A White Paper Overview of

Connecting Health and Care for the Nation

A Shared Nationwide Interoperability Roadmap

Draft Version 1.0

In Response to the Call for Public Comment from

Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Presented by:

C.He.S.S

The Winning Move

Collaborative Health Support Services

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

The Healthcare Information Technology landscape is a complex ecosystem with multiple components that possess varying degrees of sophistication and different perspectives on how best to collaborate, share information, and drive economic growth. For a learning health system to succeed and evolve, the underlying healthcare information technology ecosystem must integrate those key components and enable seamless flows of various content forms including, protected health information, financial data, and research results across the stakeholder population. Collaborative Health Support Services Consortium (hereafter referred to as "C.He.S.S.") is well-positioned to offer commentary on how elements the proposed Interoperability Roadmap for Healthcare can orchestrate the dynamic elements of the ecosystem so as to move toward an efficiently functioning learning health system.

C.He.S.S. consists of multiple small technology and service businesses that integrate our various capabilities in Healthcare and Information Technologies capabilities to drive solutions for our clients. The model for how we work together or "interoperate" as separate but teamed businesses informs our judgement and qualifies us to offer feedback to the call for public response on the Office of the National Coordinator for Health Information Technology' Interoperability Roadmap. The nature of our internal interactions, combined with our history of engagements in both the private and public sectors enable us to respond to five of the eight questions for which comment is sought. Specifically, Advanced Resource Technologies, Inc. offers perspective on the proposed actions and actors identified as contributors to near and long term success for a learning health system. The combined team offers priority use case recommendations. VIA Consulting provides a view of how ONC can best recognize and support industry led governance efforts while The Coleman Group outlines what RESTful privacy and security aspects need to be addressed and in what manner. Lastly, DYONYX presents its position on how best to measure the disparate components of the roadmap including the overall framework concepts, data sources, and potential gaps in the logic and execution of test protocols. The content of our responses directly support the overall goal of achieving a learning health system.

Why C.He.S.S.?

- Broad Healthcare IT experience across private and public sectors
- Expertise in the major Healthcare IT disciplines
- Separate, distinct components that mirror the Health IT landscape
- Success in delivering patient-centered value

As a result of our study and review of the roadmap, C.He.S.S.' recommendations positively impact moving the country forward in pursuit of a learning health system and advance the model of patient-centered care in achieving the triple aim of improved quality of care, improved outcomes, and lower costs. Our responses are formatted with the original question from the Roadmap as the overall headline topic followed by direct answers to the questions. Due to the breadth of some questions, a few of the responses contain sections with summary comments outlined.

We would greatly appreciate an opportunity to further the dialogue through in-person discussions with any range of stakeholders as they relate to the content of our responses.

Thank you for this opportunity.

C.He.S.S.

Question 1: General

1.1 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?

C.He.S.S. Response (1.1)

Overall the proposed actions appear to be the right ones to address the broader task of EHR interoperability and the aligning the appropriate actors with their designated assignments. The larger challenge is the continued coordination of the actions to validate the sequence is correct (e.g., C.3 Privacy and Security for Individuals should Call to Action 3. Individuals should be able to trust that their health information (such as that generated/collected via home monitoring devices or other emerging technologies) is protected and secure be implemented prior to Call to Action 1. Public and private stakeholders should assess whether people understand how to safeguard their health information and the need for resources related to this topic.) One can argue that home health data be secure before the individual user makes the assessment. The key is to ensure accurate measurement protocols are in place and the necessary flexibility exists to change direction mid-course. Just as in a true learning organization, the ideas and ideals in the desired learning health system will "co-evolve" as the disparate components influence each other with the goal of achieving the desired goal[1].

1.2 What, if any gaps need to be addressed?

C.He.S.S. Response (1.2)

Although the roadmap address critical actions in broad strokes, key elements of granularity appear to be missing. C.He.S.S. recommends the following considerations to bring the initiative into better focus while engaging the right stakeholders at the right times:

1.2.1 C.He.S.S. recommends government entities document and publicize concrete examples of cost benefit analyses to demonstrate to those wary of how interoperability affects their market position why interoperability establishes a positive value proposition for them.

1.2.2 C.He.S.S. suggests government entities embark on a nation-wide campaign educating consumers (patients and their families) of the benefits of receiving care from a provider who has been certified in their meaningful use of EHR. We recommend the campaign emphasize how seeking care from an EHR-approved provider benefits the patient and meets the primary goals of the triple aim: improved quality of care, improved outcomes, and lower costs.

1.2.3 C.He.S.S. recommends establishing a baseline set of EHR standards [e.g., clinical data set elements, minimum technology specifications (RAM, Hard Drive size, etc.)] and allowing them to remain in place for 3-5 years. During the 3-5 year period, we advise conducting a standards review in conjunction with an uptake/adoption assessment to determine user penetration. This gives all stakeholders (providers and Health IT Vendors) an opportunity to refine their business models while continuing to deliver measureable quality healthcare.

1.2.4 C.He.S.S. recommends the federal government use its considerable leverage as a health care payer and purchaser to drive increased demand and coordination of interoperability. For example, on the next version of the Physician Fee Schedule[2], HHS can require physicians for treatments other than chronic care management to be billable only if care was provided by a physician using a documented. C.He.S.S. recommends beginning this process

[1] "What are the Characteristics of a Learning Organization?" Dr. Eve Mitleton-Kelly, London School of Economics

[2] CY2015 Revisions to Payment Policies under the Physician Fee Schedule & Other Revisions to Medicare Part B. CMS-1612-FC. November 2014

using all Radiology Tests and Laboratory. Tests could only be billed if the results were stored in an ONC-approved EHR. (e.g., MRI).

1.2.5 C.He.S.S. recommends all health care providers be issued an EHR license number for tracking similarly to the license plates system currently in place at the state level. We suggest license renewal timeframe requirement be established consistent within defined periods of time after minimum technology standards updates have been issued by ONC. For example, all licenses should be renewed within 2 years of new standards being published. This gives providers time to understand the new standards and acquire the upgrades without significant disruption to the business. Using the license # system also works as a check and balance for issuing payments on approved billable services where an approved EHR system is required.

1.2.6 Based on changes created by the Affordable Care Act, states have reengineered a number of their information technology systems to redefine Medicaid Eligibility rules. This effort has enabled closer collaboration, improved information exchange protocols, and reduced service delivery time across multiple providers[3].

C.He.S.S. recommends states continue to leverage their innovation leadership by applying the same reengineering principles it did with Medicaid Eligibility rules to its adoption of the use of Electronic Health Records across state hospitals and medical care facilities.

1.2.7 C.He.S.S. recommends payers stipulate the use of minimum standard EHR systems for all in-network providers and charge higher premiums for use of out of network providers. This directly impacts payers' ability to control cost and steer demand toward the in-network providers.

1.3 Is the timing of specific actions appropriate?

C.He.S.S. Response (1.3)

Most if not all commercial businesses create strategic plans with near intermediate and long-term horizons. These time frames generally depend on market forces and the competitive dynamics within the industry itself[4] but most managers still use 3 and 5 year ranges.

1.3.1 C.He.S.S. recommends changing the 3, 6, and 10 year time frames to 3, 5, and 10 year buckets. This allows those entities to better align their strategies with commonly used business cycles as well as support mid-stream adjustment for those who may be 1 or 2 years into their newly adopted strategies. This approach also encourages adding shorter and longer range views (18 mos.) or (15-20 yrs.) depending on whether they are driven (or limited) by technological advancement (EHR Vendor), capital investment (Large Hospital System) or a combination thereof (mid-sized physician practice).

1.4 Are the right actors/stakeholders associated with the critical actions?

C.He.S.S. Response (1.4)

In as much as the actors are assigned actions, the first draft of the Interoperability Roadmap appears to layout effective assignments to the stakeholders within the ecosystem. As the moving forward phases approach, stakeholders must be willing to acknowledge that in some cases scope, scale, liability belong to a different set

[3] Center on Budget and Policy Priorities: State Innovations in Horizontal Integration: Leveraging Technology for Health and Human Services, by Terry Shaw and Lucy Streett, March 24, 2015
[4] What Should Be the Planning Horizon of a Business, Dr. Jacques Saint-Pierre, Adjunct Professor, Department of Finance, Insurance and Real Estate School of Business Administration Laval University, QC, Canada

stakeholders. As the learning system actually learns, the ability to be flexible in stakeholder action and responsibility reassignment becomes a critical success factor.

Summary

The most obvious use of an Electronic Health Record is its role as a shared resource to drive the care plan for a specified patient. Therefore, the patient centered medical home model (also known as the primary centered medical home[5]) serves as an ideal framework for which electronic health record interoperability can be implemented. Further, it has been recognized that care coordination is a priority area for improving health care delivery[6]. As a result, interoperability is a key component in the ability to measure progress toward achieving the triple aim of improved quality of care, improved outcomes, and lower costs. Actors responsible for implementing the Interoperability Roadmap must take into account how and where information transfers across electronic boundaries in order to provide an opportunity to enhance and contribute to the development of a learning health system.

First, the person centered approach has to be tangible with the "person" having access, control, and topographical awareness of the electronic health record. Next, there must be a champion to drive the cultural shift that empowers the individual to participate in their health care. There has to be an active "What's in it for me" (WIFM) campaign to drive individual patients to move toward adoption. Accordingly, **C.He.S.S. recommends ONC ad-hoc Patient-Centered EHR Advocacy group be created with the intent driving the cultural shift and bridging the digital divide**. Next, there must be a competitive yet complimentary landscape for EHR providers and for care systems of differing sizes. The primary requirements include: 1) service the basic needs of informing the patient-centered care model; and 2) allow for scalability and account for the complexity of larger care provider organizations (i.e., smaller physician practices vs large practices). HHS should strive to promote financial transparency relative to development costs and Total Cost of Ownership with respect to Electronic Health Records. This prevents at worst, regional or technical collusion through price-fixing or monopolization and, at best, organizational conflict of interest by a strong regional provider offering its own EHR as a solution to smaller entities who have limited or no alternative options.

Lastly, to confirm a vital population of citizens is not overlooked, **C.He.S.S. recommends including veteran status as a standard field in all clinical data sets**. The goal of this field is to identify those citizens who by way of their military service may have encountered circumstances whose symptoms mimic those of non-veterans but whose causal may require a completely different treatment plan [e.g., headaches as a result of Traumatic Brain Injury (TBI)]. In a learning health system world, the field should then be a flag in ALL EHR systems to seek a connection to the ALTHA (DOD) or VISTA (VA) EHR systems to obtain a more complete picture of the veteran's service profile, active-duty medical history, etc. This would support judgments made by current care providers to ensure the veteran receives the quality of care they deserve.

[5] Prospects for Care Coordination Measurement Using Electronic Data Sources, AHRQ Pub No.12-0014-EF p.1
[6] Ibid

Question 2: Priority Use Cases

2.1 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 need 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

C.He.S.S. Response (2.1)

Priority Use Case Recommendations

The goal of a learning health system compliments the structure of a patient-centered model by enabling the care providers to share information across platforms and make the best judgment possible about the treatments necessary to improve the patient's health. C.He.S.S. has prioritized three use cases that focus primarily on either patient access, provider access, content sharing or a combination thereof. Each of the use cases has a direct effect on achieving the triple aim of improved quality of care, improved outcomes, and lower costs. Another critical factor in the selection was the ability to easily implement the use case thereby creating a quick win for the overall Interoperability initiative. Identifying quick wins traditionally serves to break down resistance from naysayers and creates a groundswell of momentum supporting the cause.

Use Case #12

Providers are able to access x-rays and other images in addition to the reports on patients they are treating, regardless of where the films were taken our housed.
In the fee-for-service model, images and laboratory results were often siloed causing duplication of effort and rising costs. By having the radiology images accessible to and shared amongst providers, unnecessary duplication will be avoided. Existing technologies and business processes allow this functionality to be implemented immediately.

Use Case #18

Patients have the ability to access their holistic longitudinal health records when and where needed.
Succinctly interpreted, the patient-centered medical home model implies the patient owns the degree of control required to offer input to their care. Ubiquitous access to one's longitudinal health record defines the starting point onto which the other components are attached (e.g., primary care access, file distribution, patient-authored access restriction, etc.). The use case as becomes the basis for leveraging existing mobile technologies to the degree that privacy and security protocols allow.

Use Case #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.
From a functional perspective, providers sharing information back and forth lessen the burden on the patient to provide the same information thereby reducing the likelihood of error and improving the quality of the experience and achieving one of the goals of the triple aim. This functionality already exists in highly functioning accountable care organization and should be held as a best practice for other to emulate.

Question 3: Governance

3.1 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?

C.He.S.S. Response (3.1)

According to ONC, the challenge with governance is complex due to four (4) main issues[7]:

1. There is no single group empowered to come up with the rules across all exchange activity, and there is no authority to impose and enforce mandatory rules on others.
2. In current non-regulatory environment, HIE governance entails consensus building which involves potentially thousands of entities which may or may not have conflicting or competitive business interests.
3. HIE governance is an ongoing challenge and will remain so as HIE and stakeholder needs and expectations continue to evolve.
4. As experience in HIE grows, there will be new issues on which the community will need consensus as well as a mechanism or mechanisms for dispute resolution.

Although the initial industry response to the Nationwide Interoperability Roadmap indicated a general desire for ONC to "refrain from formal governance activity and to allow nascent and emerging governance efforts in industry to take shape", ONC continues to play a vital role in addressing these governance issues. In C.He.S.S.' review of ONC's Nationwide Interoperability Roadmap and ONC's work to date in the area of HIE governance, we have identified three (3) Key "***Governance Activity Areas***" in which we believe ONC can best recognize and support industry-led efforts to establish a coordinated governance process for nationwide interoperability.

Governance Activity Area 1 – Building Communities of Engagement and Trust

It is widely recognized among health IT stakeholders that communities of engagement and trust must be established to allow information to be shared across the Health IT ecosystem. Furthermore, it was noted on Page 11 of the Nationwide Interoperability Roadmap "…***there is no reliable and systematic method to establish and scale trust across disparate networks nationwide…***" As such, C.He.S.S. recommends ONC continue to focus on providing leadership in facilitating collaborative efforts designed to build communities of engagement and trust between the various stakeholders.

ONC's work should also include continued activities that recognize and support the establishment of a "Single Trust Framework". If successful, this framework strengthens collaborative processes for defining, developing, piloting and ultimately implementing mechanisms fostering a trustworthy exchange between otherwise unaffiliated creators and users of health information.

Governance Activity Area #2 – Supporting Existing Governance Initiatives Among Health IT Stakeholders

Consistent with the *Governance Framework for Trusted Health Information Exchange* released by ONC in 2013[8], C.He.S.S. suggests that ONC continue to work collaboratively with entities already involved in governance of health information exchange. This encourages the continued development and adoption of policies, interoperability requirements, and business practices that increases the ease of electronic health information exchange, reduces implementation costs, and assures the privacy and security of data being exchanged.

[7] http://www.healthit.gov/sites/default/files/trustframeworkfinal.pdf

[8] http://www.healthit.gov/sites/default/files/GovernanceFrameworkTrustedEHIE_Final.pdf

ONC should also continue to recognize and support collaborative efforts such as "National HIE Governance Forums"[9] that convene key stakeholder governance entities to address cross cutting governance issues among various exchange approaches. Such ONC-led forums will continue to benefit HIT stakeholders in the following areas while helping to establish an environment of community and trust:

1. Listening – Providing a neutral non-competitive collaborative environment to interact with other HIE leaders
2. Learning – Sharing lessons learned and gain common understanding of key governance components, what is working and not working
3. Networking – Introduction and interaction with other HIE leaders
4. Convergence - Work toward greater consensus on trust framework, common scalable elements of trust, and select business principles

More importantly, C.He.S.S. advises that ONC's activities continue to support existing governance initiatives that are critical to advancing the following governance goals of nationwide health information exchange in the following areas:

1. Increased interoperability;
2. Increased trust among all participants to mobilize trusted exchange to support patient health and care; and
3. Decreased the cost and complexity of exchange

Governance Activity Area #3 – Working Collaboratively to Establish Common "Rules of the Road"

According to the RFI (Page 30), it is ONC's goal to work collaboratively to establish common "rules of the road" for governance ONC continues to play a critical role in the establishment of these rules by participating in collaborative efforts to identify what information needs to flow efficiently across HIT ecosystem. It has been noted that ONC provides a foundation for an HIE governance approach that includes both policy and collaboration across industry, government, and consumer representatives [10]

ONC can best recognize and support the industry-led governance efforts by continuing to seek input from, and collaborating with, private sector and federal agencies who can inform governance implementation and ensure broad participation across existing operating health information networks at the vendor, enterprise, regional, and state levels.[11]. ONC's willingness to also provide financial support to existing governance organizations such as DirectSupport.org through the "Exemplar Health Information Exchange Governance Entities Program"[12], builds trust and further demonstrates ONC's commitment to help establish common "rules of the road".

[9] http://www.healthit.gov/sites/default/files/nationalhiegovernanceforumfinalreport.pdf

[10] http://www.healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf

[11] http://www.healthit.gov/sites/default/files/nationalhiegovernanceforumfinalreport.pdf

[12] http://www.healthit.gov/policy-researchers-implementers/exemplar-hie-governance-entities-program

Question 5: Privacy and Security Protections for Health Information

5.1 What security aspects of RESTful service need to be addressed in a standardized manner?

C.He.S.S. Response (5.1)

Nationwide sharing of health information touches all areas of the health-related industries, from public health to private industries. The increased use of information technology can reduce healthcare costs and improve the quality of patient care. Technology such as data distribution to the cloud and accessibility via mobile devices, also increases data vulnerability due to exposure to cyber-attacks and unauthorized access. In addition to a thoughtful discourse on the security aspects of RESTful service, C.He.S.S. recommends including the privacy of health information as part of the discussion. The adequate protection for the privacy of health information is critical and is the first step in the security of health information.

5.1.1 Privacy

C.He.S.S. Response (5.1.1)

As ONC has outlined, a learning health system's cybersecurity program includes Contracts, Memorandum of Understanding ("MOU")/Memorandum of Agreement ("MOA), Business Associate Agreement, and Interconnection Security Agreements. These Agreements have different terms and definitions. This significantly increases the likelihood of confusion regarding expectations among providers and organizations. This creates unnecessary delays in deliverables and greatly impacts privacy and security of patients and organizations' HIT. Due to the variability in the terms and conditions, C.He.S.S. recommends ONC create standard terms and definitions and they be approved by an objective 3rd party entity and disseminated industry-wide. It is equally important that contracts, particularly, Business Associate Agreements, readily define who is a Covered Entity and who is a Business Associate. The rationale for this recommendation is that consideration should be given to the question of the use and disclosure of health information by the providers, organizations, and public health.

C.He.S.S. acknowledges that the success of health IT and interoperable systems is dependent on a person's trust that their information is kept private and secure and their rights are respected. The Privacy Rule permits disclosures for treatment, payment, and healthcare operations with patient authorization. However; public health, research, law enforcement, fundraising, and marketing require additional protections given the sensitivity of the protected health information. Furthermore, many state laws limit the ability to use and disclose health information. Laws regarding HIV/AIDS, mental health, substance abuse treatment, developmental disability and genetic testing function on the fundamental premise that disclosure of the sensitive information is prohibited unless specifically permitted by law.

C.He.S.S. recommends that all health IT providers and organizations consider how this information is included in the system and provide a standard process for the disclosure of sensitive information. C.He.S.S. proposes that standard processes are developed for the disclosure of the information including: 1) who is authorized to disclose information; 2) what information can be disclosed; and 3) what information requires additional documentation for disclosure due to its sensitive nature, the reason for disclosure and/or the process used to disclose the information.

The Privacy Rule and many state laws impose administrative requirement which include training the workforce, imposing sanctions on those who violate policies and procedures, handling complaints, mitigating non-compliance, and documenting compliance. To mitigate this issue, C.He.S.S. advises creating a set of workforce training standards focus on decreasing errors, reducing the incident of a breach, and improving the quality of care. C.He.S.S. also recommends that providers and organizations consider centralizing or standardizing training regarding the system interoperability. This enables all the workforce participants to receive the minimum level of training.

5.1.2 Security

C.He.S.S. Response (5.1.2)

C.He.S.S understands that the sharing of information with multiple providers/organizations leads to inconsistencies in policies and procedures across multiple organizations. Organizational interchanges of health data are challenged by nonstandard message formats, locally unique data encoding, and use of different communication protocols[13]. Even in cases where data is shared between applications, there are numerous incompatible terminologies and ontologies involved. Semantic interoperability continues to be a major challenge, and if not addressed has a serious impact on the quality of care[14].

C.He.S.S. has identified that healthcare organizations and government agencies have the following challenges to the security of interoperability systems:

- Different security requirements among the organizations.
- Different policies and procedures within the organizations' structure.
- Different security systems.
- Different authentication and authorization services, identity proofing systems, message integrity, message confidentiality, client server authentication.
- Organizations either have different trust relationships or do not have any trust relationship at all for exchanging sensitive health information.

C.He.S.S. proposes: 1) uniformed minimum security requirements among the participants; 2) uniform policies and procedures across all participating organizations and providers; and 3) consistent, uniform and standard procedures regarding the authentication/identification of users, integrity controls; and 4) confidentiality of the message/system.

Data is not universally encrypted across health care and governmental organizations. Additionally, Health care organizations do not regularly comply with the HIPAA Breach Notification Rule. C.He.S.S. believes that there is also the high probability for intrusion/breach of multiple organizations along with inconsistent management response to intrusion/breach, i.e., timing/notification of breach, type of response. This is also exacerbated by a lack of coherent corrective action plan(s) to intrusion/breach.

Interoperable systems do not work unless there are standard encryption mechanisms in place that work easily among the participants. Secondly, C.He.S.S. recommends consistent policies and procedures across the board regarding the response to a breach, what constitutes a corrective active plan, and notification/timing to other participants within the interoperable system. Timing of notification is important as it affects other participants due to cross functionality of system.

Security of Clinical Communication for mobile technologies, smart phones and email is the third rail of health care communication. These technologies presents additional concerns as there is a heighten sense of breach capacity among these platforms. C.He.S.S. recommends developing a standard and uniform process and procedure specifically targeted to address the use of mobile technologies, smart phones and email.

[13] Charlie Peng, PhD, Gautam Kesarinath, MS, Tom Brinks, PMP, James Young, PMP, David Groves, MBA, National Center for Public Health Informatics, CDC, Atlanta, GA, SAIC, , Atlanta, Ga, AMIA Symposium Proceedings, 2009, pg. 516

[14] www.healthcareitnews.com/blog/interoperability-not-non-issue

5.1.3 Technology

C.He.S.S. Response (5.1.3)

When considering the security aspects for RESTful web services and securing web services in general, C.He.S.S. recommends that the Roadmap include a security program that identifies potential vulnerabilities, mitigation of the vulnerabilities and open discourse among security researchers. Also C.He.S.S. suggests incorporating best practices and standards to assist in governing interoperability and data sharing among health care providers/organizations and government. This is a vital element in to addressing the security requirements in health information interoperability.

Protecting against cyber-attacks requires addressing parameter attacks; identity attacks; and “middle-man” attacks. These attacks can be mitigated by the developing API security architecture and standards that prevent immediate data breaches or attempts. C.He.S.S. recommends the following generally accepted strategies for securing APIs and mitigating attacks: validation of all incoming data against standard expected parameters or domain values; application of appropriate threat detection practices; usage of SSL/TLS for all data exchanges; and separation or segregation of user and application authorization.

Since the crux of REST is stateless services, it can adopt existing Web services specifications, referred to as Resource Access Web (RAW) Services, to provide secure, reliable transacted services using proven Web services standards within the broad framework of a resource-oriented approach. RAW Services allow for more automated, consistent service and client development because of the uniform service interface and well-defined operations. There are no consistent REST specifications that allow REST implementations to meet the service interaction requirements of the Global Reference Architecture, reference formal specifications, and guaranteed reliability or security. REST does have a potential approach to many of the Global Reference Architecture Requirement but many are non-standard, which tend to become more proprietary. C.He.S.S. recommends adopting a standard security framework for REST such as The Open Authorization (OAuth) Core specification which major corporations, such as Amazon, have implemented.

Because REST relies heavily on the HTTP protocol, many available tools can be used to standardize and secure data. Because REST is not a standard but rather an architecture; C.He.S.S. recommends standardizing best practices in order to implement well-designed APIs and to facilitate secure web applications. Some tools and best practices include but are not limited to: 1) the usage of HTTP/S for data transfer; 2) PKI or HTTPS/TLS for authentication; and 3) authorization services such as LDAP. Other best practices to promote secure interoperability among version systems are: 1) to allow representations in multiple formats (e.g., HTML, XHMTL, XML, JSON); and 2) to require unique resource identification (URIs) so that data is directly addressable and linked. C.He.S.S also recommends standardizing specifications consistent with WebDAV (World Wide Web Distributed Authoring and Versioning), the Internet Engineering Task Force (IETF) standard for collaborative authoring on the Web. This provides a set of extensions to the Hypertext Transfer Protocol (HTTP) that facilitate collaborative editing, file management, and interoperability between users of health IT data.

C.He.S.S. has identified a number of other areas not contained within the roadmap which deserve consideration. These are: 1) voice encryption; 2) the convergence of the physical and cyber domains; 3) preemption; 4) and the incorporation of best practices to ensure interoperability and sharing of data.

Protecting data alone may not provide the viable Learning Health System as anticipated in the roadmap. An approach is required to not only protect data in transit and stored, but must to protect sensitive calls between providers (doctors, nurses, administrative personnel, or stakeholders), and beneficiary (patient). Protection of such sensitive data can best be satisfied by software based voice encryption, which must be low cost, agnostic, scalable, interoperable, and require no new hardware—universal software upgrade can be installed to the allocated memory modules of virtually any wireless device. Encryption will be applicable for IP switched system environments (e.g., cell phones, VoIP, email, etc.). Such incorporation necessitates Mobile data and voice Governance be developed and enforced.

The convergence of the physical and cyber domains into a single integrated and interoperable common operating framework provides a comprehensive and holistic approach that enables HHS' monitoring, pre-emption, detection, preparation, prevention, protection, management, control, response and recovery from physical and cyberattacks against any HHS sensitive resources. Incident reporting and continuous monitoring as outlined in the Roadmap may not be sufficient to prevent attacks/penetrations. Preventing attacks is no longer viable in this ever increasing cyber threat environment—to better ensure success, preemption becomes a necessity. C.He.S.S. recommends preemption as a way to provide a holistic approach to continuous computer network security support through predefined or tailored services which include the transition from incident response to incident prevention. Through the application of its Relational and Integrated Pre-emptive Analysis methodologies, anticipatory intelligence and pre-emptive measure recommendations can be provided. This establishes a more sophisticated Security Information and Event Management (SIEM) system with data and intelligence-analysis capabilities.

QUESTION 8: MEASUREMENT

Question 8 – Measurement

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

C.He.S.S. Response (8.1)

Interoperable measurement requires the establishment of a standardized foundation that remains flexible as new technologies and federal guidelines are established and/or modified. The Health IT Dashboard depicts numerous data collections related to EHR and HIE adoption by hospitals, healthcare providers, health IT professional, etc. As part of that standardized foundation, in order to effectively measure initial interoperability C.He.S.S. recommends the following areas/concepts/concerns be included to evaluate the framework:

- Meaningful Use (MU) requirements are currently not standardized across all federal agencies. For example: The VA and Department of Defense (DoD) could not reach agreement on MU compliance in the past due to differences in requirements while attempting to share a common EHR platform. Questions for ONC to consider as part of the framework evaluation:
  - Does ONC measure the understanding of MU across each agency, medical office, and end-users?
  - MU is likely well understood within compliance offices of agencies and hospitals, but do the physicians, Health and IT professionals understand MU?
  - What are the differences in MU compliance requirements across all federal agencies and DoD?
- The adoption of a federally funded incentive program similar to the Centers for Medicare and Medicaid (CMS) EHR incentive program to provide incentive payments to eligible professionals, eligible hospitals, and critical access hospitals (CAHs) as they adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology. A national EHR MU incentive program has profound effects on the accelerated adoption of certified EHR systems, resulting in increased participation across hospitals, physicians, end-users, etc. for widespread measurement and evaluation. Moreover, an incentive program provides resources for physicians/offices to invest in EHR platforms, HIT security requirements, training, etc. A question for ONC to consider as part of the framework evaluation:
  - Does ONC understand the current factors that are holding back physicians, medical offices and end-users from implementing an EHR infrastructure capable of national HIE?
- Measurement of the security posture of EHR IT infrastructures, mobile devices used in field services, medical offices and by end-users. Currently, security requirements alone are a significant deterrent in many medical offices adopting HIE technologies. C.He.S.S. recommends simplified and standardized security guidelines for end-users, medical offices and physicians and providing free on-line resources to assist in meeting the security requirements. Questions for ONC to consider as part of the framework evaluation:
  - Are the existing security requirements cost prohibitive for end-users and medical offices to provide an environment for sharing medical information?
  - If/when the government approves legislature for all health related service entities, e.g., hospitals, medical offices, end-users, etc., mandating adoption of EHR/HIE what are the obstacles and concerns of these entities?
  - Can all of the data fields from each of the approved EHR platforms be ported into a common HIE dashboard? A common HIE dashboard reduces issues with disparate EHR platforms, enable EHR platform providers to ensure their data fields are compatible to feed into the common HIE dashboard, without having to share their proprietary developmental information with competitors.

  - How to handle results from a doctor visit that did not have the ability or access to update the patient's electronic medical record? Is there a mechanism in place to input that data post visit?
  - What QA processes are in place to ensure a medical care provider is viewing a patient's complete medical record?
- Roles and responsibilities are not fully defined in the framework. It supports accountability and that the goals of the framework are being met to improve flow and usage of information. It must be identified who will be gathering feedback and implementing measures to address the recommendations provided by industry and health professionals.
- The framework is best aligned to the timeframe outlined in Figure 10 of "A Shared Nationwide Interoperability Roadmap". This increases the accountability to reaching and incorporating the goals of ONC, which includes the 3 year Agenda (2015-2017), the 6 Year Agenda (2018-2020), and the 10 Year Agenda (2021-2024).
- Recent medical care, procedures or medications not included in a patient's medical record potentially have negative consequences during a subsequent visit to a different medical office or hospital emergency room. Recommendations for ONC to consider as part of the framework evaluation:
  - One possible option would be for the physician's office to fax the report to the patient's primary care provider to have them include the information into the patients' EHR.

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

C.He.S.S. Response (8.2)

C.He.S.S. recommends that the following be included in the "core" measure set:

- What platforms of technology are being used
- Percentage of doctors utilizing technology available and working with the system
- Data collection
- Movement towards universal EHR system
- Percentage of user adoption as moving towards total user adoption and nationwide system by 2024
- Of the approved EHR platforms, what reporting metrics from each of the platforms can be accurately reported into a common EHR HIE dashboard?

The study from the ***Journal of Biomedical Informatics***, "A framework for systematic evaluation of health information infrastructure progress in communities"[15] outlines additional measurements that are key requirements for functionality of a community health information infrastructures:

1. Completeness of information: all medical information on everyone in the community is in the system and accessible at all points of care
2. Degree of usage: relevant parties in the community are using the system—providers and patients alike
3. Type of usage: the information is used for the entire spectrum of health care needs: patient care, public health, clinical research, quality improvement and healthcare operations
4. Financial sustainability: The implementation of the information infrastructure is financially sustainable, funded by an ongoing permanent source of operational revenue

[15] http://www.j-biomed-inform.com/article/S1532-0464(06)00018-9/fulltext#Background: the need for progress metrics

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

C.He.S.S. Response (8.3)

C.He.S.S recommends that ONC focus on measuring and categorizing by certain levels of the ecosystem. We outline several examples below that recommend different approaches to measurement focusing on distinct ecosystems or "clusters". Specifically selected use cases could provide significant feedback on a smaller scale, that when each use case combined represents a cross section study prior to a national roll-out. A few potential agencies for use cases is provided below.

By viewing and measuring best practices on a regional level, ONC does not isolate by specific populations and limit the number of ideas and practices recommended to improve measurement. In order to increase involvement and improve measurement, multiple viewpoints and stakeholder engagement are essential.

Federal Occupational Health – Potential Use Case

Federal Occupational Health (FOH) is an agency within the Program Support Center (PSC) of the Department of Health and Human Services (HHS). FOH works in partnership with federal organizations nationally and internationally to design and deliver comprehensive occupational health solutions exclusively to federal employees. FOH is the largest provider of occupational health services in the federal government, serving more than 360 federal agencies and reaching 1.8 million federal employees.

The Medicare and Medicaid EHR Incentive Programs provide incentive payments to eligible professionals, eligible hospitals, and critical access hospitals as they adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology.

In addition to including federal agency use cases, we recommend the following use cases:

- Private/public hospitals, medical offices, physicians, academia and end-users. End-users should be diverse to include young and older patient populations, individuals with little IT knowledge to those more capable.
- Recommend a use case for mobile platforms to address remote accessibility, transmission of data effectiveness, ease of use and security.
- Recommend a use case for editing and transmitting X-rays, EKGs, Sonograms, mammograms and CT Scans.
- Recommend use case for prescriptions from doctors and prescriptions filled by pharmacy.

National Institutes of Health-Potential Use Case

In the US National Library of Medicine National Institutes of Health article, "A draft framework for measuring progress towards the development of a national health information infrastructure" NIH is implementing a program in which they begin by looking at clusters. Recent research on the growth and behavior of networks suggests ONC could anticipate significant increases in the capability of these networks as the number of connections grows[16]. This directly benefits ONC in the creation of a universal health system, as they can determine best practices as well as examples of what is not successful in practice on a smaller, regional scale prior to national implementation[17].

[16] Barabási AL. Linked: The New Science of Networks. Perseus Publishing, Cambridge, MA; 2002.

[17] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1177954/

Agency for Healthcare Research and Quality-Potential Use Case

The Agency for Healthcare Research and Quality provided a Factsheet for "Improving Health Care Quality", where they reviewed examples of how AHRQ supported research[18] that is now in progress focuses on improving health care quality. They focus on the following key metrics:

- Bringing evidence-based medicine to the hospital bedside
- Evidence-based reminders in home health care
- Understanding variability in community mammography
- Racial and ethnic variation in medical interactions
- Otitis media

National Quality Forum from Community Alliances-Potential Use Case

This case takes a regional view as well as stakeholder involvement to recommend the following: Engage the leadership of national provider organizations, especially medical/specialty societies and boards, to generate support for local initiatives related to performance measurement, public reporting and quality improvement[19]. The article provided as Recommendations for the National Quality Forum from Community Alliances, "In Support of Regional Healthcare Improvement", provides use cases regionally.

As stated in the article, "Betsy Mulvey, Executive Director of the New York Quality Alliance (NYQA), recruits a group of physicians to help the alliance select acceptable measures. It gives alliance leaders a chance to hear physicians' views but also gain their acceptance of the process. She says encouraging the profession as a whole to become more involved in vetting measures and methods would reinforce her local efforts." This involvement in local efforts flows into the region, which provides case studies and best practices for ONC.

Another example in the article is in Hawaii, where Richard Chung, MD, the Senior Vice President with the Hawaii Medical Services Association (HMSA), says "the independent Blue Cross Blue Shield Association affiliate finds many physicians have reservations about the group's Pay for Performance (P4P) measurement process, seeing it as a move to reduce their fee schedule. And they raise questions about the accuracy of currently available claims data as undermining the validity of any reports." By taking another cross-section of the U.S., there are disparities that are raised before they become national concerns, allowing test cases to succeed or fail on a smaller scale and not that of a national stage.

8.4 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?

C.He.S.S. Response (8.4)

Evidence suggests that stakeholders and industry experts would be willing to propose novel metrics and provide test cases. C.He.S.S. has highlighted several in the section above. In the US National Library of Medicine National Institutes of Health article, "A draft framework for measuring progress towards the development of a national health information infrastructure", additional metrics are identified for measurement[20].

- Patient Experience of Care – Clinic
- Patient Experience of Care – Hospital

[18] http://archive.ahrq.gov/research/findings/factsheets/errors-safety/improving-quality/improving-health-care-quality.pdf
[19] file:///C:/Users/mannma/Downloads/NQF_Community%20Alliances%20White%20Paper_FINAL%202.pdf
[20] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1177954/

- Health Information Technology (HIT) measure
- Hospital measures

The VA and other agencies can potentially provide metrics related to mobility and mobile devices. In the World Health Organization's (WHO) "Guide to Producing Regional Health Accounts within The National Health Accounts Framework"[21], WHO recommends the classifications of functions of health care as follows:

- Services of curative care
- Services of rehabilitative care
- Services of long-term nursing care
- Ancillary services to medical care
- Medical goods dispensed to outpatients
- Prevention and public health services
- Health administration and health insurance
- Health related functions

They identify this as important to define and classify in order to move towards a universal system, especially because it decreases confusion across regions as universal HER use is implemented.

8.5 What measurement gaps should be prioritized and addressed quickly?

C.He.S.S. Response (8.5)

In addition to those challenges addresses in the introduction, C.He.S.S. understands that additional enhancements to the current EHR platform need to occur in order to scale out to more patients and to increase the care and quality of services providing through this method. These include, but are not limited to:

- **Scalability through Social Media & mHealth:** Leveraging EHR, social networks and mHealth, ONC could more rapidly respond to the needs that have been exposed, and at the same time provide a platform to show leadership in how to improve care delivery through EHR to the wider U.S. healthcare system. It has been demonstrated that EHR and mHealth solutions combined have the ability to address access and screening of individuals efficiently, leveraging resources in central locations to reach individuals who are widely dispersed geographically. Communications and IT solutions can also go beyond screening to engagement, assist in care coordination between primary care staff and specialists, and in connecting the community of patients, such as specific populations like the veterans community, that are facing similar health challenges.
- **IT Infrastructure:** EHR infrastructure includes a tiered approach that addresses:
    - Network infrastructure for efficiently handling EHR-specific traffic, such as video
    - Data layer architecture that addresses the storage of large volumes of monitoring data in repositories suitable for analytics
    - Data analytics tools for the extraction of information from large volumes of data
    - Web services that expose data and information to application programs
    - The ability to feed into the patient's longitudinal health record with the ability for granular controls around sharing and collaboration for complex health issues

[21] http://www.who.int/health-accounts/documentation/guide_to_producing_regional_health_accounts.pdf

  - Standardized mobile device management
  - Information security

- **mHealth:** M-health is defined as any medical and public health practice supported by mobile devices such as smartphones, patient monitoring devices and other wireless technologies. mHealth typically refers to portable devices with the capability to create, store, retrieve and transmit data in real time between end users for the purpose of improving patient safety and quality of care. The flow of mobile health information is characterized by portable hardware coupled with software applications and patient data that flow across wireless networks. mHealth enables clinical access to a variety of major software applications central to patient care, which subsequently increases clinicians' reach, mobility and ease of information access, regardless of location.
- **Privacy & Security:** Under HIPAA, Telemedicine clinicians have the same responsibility to protect patients' medical records and keep information regarding their treatments confidential. Electronic files, such as images or audio/video recordings, must be stored with the same precaution and care as paper documents. This includes ensuring two-factor authentication and data encryption mechanisms are in place to protect data in transit, at-rest and through disposal among other security controls.
- **Availability of Healthcare Resources:** The ONC faces resource shortages ranging primarily from general practitioners to highly specialized doctors. By approaching EHR as a program and not a system, ONC could reduce resource contention amongst its medical community by credentialing and integrating additional doctor networks outside of the various agencies' current models. There is potential in credentialing teaching hospitals and related systems as a potential area of resource expansion. ONC will benefit from the additional Research and Development (R&D) access emerging from the health education institutions and through training doctors early in their careers to embrace EHR. This ensures that future medical practitioners gain the skills and experience necessary early in their careers to maximize capabilities while also preventing future cultural resistance that is common among a sector of current health providers. The doctors and residents would benefit by being able to incrementally build on their practice while providing significant social contributions in support of patient's health. This increases the number of EHR endpoints making medical care more available to patients located in metropolitans and rural areas alike.

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

C.He.S.S. Response (8.6)

As identified previously in Section 2.4, a common vocabulary or classification system for describing the health care services streamlines and distributes health care services universally. In addition, reporting using regional reports can then be combined into an annual report. This allows for additional measures and milestones to examine and determine progress at a national and regional level. Annual reports support moving forward into refining the "building blocks" outlined in the Measurement and evaluation framework.

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

C.He.S.S. Response (8.7)

C.He.S.S. champions implementing legislation requiring all federal agencies, hospitals, medical care providers and potentially end-users to adopt EHR HIE at the federal and state levels. Our team focuses on incentives for addressing gaps as well as disincentives on a sliding scale for those who fail to address gaps. As a best practice, whatever penalties are paid can be redirected to fund paying out incentives.

Modern EHR systems are moving beyond health records management and towards supporting real-time health. Gartner Inc.,[22] a leading IT industry analyst, defines real-time health systems as having the following characteristics that can be used to address gaps in healthcare:

- **Aware**: Awareness is about providing visibility into important patient-related activities and event data to satisfy revenue, cost, quality and patient experience expectations.
- **Adaptive:** Patient event data and operational intelligence can be used to anticipate situations before they materialize, so that responses can be proactive and prompt.
- **Collaborative:** Real-time healthcare system will continue to extend its reach and influence across the inpatient, outpatient, long-term and home care settings to manage care.
- **Mobile:** Mobility contributes to better-coordinated and -optimized workflows, as well as to timely access to patient information, and is a defining characteristic of the real-time healthcare system.
- **Demanding:** Real-time healthcare system has a prodigious appetite for information, and has the IT resources necessary to handle, house, process, share, and analyze information.

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

C.He.S.S. Response (8.8)

C.He.S.S. suggests ONC examine how hospitals and organizations regionally share information and examine best practices currently in place. As with the use cases provided in our response, there are many test cases that ONC can examine to gather best practices, especially in terms of data gathering and analysis. Those regional test cases that have reached the greatest efficiency can be tested and examined in order to assist ONC and other agencies with the creation and standardization required by a universal system. Too many lags in data sharing exist if it is not conducted electronically, and as such, an electronic platform supports multiple systems and provide a single interface that standardizes information on a universal dashboard as part of the EHR solution.

Many of these applications across disparate systems may utilize common storage, network, and server and application level functionality. The purpose of this measurement is to support ONC's mission of increasing access for patients and end-users to receive services, enhancing mobility and to enhancing, expanding and modernizing ONC and health care systems to meet continuously growing patient service requirements.

8.9 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?

C.He.S.S. Response (8.9)

In the short term, C.He.S.S. identifies these as potential sources for measuring impact:

- System and personnel security meeting NIST 800-53, HIPPA and PII requirements
- Commonality of EHR platforms for populating a universal dashboard
- Meaningful Use compliance: Agency and hospital MU requirements and knowledge
- EHR HIE Understanding and education by medical offices and end-users
- Knowing who the stakeholders are and what they require specifically

In the long term, C.He.S.S. identifies these as potential sources for measuring impact:

- System and personnel security meeting NIST 800-53, HIPPA and PII requirements
- Standardized EHR HIE platform requirements (including mobile devices) for small, medium and large medical institutions, medical offices, physicians, pharmacies and end-users

Additional risks and recommended mitigation with the analysis performed by C.He.S.S. of the impact and probability of occurrence are outlined in the table included in Appendix A.

[22] Gartner, Inc.; "2014 Strategic Road Map for the Real-Time Healthcare System"

Summary

C.He.S.S realizes that no single measurement method or approach is appropriate in every situation and that ONC is involved in a vast undertaking in moving towards a universal system and interoperability to provide superior and quality healthcare. ONC faces various challenges in not only the measurement and analysis of data, but in the initial gathering and classification of data that arrives through various mediums from doctors, patients, hospitals, and clinics. C.He.S.S. has identified additional challenges outlined in the following section as well as recommendations throughout our response to Question 8 – Measurement to address these challenges.

The industry as a whole is working toward standardization and interoperability and ONC is no exception. To help close this gap, it is anticipated that the continuing integration of the ONC's EHR data with EHR systems and data will expand the availability of patient medical data to all providers in the ONC system. The environments to be measured may include a broad range of applications ranging from simple intranet portals and Commercial-off-the-shelf (COTS) products to highly complex, distributed Systems of Systems (SoS) and other systems which integrate with one or more ONC core applications.

Challenges

Additional challenges include training, IT support, and Quality Management:

1. **Training**: Electronic Health Record (EHR) training is not broadly offered in medical schools, nor is it included in health professional curriculums. More than 60 requirements exist for establishing new EHR programs that are beyond the competency of most individual staff (e.g., scheduling, privileging, Memoranda of Understanding (MOUs), IT compatibility, etc.). ONC has to train providers, and support patients, as they simultaneous enhance the platform, expand participation and conduct the delivery of care using EHR.
2. **IT Support:** With over 900 sites of care many in rural and remote locations for the Department of Veterans Affairs (VA) alone, technology support is a critical success factor in developing EHR services, and a risk that must be mitigated in their subsequent sustainment. EHR crosses traditional boundaries between IT and biomedical engineering services, requiring comprehensive and dedicated support.
3. **Quality and Risk Management:** Poor practices in the implementation and delivery of EHR-based care clearly expose medical centers and hospitals to questions regarding the safety and adequacy of their EHR programs. In addition, current Quality and Risk Management processes are centered on "brick and mortar" concepts where health delivery is performed at a specific facility by staff credentialed for that system. EHR by its nature, blurs these lines and requires unique controls and safeguards that are specific to the mobility and patient endpoint flexibility not accounted for under current quality and risk programs. This will impact a range of activities including, but not limited to routine outcomes monitoring, credentialing & privileging, and ONC reviews.

Recommendations

C.He.S.S recommends categorizing systems to be measured by dependency, risk range and systems scope to determine the most appropriate measurement path that reduces risk and provides tailored approaches to ensure measurements are being met. Categorization at this level is critical in ensuring that measurement approaches account for variations in application and system requirements, specifically those related to the availability, integration, security and end-user impact. When all of the systems have been categorized, data will be easier to extract and measure.

Once these systems have been categorized, it assists with the transition into migrating and integrating all of these systems. With the move towards the universal system, C.He.S.S. is positioned to offer a hosting solution to ONC that provides the security and protection the government requires. In C.He.S.S., we apply our expertise in application, cloud and data center infrastructures; automated and standardized security hardening of hardware and software platforms in accordance with the Health Insurance Portability and Accountability Act (HIPAA) National Institute of Standards and Technology (NIST) SP 800-37 and the Federal Information Security Management Act (FISMA) guidelines to promote and verify the integrity and confidentiality of sensitive data; and our understanding that protecting patients' personal information remains a vital IT objective. Our team has incorporated these and other federal mandates into our migration and sustainment approaches to ensure our solutions meet federal directives and other compliance mandates. The sustainment support will be tailored based on the specific use case for any systems that are currently being supported in the cloud, such as applications used by the VA. C.He.S.S. has managed and hosted the EHR applications at DHS/ICE since 2006.

1. **Training:** The requirements for establishing new EHR programs are beyond the abilities of most hospital staff, forcing them to train its own providers as they go. Training is a critical element in closing gaps and successfully providing services from any medical center or outpatient clinic to any medical center or outpatient clinic.
2. **IT Support** - Because EHR crosses traditional boundaries between IT, biomedical engineering services and informatics, it requires comprehensive and dedicated support. With over 7,650 sites of care many in rural and remote locations, technology support is a critical success factor in developing electronic healthcare services, and a risk that must be mitigated in their subsequent sustainment. For rural programs in particular or those in small hospitals, outpatient clinics and practices, technical support remains a significant challenge.
3. **Quality Management:** The Quality and Risk Management process for projects of this scope are composed of the following sub-processes, as defined by the Project Management Institute (PMI):
    - **Risk Management Planning**: How the project will approach Risk Management planning and activities
    - **Risk Identification**: How the project will identify the risks which may impact a project and recording the risks characteristics
    - **Qualitative Risk Analysis**: Conducting a qualitative assessment of the risks
    - **Quantitative Risk Analysis**: Determining the probability of occurrence and impact on the project
    - **Risk Response Planning**: The process of developing the procedures the project will follow to reduce the impact of a particular risk on the project

Risks are reported at the project level in Milestone Review slides, Quad Charts, and Risk Registers. Project level risks are reported to the Office of Management and budget (OMB). All risks align with one of the 19 Risk Categories from the OMB 300 reporting requirements.

<u>Related expertise of C.He.S.S</u>

C.He.S.S. has conducted over 100 cloud migrations and owns the infrastructure operations in delivering public, private, community and hybrid Infrastructure as a Service (IaaS) cloud services both on premise and externally hosted within our facilities. Our work specifically in supporting Health Information Technology (HIT) mission requirements for the Department of Homeland Security (DHS) Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) encompassed a similarly broad range of systems currently and required several migrations from physical to virtual, physical to cloud and virtual to cloud services. The migrations were holistic as we were required to identify target state IaaS requirements, establish availability requirements, revise application and infrastructure architectures to support the functionality and deploy full pre-production, test and production environments with Disaster Recovery (DR), High Availability (HA) and Global Data Center failover capabilities running on FedRAMP certified IaaS cloud services. The expertise we learned from these projects will be applied to our technical approach for the ONC. Most notably, we are applying lessons learned from:

- Physical Servers to IaaS bare-metal to ensure performance maintainability
- Security differences from an Agency Authorization to Operate (ATO) to obtaining a FedRAMP ATO
- Security level of effort in achieving a FISMA HIGH baseline ATO on top of FedRAMP certified infrastructure

The Impact of Encryption overhead when replicating sensitive data to create more accurate migration schedule estimates based on Volume of Data and Encryption mechanisms.

APPENDIX A

Outlined in the table below are some identified risks as the movement towards a universal system is measured:

RISK	IMPACT	PROBABILITY	MITIGATION
Violating State Medical Laws/Standards	High	High	Delivering EHR services crosses state boundaries. Ensuring a routing feature is considered based not only on patient need/condition, but also, and only, to Doctors authorized to practice medicine in the patient's State is a key compliance area. Currently not all EHR capabilities support this level of routing logic. This is be a key requirement for which to test when evaluating EHR solutions.
Inability to efficiently perform data integrations and achieve interoperability with EHRs	High	Low	EHR aims to streamline clinical processes, but without integration and interoperability of EHR data with EHR systems, health resources will be burdened with duplicate entries. Ensuring EHR solutions support open standards and adhere to healthcare policies and Directives is a critical risk mitigation component.
Unable to achieve ATO for enhanced EHR capabilities	High	Low	C.He.S.S. leverages its expertise in providing private cloud hosting services to VA, DOD, DOJ, HHS and DHS at both FISMA High and FISMA Moderate. We have prepared several ATO packages for our Federal customers and understand FedRAMP A&A processes.
Inability to engage critical stakeholders to participate in the Study Team which will guide key design requirements	Low	Low	C.He.S.S. develops a comprehensive Team Charter and communicate both the benefits and criticality of their participation, not only to the study team participants, but to ONC leadership to ensure accountability, action and participation in the development of enhanced and expanded EHR capabilities.
Ability to identify system compromises accurately and quickly	High	Low	Monitoring and incident response is the cornerstone of ONC's Network Security Operations Center. C.He.S.S. ensures that all EHR systems support integration with ONC's NSOC.
Inability to generate interest and participation from health providers to overcome increasing scarcity of healthcare resources	Medium	Medium	C.He.S.S. can assist ONC in crafting and deploying a marketing and communications plan to recruit and credential health providers outside of the current VA system. To assist with adoption and expansion, C.He.S.S. recommends targeted teaching hospitals and medical residents who might more culturally be open to adopting and integrating EHR into their practices. In addition, for new doctors, ONC EHR could be a way to incrementally grow their own medical practice while resolving a major issue for ONC.
Inability to gain funding for adopting advanced EHR capabilities after a successful pilot	Medium	Medium	C.He.S.S. is an expert in acquiring technologies and have proposed a comprehensive approach to systems acquisition that includes building a sound business case justification and solicitation approach to ensure fair value for the government in acquiring EHR capabilities.