

Key principles for a national clinical decision support knowledge sharing framework: synthesis of insights from leading subject matter experts

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ABSTRACT

Objective To identify key principles for establishing a national clinical decision support (CDS) knowledge sharing framework.

Materials and methods As part of an initiative by the US Office of the National Coordinator for Health IT (ONC) to establish a framework for national CDS knowledge sharing, key stakeholders were identified. Stakeholders' viewpoints were obtained through surveys and in-depth interviews, and findings and relevant insights were summarized. Based on these insights, key principles were formulated for establishing a national CDS knowledge sharing framework.

Results Nineteen key stakeholders were recruited, including six executives from electronic health record system vendors, seven executives from knowledge content producers, three executives from healthcare provider organizations, and three additional experts in clinical informatics. Based on these stakeholders' insights, five key principles were identified for effectively sharing CDS knowledge nationally. These principles are (1) prioritize and support the creation and maintenance of a national CDS knowledge sharing framework; (2) facilitate the development of high-value content and tooling, preferably in an open-source manner; (3) accelerate the development or licensing of required, pragmatic standards; (4) acknowledge and address medicolegal liability concerns; and (5) establish a self-sustaining business model.

Discussion Based on the principles identified, a roadmap for national CDS knowledge sharing was developed through the ONC's Advancing CDS initiative.

Conclusion The study findings may serve as a useful guide for ongoing activities by the ONC and others to establish a national framework for sharing CDS knowledge and improving clinical care.

BACKGROUND AND SIGNIFICANCE

Since McDonald first demonstrated the value of clinical decision support (CDS) in a landmark randomized controlled trial of clinical reminders in the 1970s,¹ dozens of investigators have shown that, appropriately implemented, CDS can significantly improve clinical care.² Indeed, the potential for advanced CDS is a central rationale for investing in health information systems,³ and its availability serves as an important criterion for assessing the maturity of electronic health record (EHR) system implementations.⁴

Despite significant evidence of their clinical utility, however, CDS capabilities are not widely

available.^{5,6} There are many reasons for the limited deployment of CDS capabilities, but an important factor is the lack of a framework for sharing CDS resources and capabilities nationally.^{5,7,8} There have been several previous efforts to enable widespread CDS sharing.^{9–12} For example, the Knowledge Bank initiative sought to share documentation templates and other knowledge resources across users of a commercial EHR system,⁹ the Institute for Medical Knowledge Implementation¹³ attempted to share Arden Syntax medical logic modules¹⁴ across EHR system vendors, and the Morningside initiative¹⁵ attempted to create a shared community repository of executable medical knowledge. However, there is still no widely accepted approach for sharing CDS nationally. Thus, to address this important need, the RAND Corporation and Partners HealthCare were commissioned by the United States (US) Office of the National Coordinator for Health IT (ONC) to develop a proposed national framework for CDS content sharing and to pilot an initial implementation of that framework. This effort, undertaken as a key component of the ONC's Advancing CDS initiative, builds on critical foundations for knowledge sharing previously developed by the CDS Consortium.¹⁶

To inform this effort, the project team surveyed and interviewed subject matter experts (SMEs) from relevant stakeholder groups to identify key principles for the establishment of a national CDS knowledge sharing service model. Here, we describe the insights and principles gained from this process and discuss how these principles have affected the development of an initial CDS knowledge sharing framework that is being piloted with several major commercial EHR system vendors. Furthermore, recommendations are provided for establishing a national CDS knowledge sharing framework.

MATERIALS AND METHODS

SME identification and invitation

SMEs were identified in consultation with the ONC. The project team sought to ensure the representation of key stakeholders groups, including healthcare provider organizations, EHR system vendors, knowledge content producers (both commercial and non-commercial), and the informatics community. SMEs were invited primarily through email. Participating SMEs consented to their insights being shared with the ONC and with the public in a pseudo-anonymous manner, in which insights are not directly

associated with any individual. The study was conducted outside an institutional review board research protocol, as the US Department of Health and Human Services does not consider the consultation of domain experts to be human subjects research.^{17–19}

Surveys

SMEs from EHR system vendors and knowledge content vendors were first asked to complete a brief survey to obtain background information and to guide the interviews (online appendices I and II). An online survey tool (SurveyMonkey) was used. The surveys inquired about vendors’ current CDS practices and their interest in CDS sharing. The CDS types referenced in the survey were based on the CDS taxonomy of the Healthcare Information and Management Systems Society.²⁰

Interviews

Interviews generally lasted for one hour. The focus was to obtain the SMEs’ insights into the guiding principles for establishing a national framework for CDS knowledge sharing. To facilitate discussion, three potential frameworks were presented to the SMEs for consideration: (1) the sharing of human readable but non-computable knowledge artifacts; (2) the sharing of structured, computable knowledge artifacts; and (3) the sharing of CDS interfacing capabilities themselves through web services—software systems designed to support interoperable machine-to-machine interactions over a network.²¹

In most cases, the interviews were audio-recorded with the SMEs’ permission to serve as supplements to detailed interview notes. Open-ended questions were used. When available, survey responses were used to guide the interview. Two core interviewers (KK and TH) participated in most interviews, and one interviewer (TH) participated in all interviews.

Data analysis

Survey responses were summarized narratively and through descriptive statistics. The interviews were analyzed using content

analysis techniques, in which the base *meaning unit* was considered to be the constellation of words or statements from an SME that related to the same central meaning, while a *condensed meaning unit* was considered to be a shortened version of a meaning unit that still retained its core meaning.²² First, detailed interview notes and audio recordings were reviewed to generate a comprehensive set of condensed meaning units provided by the SMEs (eg, the lack of common information models for CDS inputs and outputs is a barrier to CDS knowledge sharing). Then, the condensed meaning units were combined into unifying themes, which we labeled as *insights* (eg, there are significant gaps in the required standards, and many existing standards have significant limitations). Condensed meaning units were then summarized within their organizing insights. Condensed meaning units were not further abstracted into codes because the level of abstraction for the condensed meaning units was sufficient to allow their logical categorization into themes.

Finally, the project team reviewed the SME insights to formulate key principles for a national CDS knowledge sharing framework. This formulation of key principles was achieved through discussion, consensus building, and the leveraging of the team members’ collective experience in designing scalable solutions for CDS sharing.

Validation of conclusions

To validate the study conclusions, as common insights and principles emerged from earlier interviews, later interviewees were asked to comment on these insights and principles to obtain feedback on their validity. Also, after completion of the analysis, the primary data (eg, interview notes) were reviewed to ensure the validity of the conclusions drawn from them.

RESULTS

SMEs recruited

Nineteen SMEs participated (table 1). Together, they provided insights from the perspectives of six EHR system vendors, three

Table 1 Subject matter expert (SME) participants

SMEs	Affiliated institution(s)	Primary stakeholder viewpoint represented
Jacob Reider, MD, Chief Medical Informatics Officer	Allscripts	EHR system vendor
David McCallie, Jr, MD, Vice President, Medical Informatics	Cerner	EHR system vendor
Tom Yosick, Research and Development, Inpatient Clinical Products	Epic	EHR system vendor
Steve Silverstein, MD, Vice President, Chief Clinical Architect	McKesson	EHR system vendor
Sarah Corley, MD, Chief Medical Officer	NextGen	EHR system vendor
Sam Brandt, MD, Vice President, Chief Medical Informatics Officer	Siemens Healthcare	EHR system vendor
Jerry A Osheroff, MD, Chief Clinical Informatics Officer	Thomson Reuters	Knowledge vendor
Jill Sutton, Vice President, Product Management	Thomson Reuters	Knowledge vendor
Howard Strasberg, MD, MS, Vice President, Medical Informatics	Wolters Kluwer Health	Knowledge vendor
Victor Lee, MD, Director of Content Development	Zynx Health	Knowledge vendor
Floyd Eisenberg, MD, MPH, Senior Vice President for Health Information Technology	National Quality Forum	Non-commercial knowledge producer
Daniel Rosenthal, MD, MS, MPH, Senior Advisor, Health Information Technology	National Quality Forum	Non-commercial knowledge producer
James E, Tchong, MD, Co-chairman, American College of Cardiology Informatics Committee; Director, Biomedical Informatics Core, Duke Translational Medicine Institute	American College of Cardiology; Duke University	Non-commercial knowledge producer
Gilad J Kuperman, MD, PhD Associate Professor, Department of Biomedical Informatics, Columbia University; Director of Quality Informatics, New York-Presbyterian Hospital; Chairman of the Board, New York Clinical Information Exchange	Columbia University NewYork-Presbyterian Hospital New York Clinical Information Exchange	Clinical informatics
Keith Boone, Standards Architect	GE Healthcare	Clinical informatics
Emory Fry, MD, Medical Informatics Researcher and Neonatologist	Naval Health Research Center	Clinical informatics
Todd Rothenhaus, MD, Senior Vice President and Chief Information Officer	Caritas Christi	Healthcare provider
Larry Garber, MD, Medical Director for Informatics	Fallon Clinic	Healthcare provider
Peter M. Kilbridge, MD, Chief Medical Information Officer	New York University	Healthcare provider

EHR, electronic health record.

commercial knowledge vendors, two non-commercial knowledge producers, the clinical informatics community, and the healthcare provider community.

Survey results for EHR system vendors

All six EHR system vendors responded to most of the survey questions on their CDS practices and their interest in CDS sharing.

In-house CDS content

EHR system vendors noted that they provided a variety of in-house CDS content (table 2). The approach to content updates included regular updates and one-time delivery followed by client maintenance.

Third-party CDS content

EHR system vendors noted that they used several types of third-party CDS content (table 2). Updates varied from annual to daily, and formats varied by vendor.

Current knowledge sharing

Two-thirds of the EHR system vendors reported that they provided a knowledge sharing environment at some level. These environments included (1) a vendor-hosted portal where clients can access human-readable information provided by the vendor or by its clients on how to implement a specific CDS capability; (2) a vendor-hosted environment where clients can share resources such as rules and workflows; and (3) a shared benchmarking database with associated analytics.

Interest in CDS sharing

All EHR system vendors expressed interest in learning more about the ONC Advancing CDS knowledge sharing effort. They noted that several types of structured CDS content would be valuable to their clients if they were made available in a public knowledge repository (table 3).

Survey results for knowledge content vendors

Two of the three content vendors completed the survey. The survey responses were generally consistent with the insights provided by the third content vendor through the SME interview.

Product line

The content vendors reported that their primary customers included both healthcare providers and clinical information

Table 2 In-house and third party CDS content provided by EHR system vendors

CDS content type	Vendors providing in-house CDS content of type, % (n/N)	Vendors providing third-party CDS content of type, % (n/N)
Order sets	100 (6/6)	80 (4/5)
Documentation templates	100 (6/6)	60 (3/5)
Alerts and reminders	100 (6/6)	60 (3/5)
Flow sheets	100 (6/6)	40 (2/5)
Drug–drug interaction checking and allergy checking	83 (5/6)	20 (1/5)
Relevant data display for ordering	83 (5/6)	20 (1/5)
Dictionaries	67 (4/6)	20 (1/5)
Expert dosing	50 (3/6)	0 (0/5)
Indexed reference information for integration via infobuttons	17 (1/6)	0 (0/5)

CDS, clinical decision support; EHR, electronic health record.

Table 3 Artifact types EHR system vendors thought clients would find valuable if available in a structured format on a public web site

CDS content type	Vendors identifying content as being of value, % (n/N)
Alerts and reminders	80 (4/5)
Indexed reference information for integration via infobuttons	80 (4/5)
Order sets	60 (3/5)
Documentation templates	60 (3/5)
Dictionaries	60 (3/5)
Drug–drug interaction checking and allergy checking	40 (2/5)
Expert dosing	40 (2/5)
Relevant data display for ordering	40 (2/5)
Flow sheets	40 (2/5)

CDS, clinical decision support; EHR, electronic health record.

system vendors. CDS products offered by these vendors included order sets, documentation templates, alerts and reminders, dictionaries, drug–drug interaction checking, allergy checking, expert dosing, and indexed reference information for integration via infobuttons. These vendors reported providing content in formats that were tailored to their clients' needs. One of the vendors noted that they map their content to a variety of standard terminologies. The vendors did not report using a standard content representation formalism such as the Arden Syntax¹⁴ or GELLO.²³

Integration of content into clinical information systems

The content vendors noted that they provide tools to facilitate the customization and integration of their content into clients' clinical information systems in a semiautomated fashion. This integration process includes the mapping of order item catalogs to client-specific order item catalogs.

Interest in CDS sharing

The content vendors were divided in their view of the creation of an online, public-domain CDS knowledge repository and marketplace. While one vendor viewed this type of sharing service as a potential new marketplace for their products, another vendor was not interested owing to its existing commercial success without such an interoperable marketplace.

Insights from SME interviews

Insights into CDS sharing were obtained from interviews with the 19 SMEs (table 1). These insights and the associated SME comments are detailed in table 4 and discussed below.

In the US, government power is shared between the federal government, whose authority extends across the nation, and the governments of individual states within the nation. In 2009, the US federal government established a law providing approximately \$30 billion in incentives for clinicians and hospitals to make 'meaningful use' of EHR systems.²⁶ Regulations accompanying this law establish functionality that an EHR system must support in order for its users to qualify for incentive payments. A primary insight from SMEs was that Meaningful Use dominates US health IT efforts, and that widespread adoption of a CDS knowledge sharing approach will probably require tight coupling to Meaningful Use regulations. Barring such fiat or regulation, the SMEs noted that a CDS knowledge sharing framework would only be widely adopted if it met an unmet business need, and in a manner that is more cost-effective than alternative approaches. Moreover, SMEs noted that fundamental to establishing a business case for CDS knowledge

Table 4 Insights obtained from SME interviews

Insight	Source SME comments
Meaningful use dominates US health IT efforts. Widespread adoption of a CDS knowledge sharing approach will probably require tight coupling to meaningful use regulations.	SMEs consistently noted that their health IT strategies are driven by Meaningful Use regulations. SMEs believed that requiring vendors to support a specified knowledge sharing approach through future Meaningful Use regulations would be effective in achieving widespread adoption. However, many SMEs expressed concern that such a mandate would stifle innovation. SMEs generally preferred that additional Meaningful Use requirements for CDS focused on CDS capabilities and related clinical goals rather than on specific technical approaches. SMEs believed that such regulations should be accompanied by resources that facilitate the achievement of the required CDS capabilities.
Barring fiat/regulation, in order for a CDS knowledge sharing framework to be adopted, it must meet an unmet business need, and in a manner that is more cost-effective than alternative approaches	Several EHR system vendors noted they would find little value in engaging with a knowledge sharing effort focused on CDS content areas that they already supported. Areas of unmet CDS needs identified by these vendors consisted of areas with rapidly evolving knowledge and/or high-cost diagnostics or interventions, such as oncology. Some SMEs suggested that knowledge sharing efforts initially focus on relatively “CDS poor” organizations such as smaller EHR system vendors, personal health record vendors, and health information exchanges. SMEs noted that the CDS knowledge sharing framework must be more cost-effective than alternate approaches for fulfilling unmet CDS needs. Many SMEs emphasized that the approach must be relatively easy to understand and to implement by their existing workforce.
Fundamental to a business case for CDS knowledge sharing is a reimbursement model that encourages the provision of higher-quality care	SMEs noted that, barring regulation, the business case for CDS knowledge sharing depends on a reimbursement model that rewards the provision of higher-quality care and improvements patient outcomes. SMEs noted that given the predominant fee-for-service payment model, there is often a lack of appropriate financial incentives for implementing robust CDS capabilities.
For knowledge content vendors, a national CDS knowledge sharing framework is both an opportunity and a threat	Knowledge content vendors noted that in areas where they already had market success using proprietary approaches, a knowledge sharing framework could be a threat by reducing barriers to entry for competitors. However, the vendors noted interest in a national knowledge sharing framework if such a framework created access to a larger market for their products.
There are significant gaps in the required standards, and many existing standards have significant limitations	SMEs repeatedly noted the lack of common information models for CDS inputs and outputs as a barrier to CDS knowledge sharing. Multiple SMEs noted the need for a standard, widely adopted catalog for orderables and their results. SMEs noted that existing standard terminologies such as SNOMED CT, LOINC, and RxNorm were inadequate owing to the lack of needed concepts or the availability of only highly detailed concepts that were more granular than desired. For example, neither SNOMED CT nor Medcin offer full coverage of concepts required for the characterization of mild traumatic brain injury. ²⁴ As another example, RxNorm does not support the notion of drug classes, such that RxNorm must be combined with other terminologies such as NDF-RT in order to identify medications that fall under a particular drug class (eg, β blocker). ²⁵ SMEs noted the lack of standards for documentation templates, knowledge representation, and clinical workflows. SMEs noted that many existing standards are too complex or cumbersome to use. Several SMEs noted the lack of adoption of available and appropriate standards. An SME noted that the typical standards development process is hindered by a “design-by-committee” approach and the limited engagement of relevant stakeholders. An SME noted the development of relevant standards could be accelerated significantly through direct US government sponsorship.
There is a “chicken-before-the-egg” dilemma	Multiple SMEs noted that many stakeholders are waiting for a robust, widely accepted CDS knowledge sharing framework to be established before joining and investing, whereas the development of such a framework requires early adopters. Multiple EHR system vendors noted that they would only allocate resources for integrating with such a framework if it provided substantial valuable content.
Important “building blocks” are missing and must be established before significant progress can be made	SMEs noted that robust standard value sets and information models are required for foundational CDS elements, such as problems, orders, results, and medications. Required value sets include comprehensive value sets for drug classes, problem classes, and test result classes. Until such building blocks are in place, SMEs noted it would not be possible to specify higher-level CDS artifacts such as order sets, documentation templates, and rules in a standard and semantically interoperable manner.
Competing approaches increase risk and hinder adoption	Several SMEs noted that the availability of multiple competing approaches to CDS knowledge sharing hinders adoption, because it is unclear which approach—if any—will end up becoming the dominant approach. Thus, while competition may foster innovation, it limits the adoption of any one of these approaches.
The US government has a critical role	SMEs noted that the US government is the only entity with the scope, resources, interests, and authority to overcome various barriers to scaling CDS. Specifically, one or more SMEs recommended the following actions by the US government: <ul style="list-style-type: none"> ▶ Spearhead the development of foundational “building blocks” for interoperable CDS, including required standards, value sets, and common order catalogs. ▶ Break the “chicken-before-the-egg” stalemate by fostering the development of a robust CDS knowledge sharing framework and accompanying content. ▶ Motivate relevant stakeholders to adopt and use designated standards and CDS knowledge sharing approaches. ▶ Modify the clinical reimbursement model to align more closely with care quality and health outcomes.
Various knowledge sharing approaches are complementary, with each having important strengths and limitations	The SMEs were asked to comment on three inter-related approaches to knowledge sharing: (1) the sharing of human readable but non-computable knowledge artifacts; (2) the sharing of structured, computable knowledge artifacts; and (3) the sharing of CDS inferencing capabilities themselves through web services. The SMEs saw both important benefits and challenges for each of the knowledge sharing approaches. Most SMEs believed that the different approaches were complementary, with their appropriateness dependent on the deployment context.

Continued

Table 4 Continued

Insight	Source SME comments
Significant work is usually required to adapt CDS knowledge resources for local use	Many SMEs noted that implementing CDS often requires significant adaptation and customization. Such efforts were noted to be needed at multiple levels, including terminology mapping, workflow integration, and the reconciliation of clinical content with local norms.
Medicolegal liability is a significant concern	Many SMEs expressed concern about the medicolegal liability associated with providing CDS directly, or allowing third-party CDS content to be provided through their products. Many SMEs were uncertain and apprehensive about the future role of the US Food and Drug Administration. Several SMEs suggested that the government sponsor sanctioned CDS resources accompanied by appropriate medicolegal protection for providers and vendors who use the CDS content.
Take one step at a time	Several SMEs expressed concern that efforts at establishing an operational national knowledge sharing framework may be premature, given that important prerequisites are not yet in place. An SME recommended using a flexible, iterative, and long-term approach so that the proposed architectures can undergo substantial operational refinement. An SME noted that large-scale CDS initiatives are often hindered by the mandate to accomplish strategic objectives according to a tactical timeframe.
A self-sustaining business model is needed	An SME noted that a self-sustaining business model is needed to enable CDS knowledge sharing at scale. Specifically, the SME noted that the business model would become difficult to scale across many knowledge producers if every knowledge producer charged each of its healthcare provider clients a modest but significant licensing fee (eg, \$25 000 a year) for relatively small amounts of content. This problem could potentially be dealt with by (i) the licensing of content by the US government for nationwide use or (ii) the achievement of economies of scale, whereby per-client licensing fees could be reduced through the widespread adoption of a common CDS sharing infrastructure.
Other SME insights	Pharmaceutical companies and insurance providers are interested in influencing clinician behavior to align with their business interests, including by making sponsored CDS content available through EHR systems. Vendors are unlikely to initiate significant activity in this area on their own. The national CDS sharing framework should be open source. CDS supportive of common standards of care should be a baseline across EHR systems and should not be a point of competitive differentiation. For true knowledge sharing, an important challenge is that participants are generally much more interested in taking rather than contributing content.

CDS, clinical decision support; EHR, electronic health record; LOINC, Logical Observation Identifiers Names and Codes; NDF-RT, National Drug File-Reference Terminology; SME, subject matter expert; SNOMED CT, Systematized Nomenclature of Medicine, Clinical Terms.

sharing in the US is a change in healthcare reimbursement models, from a primarily fee-for-service payment model to a model that encourages the provision of higher-quality care. Furthermore, SMEs noted that a national CDS knowledge sharing framework could pose an opportunity but also a threat for knowledge content vendors by removing barriers to market entry.

Technically, SMEs noted that many of the required standards do not exist, and that many existing standards have significant limitations. To deal with a central need identified by the SMEs, a foundational information model for CDS known as the virtual medical record (vMR) model has since been adopted by Health Level 7 (HL7).²⁷ While this model still requires the definition of detailed templates to constrain the base model for specific interoperability contexts, the vMR represents a promising foundation for CDS interoperability. Also, the National Quality Forum is specifying quality data models²⁸ for representing information used in quality measures, which can also be used for CDS.²⁹

SMEs noted that establishing a national CDS knowledge sharing framework faced a ‘chicken-before-the-egg’ dilemma, whereby many stakeholders are waiting for a robust, widely accepted CDS knowledge sharing framework to be established before joining and investing, whereas the development of such a framework requires early adopters. Also, SMEs believed that important ‘building blocks’ such as required standards are missing and must be established before significant progress can be made. Furthermore, SMEs noted that the existence of competing approaches increases risk and hinders the adoption of a common framework for knowledge sharing. In light of these various challenges, SMEs noted that the US government will need to play a critical role in facilitating progress.

As noted earlier, SMEs were asked to comment on three inter-related approaches to knowledge sharing: (1) the sharing of

human readable knowledge artifacts; (2) the sharing of structured, computable knowledge artifacts; and (3) the sharing of CDS inferencing capabilities themselves through web services. SMEs generally agreed that these various knowledge sharing approaches are complementary, with each having important strengths and limitations. Also, SMEs noted that significant work is usually required to adapt CDS knowledge resources for local use, and that medicolegal liability is a significant concern. SMEs recommended taking one step at a time, noting that the establishment of a national CDS knowledge sharing framework is a significant undertaking.

While the US government may be able to act as a catalyst to initial efforts, SMEs noted that a self-sustaining business model would need to be developed. SME also noted that pharmaceutical companies and insurance providers are interested in making sponsored CDS content available through EHR systems. Furthermore, SMEs noted that vendors are unlikely to initiate significant activity in this area on their own, and several SMEs thought that the national CDS sharing framework should be an open-source community resource. SMEs also noted that CDS supportive of common standards of care should be a baseline functionality across EHR systems rather than a point of competitive differentiation. Finally, it was noted that an important challenge to knowledge sharing is that participants are generally much more interested in taking rather than contributing content.

Principles for establishing and maintaining a national CDS knowledge sharing framework

Based on the insights outlined above, the following five principles were identified as being critical to the design, establishment, and maintenance of a national and standard CDS knowledge sharing framework.

Prioritize and support the creation and maintenance of a national CDS knowledge sharing framework

As noted by the SMEs, the establishment of a national CDS knowledge sharing framework involves many considerations and is not a small task. Moreover, no single stakeholder group can accomplish this feat on its own. Therefore, in order to establish this critical resource for enabling large-scale CDS, relevant stakeholders must prioritize and actively support the creation and maintenance of this infrastructure. In particular, there are many ways in which the US government—and often, *only* the US government—can advance the establishment, maintenance, and use of a national CDS knowledge sharing framework. Therefore, the ONC and other US agencies should play an active role in this area.

Facilitate the development of high-value content and tooling, preferably in an open-source manner

To foster adoption, the CDS knowledge sharing framework should provide both high-value content and useful tooling, so that use of the framework represents the most cost-effective means of meeting important business needs. As noted by the SMEs, facilitating compliance with Meaningful Use regulations is an important business need that should be supported by the CDS knowledge sharing framework. Moreover, the CDS knowledge sharing framework should support other important business needs faced by healthcare organizations, such as quality improvement, cost reduction, and adapting to emerging models of healthcare delivery and payment such as accountable care organizations and bundled payments.

To provide a compelling value proposition, the CDS knowledge sharing framework should be as simple as possible to understand and use, so that various stakeholder groups can easily leverage the framework and its content. Moreover, there should be a variety of user-friendly tools, such as for content searching, content retrieval, and content integration with various EHR systems. The framework and its content should explicitly acknowledge and address the need for local adaptation and customization, and the framework should be developed using a flexible and adaptive approach so that it can be highly responsive to the needs of its users. To provide optimal value, developers of the framework should coordinate closely with other relevant efforts in CDS, so that the CDS knowledge sharing framework interoperates appropriately with these various efforts and their knowledge resources. Finally, to foster adoption and collaboration, an open-source approach should be combined with a liberal intellectual property model for the software and also for the clinical content to the extent possible.

Accelerate the development or licensing of required, pragmatic standards

The development of required standards should be accelerated, including potentially through direct sponsorship by the US government. Also, the US government should consider direct licensing of relevant terminologies for nationwide use. Finally, the standards developed should be pragmatic.

Acknowledge and address medicolegal liability concerns

Medicolegal liability concerns have the potential to derail CDS efforts if left unaddressed, or if unreasonable regulations are imposed. Therefore, proactive efforts are required to work with relevant agencies of the US government, and in particular, the US Food and Drug Administration, to establish a medicolegal framework for CDS and for knowledge sharing that protects patients while promoting improved clinical decision-making.

Establish a self-sustaining business model

While support from the US government may be able to catalyze the initial development of a national CDS sharing framework, a self-sustaining business model will need to be established. Therefore, the business model will need to be explicitly considered and planned.

DISCUSSION

Summary of findings

Through surveys and interviews of SMEs representing a variety of relevant stakeholder perspectives, the ONC Advancing CDS team identified a number of insights and five guiding principles for the establishment of a national CDS knowledge sharing framework. These five key principles are (1) prioritize and support the creation and maintenance of a national CDS knowledge sharing framework; (2) facilitate the development of high-value content and tooling, preferably in an open-source manner; (3) accelerate the development or licensing of required, pragmatic standards; (4) acknowledge and address medicolegal liability concerns; and (5) establish a self-sustaining business model. Our survey also showed that all participating EHR system vendors are combining locally developed CDS content with materials from third-party knowledge vendors. The complexity of maintaining such heterogeneous content could add to the need for generalizable CDS sharing approaches. Compared with another recent survey of vendors' support for CDS,³⁰ we found somewhat greater penetrance of each CDS type except for infobuttons. The previous study found that infobuttons were supported by all seven systems surveyed. A different survey found that six of nine vendors provide an infobutton feature,³¹ a rate more similar to the 60% rate that we found.

Strengths and limitations of approach

Strengths

The approach we used to identify key principles for a national CDS knowledge sharing model has several important strengths. First, we engaged a broad cross-section of relevant stakeholder types. To our knowledge, this study represents the most comprehensive study of this type to date. Second, we engaged leading SMEs with highly relevant experiences and insights. Third, we used a bottom-up approach to identify key insights and principles, so as to ensure that our conclusions reflected the collective wisdom of the SMEs. Finally, we interviewed a relatively large number of stakeholders, such that relatively few new insights were gained during the later interviews. Thus, at least for the types of stakeholders we interviewed, we believe the insights we obtained were representative and valid.

Weaknesses

As one limitation, some types of potentially relevant stakeholder groups were not consulted. For example, we did not interview representatives from small EHR system vendors, who might have been more interested in CDS knowledge sharing owing to their relative lack of in-house CDS capabilities. Given the resource and time constraints involved in this task, however, we believed it was more important to deal with the larger EHR system vendors, as they dominate the current marketplace. As another limitation, it is possible that some SMEs might have been reluctant to provide relevant insights owing to the potential to undermine their organizations' business interests. For example, SMEs from vendors might have been inclined to over-represent their current CDS capabilities and/or to under-represent their need for additional CDS capabilities. However, we ensured SMEs of their anonymity, and based on the tenor and

free-flowing nature of the conversations, we believe we obtained relatively unfiltered insights.

In summary, we believe that the relative weaknesses of the approach used in this study were more than outweighed by the relative strengths. Therefore, we believe that the conclusions reached in this study are both valid and important.

Proposed knowledge sharing framework and pilot implementation

Building upon the study findings, the ONC Advancing CDS team has developed a proposed knowledge sharing framework comprising a central knowledge repository, structured knowledge resources supportive of Meaningful Use quality criteria, a web portal for accessing these knowledge resources via various metadata-enabled search criteria, and an executable CDS service that evaluates patients using these knowledge resources. This knowledge sharing approach is being piloted with Allscripts through the ONC Advancing CDS effort and also with NextGen, GE, Epic, Regenstrief Institute, and Partners HealthCare through the CDS Consortium effort,¹⁶ and the preliminary results are promising. Based on our experience with these pilot knowledge sharing efforts, we believe that the principles outlined in this manuscript are valid and useful. In particular, the need to provide high-value content and tooling has been a core driving principle in our development and implementation of the proposed national framework for CDS knowledge.

Interaction with commercial EHR systems

As summarized in table 2 and table 3, EHR systems vendors are already integrating third-party CDS content into their systems and are interested in using publicly available CDS knowledge resources. Moreover, the ONC Advancing CDS and CDS Consortium efforts described above have shown that interfacing a CDS knowledge sharing framework with major commercial EHR systems is possible. For example, Allscripts was able to take structured knowledge resources from the ONC Advancing CDS initiative and convert them into its own knowledge representation format. Although this conversion was done manually for the demonstration project, this conversion could be automated in the future. Also, the CDS Consortium has successfully interfaced its executable CDS service with the EHR systems of GE Healthcare and Epic. Moreover, the EHR systems of Cerner and McKesson enable clients to produce functionally rich web pages that are embedded within the order entry process and interfaced with an external CDS service. Thus, while many aspects of commercial EHR systems are not designed to support the use of an external knowledge sharing framework, there are emerging examples of integration that could be built upon to establish a national, multivendor approach to knowledge sharing.

International implications

While the ONC Advancing CDS initiative has been focused on the US, we believe the insights and principles identified should also be relevant to many international contexts. The prevalence of government-funded, single-payer healthcare systems outside the US arguably enhances the case for a national CDS knowledge sharing framework, as there is greater incentive to deliver CDS-supported, higher-quality care. As examples of transnational collaboration in this area, Taipei University in Taiwan is in discussion with the CDS Consortium to interface with the Consortium's CDS service, and a CDS service known as SEBASTIAN that was hosted in the US has been operationally used by Hospital Italiano in Argentina.⁵²

Vision and recommendations

Based on the ONC Advancing CDS efforts, and based on a multistakeholder, public–private meeting on this topic facilitated by the ONC in April 2012, we propose the following vision:

A standards-based, vendor-supported, open-source framework for sharing CDS knowledge resources, encompassing both executable CDS services and the exchange of structured CDS knowledge resources.

To achieve this vision, we recommend the following actions:

- ▶ The ONC coordinates the achievement of this vision, with Meaningful Use stage 3 requirements as the target.
- ▶ The ONC facilitates ongoing multistakeholder, public–private engagement.
- ▶ The ONC facilitates the convergence of executable CDS service efforts to use a common set of standards, in particular the HL7 Decision Support Service standard³³ and the HL7 vMR standard.²⁷
- ▶ The ONC facilitates the convergence of knowledge representation approaches. The ONC Advancing CDS approach could serve as a strawman foundation.
- ▶ The ONC facilitates the development and refinement of required standards.
- ▶ The ONC coordinates demonstration projects using candidate Meaningful Use stage 3 requirements, so as to refine the requirements and to create open-source resources that can be leveraged to meet the requirements.

CONCLUSION

The insights and principles identified in this manuscript have been invaluable to the ONC Advancing CDS project team as we have developed a roadmap and prototype for CDS sharing nationally. We hope that this study will serve as a useful guide for the ONC and other stakeholders as they continue their active efforts to establish a national CDS knowledge sharing framework capable of improving clinical care at scale.

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