Comments on ONC Draft Interoperability Plan

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The ONC is to be commended for the release of its draft strategic roadmap as an approach to interoperability for health information technology[i]. This document is one vision of how to achieve interoperability of electronic health information. The document outlines an extensive strategy followed by an extended series of use cases that describe applications of health information technology for patients, providers and population health.

While there are many elements in this assessment that are commendable, the need for a document such as this in 2015 should give considerable cause for concern for the American public. The American public was told that an unprecedented investment in health information technology would improve the cost and quality of health care. Yet, after a decade of Federal efforts to spur adoption of health information technology, and massive Federal expenditures under the HITECH Act and through the ONC and CMS, there are serious questions about the impact of this technology on these two core goals.

The simplest, and yet most powerful, use case for health information technology is that patients' records will be available to a provider and patient at a time when a medical decision needs to be made for diagnosis, treatment or prevention. It's easy to understand why this use case is so compelling. In this use case, we can ensure that patients don't receive medications to which they are allergic. Further, individuals can choose any provider for a clinical service without gaps in information or the need to repeat expensive medical tests. Finally, the medical history would always be updated with current medications and vaccinations. The inability of current health information technology to support this basic use case is the core rationale for the development of the current strategic plan. A critical question, then, is why this basic failure has occurred. Any planning for future health information technology investments must understand this failure before embarking on efforts to envision and shape future health information technology investment.

To answer this question, one really needs to start with the foundational concepts surrounding health information technology strategy. At its core, technology supports the concept of a business process. A business process is really a description of how services are provided within a system. So, for our primary use case, we need to describe how patients access the health care system so that we can architect the technology to support the process of clinical care. Here we run into a significant challenge since we don't have a single answer to this question. Do patients go to independent physicians, group practices, hospitals within a system, or simply call 911? What about accessing new clinical sites of care such as Minute Clinic or WalMart? What happens if a patient moves across state lines, or if a someone gets sick on a business trip? The inability to answer this question for all, or even a majority of Americans, is the first major challenge to architecting a health information technology strategy.

This fundamental dilemma has been confronted in several ways as part of our national strategy. We had the concept of regional health information exchanges to facilitate sharing of information across providers or between providers and payors. This was followed by the regional health information exchange strategies pursued by the Obama administration. Neither approach has proven to be a sustainable solution to our core use case.

In part, the reason for the failure of these approaches is that we substituted a simpler problem to solve for our core use case. Rather than develop a solution to the business process of care of patients where they receive services, we substituted a business process that focuses on the care of patients within a specific health care environment such as a hospital. This critical logical substitution in framing our use case has guided our national health information technology strategy. However, this approach has left a critical gap between the business processes the technology was designed to support and the business processes that drove the interest of the public into supporting financing for health information technology.

This critical logical substitution in a description of the business process was inadvertent. When the HITECH Act was passed, most of the expertise in health information technology was based in the core business case of hospital information technology. By 2010, the field of health information technology had diverged considerably from other fields of information sciences in critical ways. Major technology applications in health care were based on proprietary software systems, written in computer languages dating from the 1960's. In the medical model, technology is a business cost to be minimized, with little impact on services or consumers. This concept is a divergence from an understanding of the evolving economic models in the broader market where technology drives services and value for consumers.

Since health information technology was uniquely implemented at each hospital, there were almost no scale products such as a "Word" equivalent electronic health record (AthenaHealth's electronic health record is an exception, but serves the ambulatory care market). Further, there was no experience or appreciation of the tremendous network economic values underlying business models such as Amazon and Facebook. Given the facility-centric nature of the technology expertise, supported by the privacy and security concerns fostered by HIPAA, health information technology experts lacked experience in cloud-based architectures and software-as-a-service concepts. Given the proprietary software models, there was little opportunity or interest in open software platforms. Working in fee-for-service business environments, these experts had little opportunity to develop expertise in concepts such as patient portals for clinical services[ii], or mobile health technology applications. Most importantly, few, if any, of these experts had experience in supporting individual patients in seeking health care services across providers or sites of care, our primary use case.

Given this background, it's easy to understand the failure to support a business process that was beyond the collective experience of the field.

Moving forward, we need to face the critical question of whether "interoperability" as a core concept can address the failure of health information technology to support our initial use case. We also need to address the question of why the policy process resulted in a diversion of investment from our basic use case and sustainable economic models for technology.

The explicit argument for the ONC strategy document is that the original use case and business process, of supporting patients when and where they receive care, is both sound and germane to the future of our technology strategy. "An interoperable health IT ecosystem that is person-centered makes the right electronic health information available to the right people at the right time across products and organizations, in a way that can be relied upon and meaningfully used by recipients."

Given the affirmation of this use case, we need to determine a technology architecture that will support this use case. Here, there are several approaches to be considered.

The ONC approach would keep the provider-centric architecture of the system, but envisions sharing information "across products and organizations." The strategy relies upon governance and standards to achieve their goal of a "patient-centered" system. The document then outlines a 10-year strategy to enable this transformation in information access.

It's an unknown question whether such a strategy can be more successful than the strategy pursued to date in health information technology. At its core, this approach retains the core concept of proprietary health information technology architected around providers, with gradually increasing ability to share data across providers.

Embedded in this strategy, however, there is another subtle divergence in the description of the business process driving the development of the ONC definition of interoperability. The ONC moves from solving the problem of "patient-centered" data for clinical care to the problem of "patient-centered" data for population health. This is a critical distinction and has important implications for the subsequent development of the ONC strategy.

In a "patient-centered" model for clinical care, issues related to the structure of data elements are less critical for the usefulness of the system. While it's not convenient to read clinical data in different formats, clinicians and patients can quickly sift information from a variety of sources to develop care plans for individual patients. Thus, in this use case, access to information is much more critical than the structure of the data.

In the "patient-centered" data for population health, the lack of structured data may limit the usefulness of data aggregation. Further, the use case here revolves around services provided to patients not driven by patients. This population health approach creates the requirement for common structures of recording and reporting data that drives the ONC strategy. Once again, a critical shift in the use case and business process are driving the development of the ONC strategy.

This continued shift away from a "patient-centered" clinical care business process problem statement has implications that extend across the health care system and has the potential to greatly limit the effectiveness of the proposed strategy. This is a critical issue for ONC to reconsider.

Given the limited evidence that the national investment in health information technology has realized the expected impact on cost or quality of care, we need to envision a health information technology ecosystem that is self-sustaining as a minimum criterion. In looking across the information technology space, it's easy to see successful technology business models in both the business and consumer spaces, but the greatest economic value unleashed over the last decade by technology clearly has been in the consumer space. Thus, a national model of "patient-centered" data that is built around the patient may offer the greatest potential for transformation of the health care system and for sustainability of a health care information technology ecosystem

One model of a "patient-centered" clinical care architecture to consider is a personal health record approach. If populated by patients and providers, this model would meet the core use case directly. This approach has the advantage of focusing directly on the business processes of the care delivery. The use case is clear, and there are testable hypotheses surrounding the information and information quality needed to support this architecture. If designed carefully, this model is not inconsistent with the population health use case over time. However, rather than governance and standards to drive "interoperability", this approach uses direct feedback from physicians and patients to drive information quality and "interoperability." A personal health record architecture does not require a single interface for patients to gain access to their data, but instead could entail a common platform to facilitate a diverse set of information technology products and services akin to the diversity of applications found in a consumer environment such as the iTunes store. This concept is a unique architectural model, not an extension of hospital-based information technology solutions.

Creating a viable consumer facing technology architecture will establish a pull-model of "interoperability" as consumers demand access to their data in their desired format and structure. Clearly, engaging consumers with technology has transformed our entire understanding of information technology. It seems to be well past time to drive to this model of technology development.

One question not yet addressed in these comments is the issue about the role of the policy process in health information technology. Clearly, this review has raised questions about the process of defining use cases and using the regulatory and certification process to guide investment in health information technology. This regulatory process has been almost unique in the technology investment space. It has been successful in spurring technology adoption, but not successful in achieving the original economic vision for the technology. We have already examined the failure of the technology to address our primary use case. More recent data are worrisome with respect to the impact of technology on provider productivity.[iii]

As a nation we have viewed adoption of health information technology as our strategy, rather than asking the critical questions of how technology would enable a transformation of the business model in health care. It is clearly a reasonable aspiration that technology could enable quality or value transformation of health care, and can facilitate access either at a population level or on a patient level. However, in our rush into technology adoption, we seemed to have skipped the process of examining how technology will achieve specific these goals. Further, we have not articulated economic or business models that will use current or future technology architectures or business processes to achieve these goals.

At this stage in our national journey into health information technology, ONC should consider a critical examination of both technology adoption it has stimulated and the impact of this technology on health care costs, quality and access before outlining future technology strategies. An honest examination of the questions addressed in this review could provide the framework for achieving a meaningful transformation of the health sector powered by technology.

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[i] Office of the National Coordinator for Health Information Technology. Connecting Health and Care for the Nation. A Shared Nationwide Interoperability Roadmap. DRAFT Version 1.0. 2015.
[ii] Chen C, Garrido T, Chock D, et al. The Kaiser Permanente electronic health record: transforming and streamlining modalities of care. Health Aff 2009;28(2):323-333.
[iii] McDonald C. Use of Internist's Free Time by Ambulatory Care Electronic Medical Record Systems. *JAMA Intern Med.* 2014;174(11):1860-1863. doi:10.1001/jamainternmed.2014.4506.