 years would be a more realistic timeframe for an initial set. We believe this may be a case of inflated expectations for a new and unproven technology.

The development of public APIs should ensure reliable mechanisms to search, locate, send, or receive the common clinical data set. At the same time, this development should be balanced with recognition of the continuation of the transactional model of exchange as well as shared systems and centralized data store models of interoperability. There should be a proven standardized security infrastructure and network capability in place for such APIs to be used. Ensuring the security posture of these APIs will be an issue to address.

We are uncertain at this point about advancing and accelerating the development of standardized RESTful APIs. Representation State Transport (REST) is the basic style of transport associated with the web and web services; efforts such as SMART on FHIR advocate using this transport, but whether it fully addresses all the needs associated with health data, in terms of security, permanence, provenance, etc., is an open question.

We strongly agree with the need to develop standards for interoperable electronic health devices and for clinical technology to interoperate with CEHRT reliably.

Consistent, Secure Transport Techniques

A suite of transport standards is currently in use to support various interoperability needs, including: Direct protocol, Simple Object Access Protocol (SOAP) web services, and RESTful web services. The evolving health IT infrastructure should support these and future transport protocols. Government should not select and mandate one.

ONC should also pay some attention to OAuth 2 (including some examples on OAuth 2) for the authorization protocol. This standard is well aligned with RESTful, and since RESTful is being promoted for authentication, it would make sense to mention RESTful using OAuth 2 for authorization. SAML on the other hand uses SOAP web services instead of RESTful.

Critical Actions

Near-term (2015-2017)

We agree with the actions stated in the Roadmap.

Accurate Individual Data Matching

Identity matching is one of the biggest challenges for interoperability without a national identifier for consumers of health care. The lack of standardization in patient matching methods and data elements, as well as quality of data are key factors in poor data matching results.

Overall, we strongly prefer the approach being developed by NSTIC to handle identity management across the entire ecosystem rather than using record matching mechanisms. However, considering that record matching approaches might still be needed while the industry

transitions to an NSTIC-recommended environment, we agree there is a need to establish best practices, basic guidelines, data elements, and performance metrics that can help define performance thresholds of the matching methodologies in current use, and also a need to develop Acceptable Risk Models for various use cases that require identity matching.

Identity matching is closely related to and may impact identity proofing (e.g. Am I ID proofing the right person?). Guidelines should be provided regarding the impact and relationship of identity matching to LOA of ID proofing.

Critical Actions

Near-term (2015-2017)

ONC should establish minimum recommended data elements to be consistently included in queries and should identify and disseminate/share best practices on patient matching.

ONC should not work with SDOs to require a set of data elements in all individual identity query and record linkage transactions until further development of standardized processes, methodologies and performance metrics have been completed.

COMMENTS ON "TRACKING PROGRESS AND MEASURING SUCCESS" SECTION

Measuring success and tracking progress must be tied to the overall purpose of interoperability, and not so much to interoperability *per se*. Interoperability should ensure that the right information about the right person is available at the right time, and enable patients and clinicians to make the best decisions about health and health care with person-centered information. Progress toward interoperability should be measured against these two goals, and not on data exchange or technical capabilities of health IT systems to use specified standards. We recommend that NIST should be consulted on such measurements as well as measures of the usability of patient-centered information.

We offer the follow responses to ONC questions:

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

Many concepts are missing. Since the goal of interoperability is to ensure the availability of person-centric information, the characteristics of person-centric information availability should be the yardstick instead of crude transactional measures. For instance, metrics should be designed to evaluate:

- The level of patient engagement, as measured by how the information conveys coordinated care (care of the whole person); patient-provider communication; patient-provider collaboration; health/life goals

- Provider acceptance of patient health goals, documented in the medical record; facilitated scheduling; patient experience; provider assessment; health data access and record management
- Notes, including patient narratives; extended personal data (e.g. geolocation information)
- Personal health management, including mobile tools for self-monitoring and self-care; decision management; patient to patient communication; patient advocates
- Health record management, including provider records, patient records, other data sources together; data accumulation, reconciliation, management; incentives

As we said above, the Roadmap focuses primarily on the exchange and data flow function, and less on the overall impact and purpose for interoperability. It ignores the other key components of interoperability, including semantic, syntactic and process, as well as the larger domains (business, clinical, operational, and policy).

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

The most important concepts to measure are the ones not in the framework. The framework only focuses on structure and process measures of interoperability (e.g., the number of providers adopting EHRs, volumes of exchange, etc.), and less on the desired outcomes of interoperability (e.g., improved coordinated care, more efficient care delivery, etc.)

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

Measurement should focus on multiple use cases, priority populations and levels of the ecosystem, not only on a selected group of them.

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?

Outcomes measures are much more critical than structural or process measures of interoperability success. Defining and testing valid and reliable outcomes metrics should be a critical action for ONC over the next 18 months.

What measurement gaps should be prioritized and addressed quickly?

Prioritize outcomes measures. The structural and process measures may be available but do not reflect the achievement of interoperability between systems. New measures of the availability of comprehensive patient- centered information should be developed, tested, and implemented alongside existing measures, eventually to supplant them. Measures should focus on achievement of the goal state of comprehensive patient- centered information being made available for clinician and patient decision- making, not one set of means to this end. Restricting measures to one set of standards and transactions when alternative models, methods, and innovations are viable would be a most serious mistake.

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

Participation in outcomes and quality measurement programs from public programs could be a source; measurements of new forms of care delivery (ACOs, PCMHs) would help to demonstrate achievements in care coordination and transitions of care.

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

Existing ONC mechanisms have not proven effective at addressing these measurement gaps. Building on the development of the next generation of quality-focused, evidence- and population-based outcomes measures for the new forms of care delivery and payment would be a potential mechanism to address the gaps. Noting the expertise of NIST in objective measures of information usability, we suggest enlisting the assistance of NIST in developing measures of the usability of comprehensive patient- centered information as one way to address measuring achievement of the interoperability goal.

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

Information should be shared through existing public programs and accrediting bodies.

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, we suggest structure and process measures along with new measures of information availability; for the long term, outcomes-based measures including measures of information availability, as described above.

COMMENTS ON "APPENDIX H – PRIORITY INTEROPERABILITY USE CASES"

Following is our 'top-ten' list of recommended priority use cases, from the list of over 50 uses cases presented in Appendix H of the Roadmap:

- Make the status of transitions of care available to sending and receiving providers to enable effective transitions and closure of all referral loops. (Note: transitions of care should take into account different care delivery models, including independent/non-affiliated provider systems, ACOs, PCMHs, and OCHAs)
- Preserve narrative components of the medical record for provider and patient use and augment with metadata to enable effective storage, routing and searching for these documents.
- Support population health measurement at the community level and include data from all relevant sources on each patient in the population that is accessible to providers and other stakeholders focused on improving health.

- Ensure public health agencies routinely use data derived from standards-based connections with HIEs and EHRs to plan investments in public health activities.
- Enable individuals to integrate data from their health records into mobile apps and tools so they can set and meet their own health goals.
- Base quality measures on complete patient data across multiple sources.
- Enable providers to access x-rays and other images in addition to the reports on patients they are treating, regardless of where the films were taken or housed.
- Give providers and patients access to genomics testing and data which, when combined with clinical information about patient goals, allows the personalization of care and therapies.
- Enable patients routinely to engage in healthcare encounters using electronic communications such as eVisits and telemedicine.
- Give patients, families and caregivers the ability to use their personal devices such as smartphones, home BP cuffs, glucometers and scales to routinely contribute data to their longitudinal health records and use it or make it available to providers to support decision-making.

CONCLUSION

In conclusion, we want to commend ONC for developing this 10-year Interoperability Roadmap and setting a course for the nation's health sector to become a true learning health system. Interoperability is a means to achieve a much larger goal for the country's health information systems and in that regard the Roadmap presents some important ideas on how to move forward.

We very much hope that the comments, ideas, and recommendations shared in this letter will be helpful in making the Roadmap a stronger, more practical, realistic and achievable effort for the nation.

Thank you for considering our comments. Please feel free to contact me (510-271-5639; email Jamie.ferguson@kp.org) or Lori Potter (510-271-6621; email lori.potter@kp.org) with any questions or concerns.

Sincerely,

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