

Clinical Decision Support Resource Sharing and Use

AN ASSESSMENT OF THE CURRENT STATE AND
RECOMMENDATIONS TO OCQS FOR NEAR-TERM
NEXT STEPS

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Executive Summary

Clinical decision support (CDS) is an integral part of the Office of the National Coordinator for Health Information Technology's (ONC's) vision for an electronically enabled quality improvement ecosystem. However, technical and non-technical barriers have slowed the implementation, sharing, and adoption of CDS resources. The purpose of this report is to gain a better understanding of the challenges and potential solutions to inform immediate next steps by the ONC Office of Clinical Quality and Standards (OCQS) to promote availability and clinician uptake of interoperable CDS resources.

Some obstacles to adoption of CDS are well known, such as the lack of widely used interoperability standards supporting key CDS-specific use cases, or the cost of creating, integrating, and maintaining resources. Some of the issues for clinicians are less clear. A significant barrier to the widespread adoption of CDS is the challenge that clinicians—particularly clinicians in small practices—face in evaluating the validity, reliability, relevance, and freshness of CDS resources developed outside their organizations. Each step in the complex processes of translating clinical evidence into CDS and integrating it into local systems, can introduce risks to validity and reliability of the resources.

The conditions are right for a conversation among CDS stakeholders that will lead to solutions for promoting clinician uptake of interoperable CDS resources, including the creation of guidance materials for CDS developers. Both public and private payers are moving from paying for volume to paying for value, and clinicians need support for quality improvement to succeed in the value-based environment. The Medicare and Medicaid EHR Incentive Programs have achieved a critical mass of clinicians using EHRs that support use of CDS for quality improvement. Previous federally sponsored initiatives for promoting CDS and advances in technical standards have expanded the potential for development and delivery of more sophisticated, increasingly interoperable CDS that supports improvement on performance targets for value-based payment incentives.

To build on this momentum, OCQS contracted with Discern Health to review available evidence and gather a selection of stakeholder perspectives on the current state of CDS resource sharing and use, and make recommendations for near-term opportunities to address remaining non-technical barriers to promote sharing and uptake by clinicians. Primary objectives of the project included understanding:

- What are the motivations and concerns of clinicians who are considering use of CDS resources that they did not develop?
- What are the key non-technical issues that should be addressed to foster increased availability and adoption of shared CDS resources?
- Which of the non-technical impediments to sharing and adoption are most useful and feasible to address with near-term action?

Findings

Both the literature review and stakeholder discussion information streams for this project point to the need for more effective CDS resource sharing and highlight impediments and facilitators to CDS production, sharing, and use.

Barriers for Producers

A number of significant challenges inhibit production of CDS resources. Lack of mature, effective standards at multiple levels is the most often cited reason for not pursuing development of even such relatively simple CDS resources as knowledge artifacts for sharing or distribution. Where there is motivation to produce interoperable CDS knowledge artifacts, there are a number of technical and resource impediments, such as expertise required and an absence of practical tools to facilitate translation of clinical guidelines into machine-consumable expressions such as HeD knowledge artifacts or Clinical Quality Language (CQL) expression documents. Finally, since the process for producing CDS resources is lengthy and resource intensive, cost is a significant barrier to the sustainability of CDS producers' business models.

Barriers for Users

Where CDS resources exist, they are underused or ignored by clinicians for a variety of reasons. While large provider organizations are making strides in implementing CDS, smaller practices typically do not have CDS high on their lists of priority projects and many are not yet persuaded that CDS will yield practical value to their practices. Regulatory milestones for CDS implementation stimulate uptake, but could backfire if clinicians do not see the value, or if there proves to be little value in the specific CDS uses. Clinicians cite the need to customize CDS to accommodate their workflows, the constant maintenance required for CDS resources, and the costs associated with customization and maintenance as barriers to implementation. Finally, large provider organizations may have the means to build their own CDS resources, but that approach may not be practical for smaller practices.

CDS Infrastructure Issues

CDS infrastructure needs that affect both producers and users of resources persist. Feedback loops are needed among every function for producing, sharing, and using CDS resources. To enhance sharing and uptake of CDS resources, characteristics and processes that contribute to their validity and reliability from the clinician perspective must be defined and addressed. For example, metadata can enhance transparency and decrease uncertainty for clinicians seeking CDS resources. Legal issues related to producing and using CDS resources, such as intellectual property and liability, are also important to address.

Facilitators of CDS Sharing

The stakeholder discussants and literature review sources for this project emphasized that the federal government is in a unique position to stimulate sharing and use of interoperable CDS. All sources supported ONC playing a leadership role in addressing barriers and pursuing solutions to increase adoption of CDS. While the option to use regulatory authority was noted, most preferred that the government convene stakeholders from the public and private sectors to set a vision and provide voluntary guidance without mandating a specific path for achieving the desired future state. Interestingly, nearly all discussants supported the idea of a national, public repository of CDS resources open to all users and contributors.

CDS Resource Sharing Market

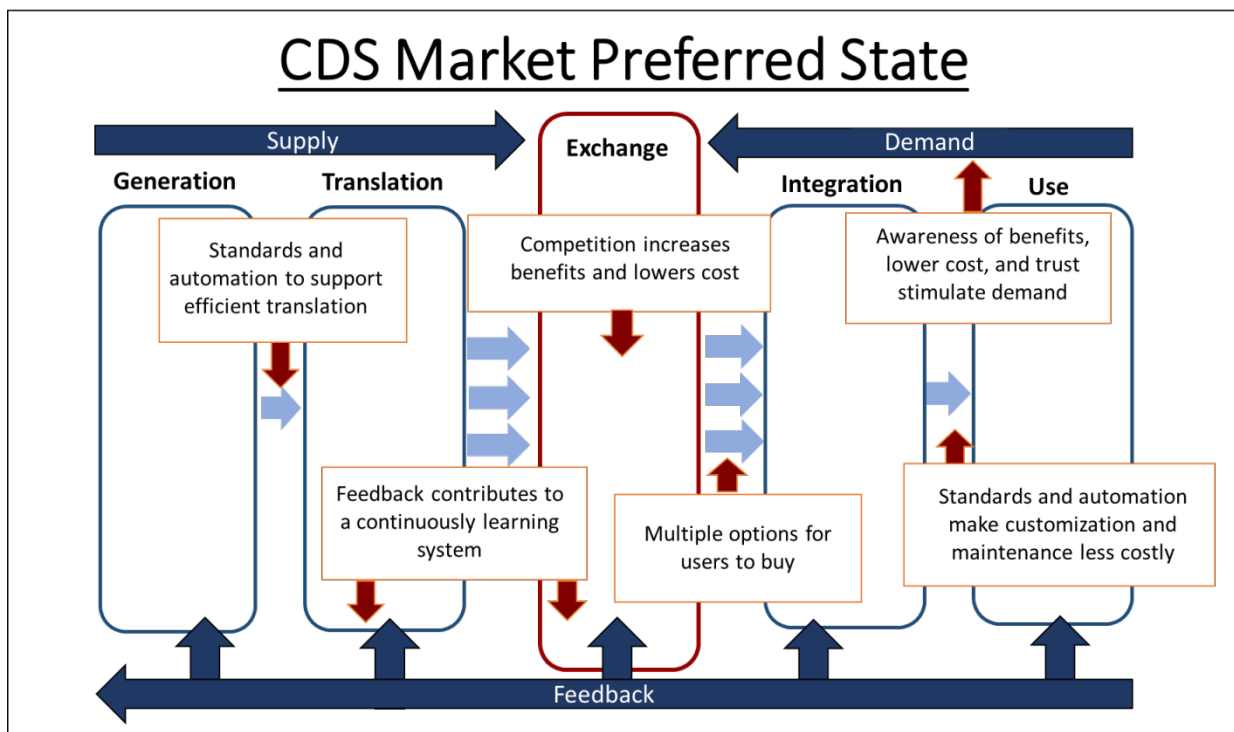
To illustrate current state barriers and preferred state opportunities for stimulating sharing of interoperable CDS resources, particularly knowledge artifacts, Discern developed a market description. The CDS market is similar to other markets in that it requires regular and balanced contributions of supply and demand in terms of CDS production and use. Through the inherent features of market exchange, the best products rise to the top based on economic transactions and feedback loops between producers and users.

The CDS market can be divided into five functions. In addition, feedback loops affect each function of the market.

- **Generation**- Clinical guidelines and other knowledge created by professional societies, researchers, or other organizations
- **Translation**- Knowledge artifacts produced in structured format, usually by EHR or CDS developers in the current state, though it is possible to envision a future state where knowledge generators publish new knowledge in structured, interoperable format alongside the narrative or other formats suited to other uses and users of the knowledge
- **Exchange**- Artifacts made available in structured, interoperable format, affecting all stakeholders
- **Integration**- Artifacts retrieved and customized for EHR/CDS system, usually by provider systems or health IT developers
- **Use**- Artifacts used in practice, by practitioners and sometimes patients

The preferred state of a robust open CDS market shown by Figure 1, below, conveys how an effective market can work when barriers are addressed.

Figure 1: CDS Market Preferred State

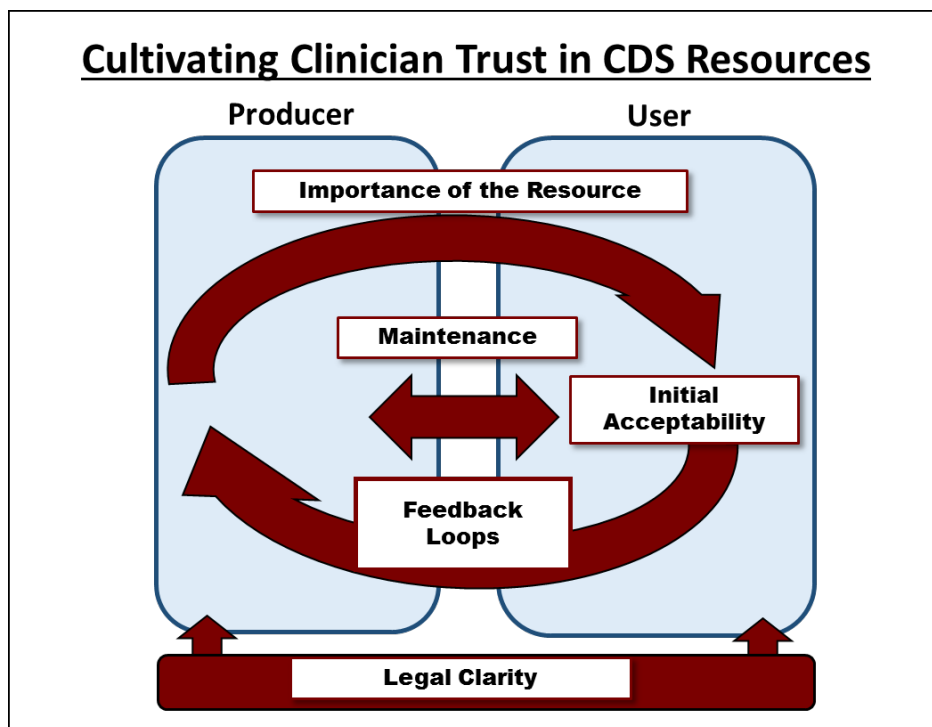


Conceptual Model for Cultivating Clinician Trust in CDS Resources

Our findings indicate that clinician trust in the processes for translating underlying knowledge into CDS resources, integrating resources into systems, and maintaining resources over time is necessary for a vibrant market. The essential elements of the conceptual model for cultivating clinician trust in CDS resources include:

- **Importance of the resource**- Assurance that clinicians have the CDS resources they need to address critical quality issues
- **Initial acceptability**- Assurance that CDS resources are valid, reliable, and relevant
- **Maintenance**- Assurance that CDS resources remain acceptable over time, in accordance with the evolving evidence
- **Feedback loops**- Assurance that we are learning about CDS resources and their contribution to quality of care over time
- **Legal clarity**- Assurance that users and producers of CDS resources will not suffer legal consequences for good faith actions

Figure 2: Trust Conceptual Model



Recommendations for OCQS' Next Steps

As an advocate for clinician use of health IT including CDS, OCQS is well positioned to sponsor a set of activities to clarify the challenges and identify solutions for cultivating clinician trust in CDS resources. Discern recommends a set of activities with the goal of creating voluntary practical guidance for the CDS developer community, so that developers are better able to build resources that clinicians will trust and use. Guidance materials would include a framework of characteristics (e.g., source and strength of the

underlying evidence, maintenance schedule) and processes (e.g., testing methods, certification) for producing trusted CDS resources.

The larger goal of producing voluntary practical guidance for CDS developers to accelerate the availability of trusted CDS resources that support clinical quality improvement can be broken down into four objectives and related questions for consideration:

- **Objective 1:** Introduce and verify with stakeholders the Conceptual Model for Cultivating Clinician Trust in CDS Resources
 - Does the conceptual model capture all of the critical elements required for clinicians to evaluate and trust CDS resources?
- **Objective 2:** Determine critical information for decreasing uncertainty in adopting CDS resources
 - What information do clinicians need about the underlying evidence, practice guidelines, or alternative sources of clinical logic?
 - What do clinicians need to know about the stewardship and processes for updating resources based on changing evidence?
 - How can we assess whether clinicians have adequate information to judge the validity and reliability of CDS resources?
 - How can the information needed to decrease uncertainty be translated into metadata that travels with the CDS resource to provide transparency?
- **Objective 3:** Determine methods for assessing acceptability of CDS resources
 - What are emerging approaches for assuring validity, reliability, and relevance of CDS resources?
 - Would testing, review, and/or certification or endorsement by widely trusted entities, such as ONC-authorized certification bodies or voluntary consensus bodies, be helpful?
 - What role should government, professional societies, and/or crowdsourcing play in validating CDS resources?
 - What processes should be adopted to assure timely updating of CDS resources based on evolving clinical evidence?
- **Objective 4:** Determine next steps for stakeholders for cultivating clinician trust in CDS resources

Discern recommends that OCQS distribute a white paper to stakeholders to notify the community of its intentions to create voluntary guidance for CDS developers. The white paper would serve as background for an in-person meeting of selected national experts and stakeholders representing various interests. Discern also recommends various pre- and post-meeting activities to maximize the usefulness of the in-person meeting time. The cumulative results of these activities would be captured in a report containing guidance materials for CDS developers and the rationale behind the guidance. In addition, an issue brief intended for broader dissemination should be prepared in a manner that is accessible to a larger audience.

Increasing clinician trust in CDS resources will have significant impact on the development, sharing, and use of CDS. The findings of this project revealed that one of the primary impediments to the availability of CDS resources is a lack of demand from clinicians as end users, and uncertainty about the trustworthiness and value of CDS decreases demand. Clarifying the value of CDS for clinicians will increase demand and providing guidance for CDS developers will enhance the supply of trustworthy resources, which will stimulate a robust market for high-quality CDS resources.

Introduction

In 2014, the Office of the National Coordinator for Health Information Technology (ONC) described a vision for an “electronically enabled Quality Improvement (QI) ecosystem that promotes better health and care, improved communication and transparency, rapid translation of knowledge for all stakeholders and reduction in the burden of data collection and reporting for providers.” Clinical decision support (CDS) is a resource that can help to promote the larger goals of a high-performing health system, while having direct impact at the clinician and patient level. An increase in uptake and use of CDS resources by clinicians would positively affect the quality and consistency of care delivery, as well as improve feedback loops with regard to CDS resources and the clinical practice guidelines that inform many of them.

It is important at the outset of this report to define and distinguish the terms “CDS resources” and “knowledge artifact,” as used within the report.

- “CDS resources” refers to a wide array of building blocks underlying delivery of CDS to clinicians at the point of care. Such building blocks can include, but are not limited to, knowledge artifacts, knowledge bases, value-set repositories, and executable code. Many of these building blocks could also support consumer-facing decision support; however, this report is focused on clinician-facing CDS.
- “Knowledge artifact” means a highly structured, computable expression of clinical logic that is readily understood by developers and/or consumed by health IT products, such as CDS modules within EHR systems, that have been built to consume logic expressed in the relevant content standard. Examples of emerging, consensus standards for such expressions include the Knowledge Artifact Specification (also known as “Health eDecisions” or “HeD” knowledge artifact) and the newer Clinical Quality Language (CQL) standards.

Problem and Opportunity Statement

Implementation, sharing, and adoption of CDS resources have been slow to evolve because of both technical and non-technical barriers. Some obstacles are clear and well known, such as the lack of effective, widely used interoperability standards for CDS resources, or the high cost of creating and maintaining some resources. The issues and impacts on stakeholders are less clear for other barriers, such as the lack of legal clarity across the creation, sharing, and use of CDS resources. Uncovering the challenges that CDS stakeholders face is a necessary first step to addressing those barriers with feasible solutions, including defining an appropriate role for the federal government in helping to resolve the issues and promote CDS resource sharing.

Clinicians face an overwhelming amount of new and evolving clinical evidence. They need CDS resources to help them assimilate up-to-date clinical guidelines and get new knowledge into practice promptly. However, clinician practices have unique needs and differing systems, typically requiring a high degree of customization for integrating CDS resources into their systems. “One-off” solutions are not reusable, which inhibits sharing, diminishes supply, and drives up the cost of CDS resources. Each step in the complex processes of translating clinical evidence into computable knowledge artifacts, and finally integrating those artifacts into local systems, can introduce risks to validity and reliability of resources. Some clinicians, particularly those in small practices, mistrust CDS resources. Together with low

awareness of benefits and high costs to obtain or implement, this lack of confidence in the resources' value contributes to low adoption.

Several developments have begun to build a foundation and momentum for an initiative to promote sharing of CDS resources. Previous work sponsored by ONC, the Agency for Health Research and Quality (AHRQ), and others has contributed findings about challenges and potential solutions for increasing CDS interoperability, adoption, and sharing. The table below describes some examples of this previous work that are immediately relevant to the current analysis.

Table: Foundational CDS Initiatives

Project	Year	Sponsor/Lead	Description
CDS Roadmap	2006	An American Medical Informatics Association (AMIA) initiative for the Office of the National Coordinator for Health Information Technology (ONC)	The report "provides recommendations and an action plan designed to advance the development, widespread adoption, and value of clinical decision support in improving health and the quality and safety of health care delivery. It includes an overview of the current state and future vision of CDS-enabled health care, outlines barriers to broader CDS adoption, and proposes specific solutions to address these barriers" (AMIA press release).
CDS Consortium	2008	AHRQ-sponsored initiative comprising more than 90 members, including academic and healthcare institutions and vendors	The goal of the CDS Consortium was to assess, define, demonstrate, and evaluate best practices for knowledge management and CDS in healthcare information technology at scale—across multiple ambulatory care settings and EHR technology platforms.
Advancing CDS	2011	ONC-sponsored project led by RAND Corporation and Partners HealthCare	The objective of this multi-part project was to align CDS and other future interoperability standards for health IT enabled quality improvement, with a particular focus on quality measurement and enabling providers to achieve meaningful use of health IT.
CDS Collaborative	2011	Self-sustaining collaborative launched with support from the California Healthcare Foundation and led by TMIT Consulting	For this initiative, healthcare providers collaborate with each other and with partners such as EHR vendors and quality improvement organizations, to “get better faster, together” at addressing healthcare performance improvement imperatives. Participants use vetted worksheets to document, analyze, share, and improve target-focused information flows and workflows.

GLIDES (Guidelines Into Decision Support)	2011	AHRQ-sponsored project	The objective of this project was the development, implementation, and evaluation of demonstrations that advance understanding of how best to incorporate CDS into the delivery of healthcare.
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In parallel to work specifically focused on advancing CDS availability, utility, and use, the Medicare and Medicaid Electronic Health Record Incentive Programs have achieved critical mass in clinician adoption of health IT and ability to use CDS via their EHR systems. Technical standards for translation of clinical knowledge into interoperable CDS resources are maturing. For example, Health eDecisions makes strides toward standardizing knowledge artifacts and the Quality Improvement and Clinical Knowledge Model (QuICK) provides a standard way to reference information in EHRs for both measurement and decision support purposes. Further, new payment and delivery models focus on increasing quality while reducing cost of care, and clinicians need tools to help them succeed in the value-driven environment.

Project Purpose and Scope

Project Objectives

To build on momentum generated by previous work, advancements in the state of the art, and support payment and delivery reform, the ONC Office of Clinical Quality and Safety (OCQS) contracted with Discern Health to review available evidence and a selection of stakeholder perspectives on the current state of CDS resource sharing and near-term opportunities to address remaining non-technical barriers to that sharing.

This project aimed to identify and develop recommendations for near-term actions that could begin to address factors contributing to clinician uncertainty about adopting CDS resources created by others. Primary research questions for the project included:

- What are the motivations and concerns of clinicians who are considering use of CDS resources that they did not develop?
- What are the key non-technical issues that should be addressed to foster increased availability and adoption of shared CDS resources?
- Which of the non-technical impediments to sharing and adoption are most useful and feasible to address with near-term action?

Project Scope

Effective sharing of interoperable CDS resources will support the learning health system by expediting the translation of new knowledge into more effective action at the point of care. While the technical barriers to sharing are significant, detailed analysis or development of recommendations specific to resolving remaining technical issues was outside the scope of this project. This report provides an assessment of the current state of CDS resource sharing, with focus on the perceived and actual risks that affect clinician adoption and use of resources, specifically including structured representations of clinical knowledge (e.g., Health eDecisions knowledge artifacts) that guide programming or configuration of applications to deliver CDS to the clinical decision maker. In addition, the report

provides recommendations for immediate next steps that OCQS can take to decrease uncertainty for production, sharing, and use of CDS resources.

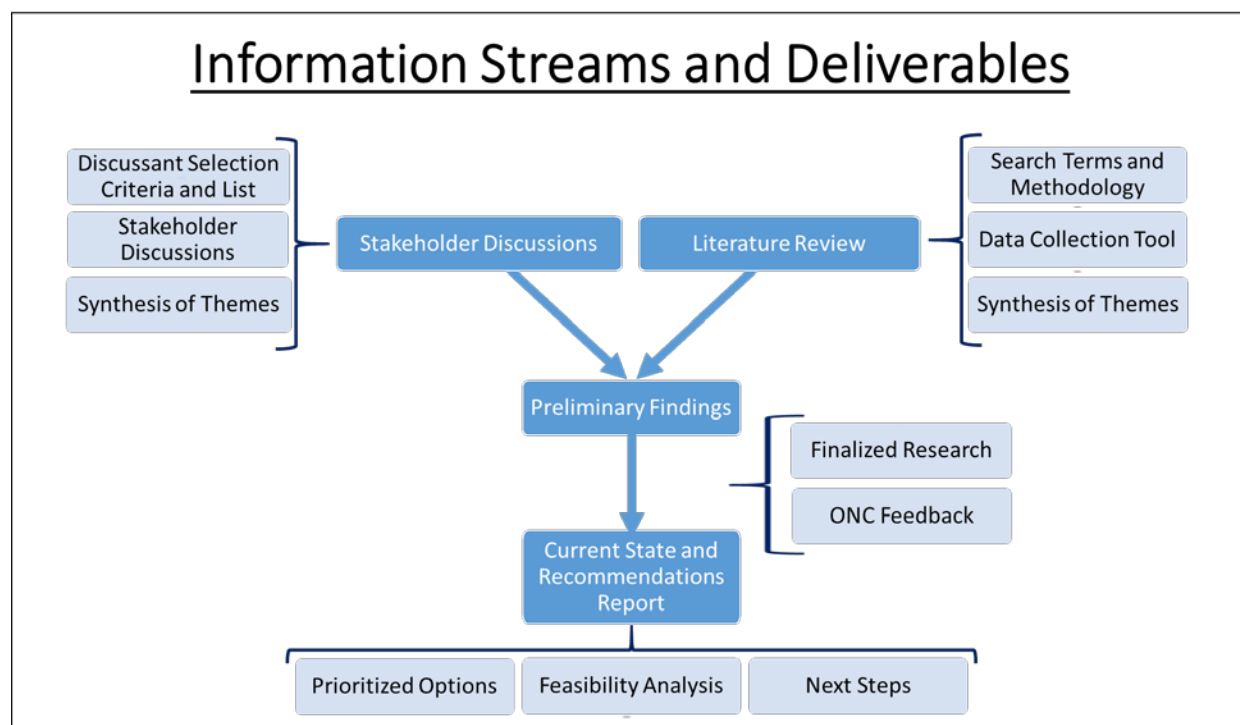
Project Approach

The primary activities of the project included:

- Identification and review of existing evidence in the literature and gathering stakeholder perspectives through discussions to inform Discern’s assessment of the current state of CDS resource sharing;
- Based on analysis of existing evidence and key stakeholder perspectives, assessment of potential opportunities to address barriers to CDS resource sharing; and
- Development of recommendations for practical, near-term actions to expedite CDS resource sharing.

Figure 3 depicts the relationship among the two information streams and the deliverables for this project.

Figure 3: Project Approach



The Discern team, in consultation with the OCQS team for this project, identified stakeholder types, organizations, and individuals for discussions. Discern conducted 17 one-hour calls with stakeholders, using a background document to stimulate discussion about a variety of important issues. Discussants included representatives of providers, health IT developers, researchers, federal agencies, and health IT implementation support entities. Appendix A contains further detail about the methodology for the stakeholder discussions.

Concurrently, Discern conducted a literature review to glean published perspectives on the relevant issues. In collaboration with the OCQS team, Discern developed search terms and inclusion criteria to guide selection of sources to review. Significant points from each source were entered into a customized data collection tool. Appendix B contains further detail about the methodology for the stakeholder discussions.

The final deliverable of this project is this Current State and Recommendations Report, which encompasses Discern's findings, conceptual models for the CDS market and for cultivating trust in CDS resources, and recommendations to OCQS for near-term next steps. In addition, Discern developed interim deliverables that informed this report, including:

- Discussion support materials
- Discussion synthesis
- Literature search terms
- Literature review methodology and data collection tool
- Literature review synthesis

Findings: Current State and Barriers

The need for more effective CDS resource sharing is clear from the stakeholder discussions and literature review for this project. Both information streams highlight the same barriers to CDS production, sharing, and use. All stakeholders experience challenges in sharing CDS resources; however, small clinician practices are disproportionately affected. This section of the report organizes the findings by barriers for producers, barriers for users, CDS infrastructure needs, and facilitators of CDS resource sharing.

Barriers for Producers

A number of significant challenges impede production of interoperable CDS resources. Lack of standards at multiple levels are the most often cited reasons for not pursuing development of even such relatively simple CDS resources as knowledge artifacts for sharing or distribution. Where there is motivation to produce sharable CDS knowledge artifacts, there are a number of technical and resource impediments, such as expertise required and an absence of practical tools to facilitate translation of clinical guidelines into machine-consumable expressions such as HeD knowledge artifacts or Clinical Quality Language (CQL) expression documents. Finally, because the process for producing CDS resources is lengthy and resource intensive, cost is a significant barrier to the sustainability of CDS producers' business models.

Lack of Standards

Lack of thorough and consistent standards for creating (semantic and content standards), sharing (transport standards), and maintaining (curating standards) CDS artifacts is a concern that stakeholder discussants and literature review sources cite frequently. The lack of mature standards impacts both CDS resource developers and end users. The technical standards that need to be fully developed and consistently used include interoperability standards such as shared logical models for representing clinical concepts and uniform language for expression of clinical logic. However, the array of standards literature and discussions suggest are needed to facilitate efficient, rapid, deployment of CDS resources include non-technical standards such as sound implementation practices for software updates, and effective practices for production and curation of valid, reliable knowledge artifacts.

Although standards relevant to producing interoperable (readily sharable) CDS production are now emerging, these are not yet fully developed and thus are not yet used to the degree necessary to reduce burden on CDS producers. Discussants lament that currently the implementation for nearly every CDS rule (clinical guideline, practice protocol, or element thereof) must be built from scratch, which quickly drains time, resources, and interest in taking on the endeavor. Significant work is required to continue the momentum and arrive at standards that will allow CDS developers to make "plug-and-play" artifacts.

Standards needed for data definitions, sharing, maintenance, and user interface

Standard data element definitions are needed, and sources also point to the need for standardization of data capture to decrease confusion and inconsistency. Standardized, commonly captured data elements would provide the building blocks for eCQI resources, including measurement and CDS applications, that are smoothly and seamlessly sharable at scale. For example, while a given knowledge artifact may

require a patient's age, there is no uniformity in how age is made available to logic engines across organizations' data systems. Age may be captured as age in years as of a specific admission or encounter and available as the current or most recent age, or "age" may not be a specifically captured and recorded field but instead a date of birth (e.g., 03/13/1988) may be recorded. Thus, in one system, the logic engine executing a knowledge artifact may need to call on the most recently recorded age or it may need to perform additional calculation to derive an "age" value to test against the patient-age value set to which the CDS artifact applies. This poses a challenge when organizations wish to use shared knowledge artifacts because the artifacts may need different data elements, or a different format of data elements, than are already available – requiring additional data capture or development of additional logic or execution code to work around the differences in available data.

Other areas where standards are needed include CDS resource sharing, maintenance, and user interfaces. Since CDS systems vary from cloud-based modules that interface with (cloud or locally installed) EHR systems to local EHR-embedded models, there is no standard way to implement updates to logic or value sets, in response to evolving clinical guidelines, in a timely manner. Given the constantly changing evidence, discussants suggested that there should be a coordinated approach for efficiently and timely updating resources and implementations. CDS programs that depend on interoperability across different systems to integrate the information needed to support high-quality care are disrupted by uncoordinated updates. Clinicians are also interested in standards for user interfaces. To be effective, CDS resources need to be integrated into workflows, and clinicians agree that consistent, context-appropriate approaches to information display would assist with efficient integration.

Priority areas for standards

Stakeholder discussants representing varying perspectives call out the need for standardized order sets and standardized processes for prioritizing alerts that are delivered to clinicians. Other areas, such as drug-drug interactions, are viewed as relatively effective in meeting clinician expectations for content and usability, though these alerts would benefit from refined prioritization and presentation.

Common Models for Sharing

Currently, many CDS resources are developed in silos exclusively for one organization or IT system and are so specialized from inception that sharing them with other systems is difficult. The lack of mature, widely used interoperability standards as well as of common expectations and model processes for sharing resources results in significant investment in developing CDS resources that have already been developed elsewhere but are not available for reuse. Challenges in sharing resources across organizations also include concerns about intellectual property and legal liability.

Proprietary issues

Most widely used CDS resources are based on specific EHR developers' platforms. This inhibits sharing either indirectly because of lack of needed interoperability standards or directly through contractual prohibitions required by EHR developers. In addition, maintenance and enhancement of CDS resources, including incorporation of updates to underlying clinical knowledge, currently depends on EHR developers, though stakeholders report that users would prefer to be able to continually assess third-party solutions and switch to better products when they appear on the market. Proprietary constraints also arise when organizations want to import resources or export information from their EHRs for the purposes of CDS, which often requires considerable expense. Further, non-disclosure agreements may

interfere with clinicians' freedom to share information about adverse events associated with use of CDS resources.

Sustainable Business Models

Presently, the business model is weak for CDS content producers who are looking to create and sell CDS resources widely on an open market. First, creating CDS resources that can be used by providers across a majority of the CDS systems and EHRs now in operation requires multiple translations. Even then, users purchasing third-party CDS resources must invest significant time and effort in customizing the resources to operate effectively within their local systems. As a result, CDS resources typically come from two sources: EHR developers that have proprietary CDS resources built to work within their systems, and large providers that build customized CDS resources to meet their unique needs.

Barriers for Users

Where CDS resources exist, the literature and discussants indicate they are underused or ignored for a variety of reasons. While large provider organizations are making strides in implementing CDS, smaller practices typically do not have CDS high on their lists of priority projects and many are not yet persuaded that CDS will yield practical value to their practice. Regulatory milestones for CDS implementation stimulate uptake, but could backfire if clinicians do not see the value, or if there proves to be little value in the specific CDS uses. Clinicians cite the need to customize CDS to accommodate their workflows, the constant maintenance required for CDS resources, and the costs associated with customization and maintenance as barriers to implementation. Finally, large provider organizations may have the means to build their own CDS resources, but that approach may not be practical for smaller practices.

Lack of Awareness about Benefits and Focus on Regulation Rather Than Quality Improvement

Stakeholder discussants and many literature review sources cite the Medicare and Medicaid EHR Incentive Programs and corresponding EHR certification criteria as drivers of CDS development and use. They state that the use of CDS to accompany quality measurement requirements from various sources is a natural tie-in and beneficial to clinicians. However, sources note that many clinicians, particularly those in small practices, see CDS as solely a requirement of the incentive programs, and not as a tool to help them improve quality of care. They suggest that for the necessary steps toward effective CDS sharing to occur, clinicians must see the value of CDS and demand it from EHR developers. Given numerous priorities competing for clinicians' attention, they will not demand high quality CDS unless they believe it can help them improve quality of care. In the end, sources agree that regulatory requirements have pushed the envelope in promoting progress, and recognize that without them, there would be less CDS uptake and use. There is a need to convey to clinicians the clear benefits of CDS for managing patient care and improving health outcomes.

User Workflow and Local Customization

Fit to user workflow

Integrating CDS into organizations' workflows is one of the primary concerns of CDS users. Sources note that all new CDS interventions will need to be coordinated at the appropriate points in the workflows of local clinicians. Ideally, workflow considerations are part of the development of the resource itself. A description of the intended insertion into the workflow may be a key piece of metadata for clinicians to

determine the usefulness of a resource. CDS resources that are not present at the point of decision are much less likely to be used by clinicians. Once clinicians are in the exam room or at the bedside, they are already in the process of making diagnostic and treatment decisions. If a CDS resource is not available at that time, the opportunity to positively influence clinician decision-making is likely lost.

Local customization required

Balancing the need for standardization is the equally important need for local customization of CDS resources. Users find that CDS created centrally cannot simply be disseminated and implemented in a plug-and-play manner, and must be adapted to fit the unique workflow and needs driven by the patient population of each practice or facility. Customization is complicated by technical and organizational challenges. There are currently no common methods for tracking and learning from modifications that providers make to CDS developed by other entities. While customizations within a hospital can be tracked by system administrators, that information may not be available to the CDS developer. Customization may affect how the CDS is presented on the screen across multiple devices, whether alerts or downloads are available in different settings, and how the programs check for possible human errors. The way CDS is customized may affect the outcomes of its use and make it harder to compare experience with CDS resources across users.

High Cost

Clinicians often cite the high cost of obtaining and applying CDS resources. The process of production is costly, which flows down to the user and decreases demand for CDS resources. In addition, users face the costs of customizing and maintaining the currency of their CDS systems, which is often technically complex and resource intensive. Smaller organizations that may not have the resources that larger organizations invest in CDS are particularly affected by the lack of low cost options. Where lower cost, pre-packaged solutions are available, they tend to be limited to the simplest CDS resources, such as drug-drug interaction alerts. Sources from larger organizations indicate that they are buying CDS resources from content developers, where available and affordable, but they are still making significant investments in building CDS resources on their own.

CDS Infrastructure Issues

In addition to barriers to producing and using CDS, some infrastructure needs persist across stakeholders. Stakeholder discussions and literature sources note the need for feedback loops among every function of producing, sharing, and using CDS resources. Both information streams emphasize the importance of feedback from clinicians to CDS developers and also of ensuring that feedback mechanisms efficiently capture reliable, actionable information. To enhance sharing and uptake of CDS resources, factors that contribute to the validity and reliability of resources from the clinician perspective must be considered and addressed. Stakeholders also note legal challenges in producing and using CDS resources, particularly due to a lack of well-developed case law.

Feedback Loops for a Continuously Learning System

Quality measures are an important part of a learning health system, but quality measures alone cannot fully assess efficacy of CDS due to many variables and unknowns. The lack of comprehensive feedback loops for CDS results in loss of learning about the experience of those who are using CDS resources, which could otherwise save time and cost. In addition, feedback mechanisms would improve the quality

of the resources by providing information to producers about unintended effects and whether the resources are helping to improve quality. Further, the lack of feedback interferes with communication of CDS user needs to resource producers. Sources call for feedback loops within and beyond their organizations.

Sources at large, sophisticated organizations criticize the lack of feedback loops to evaluate and improve use of CDS within their organizations. They cite a need to understand the information that providers find to be a valuable “signal” rather than a burdensome “noise.” For example, many stakeholders cite alert fatigue due to a lack of structures to collect user feedback and implement changes in CDS triggers. Clinicians who cannot turn off CDS alerts they find useless ignore those alerts and also other alerts within the system. Some sources note that non-interruptive CDS that enables active engagement, such as a standard order set, may be more valuable than interruptive alerts. CDS systems should include internal feedback loops to prioritize useful resources and silence noise.

Processes to Ensure Integrity

Concerns about integrity and the need to build trust in CDS resources affect all stakeholders. Changing clinical evidence and practice guidelines are sources of uncertainty. CDS resources must be regularly, if not continuously, updated. The CDS translation and integration processes require a significant amount of judgment, and individual clinicians and their organizations must be confident in the results of those processes. CDS developers note that government or medical specialty society endorsement of a clinical guideline gives it the backing needed to be accepted as legitimate. Sources in the literature also note the value of peer-review processes and crowdsourcing to promote clinician acceptance of CDS resources. However, direct provider involvement in vetting CDS resources remains the primary mechanism for ensuring integrity. Proven validity encourages use of CDS, but lack of proven validity or reliability lead to mistrust and decreased use.

Metadata

To decrease uncertainty for CDS users, sources note the importance of metadata for providing transparency to clinicians about the validity and reliability of CDS resources. Metadata can include the identity of the producer, source of underlying guidelines and evidence, validity and reliability testing, and methods for maintaining currency. The Health eDecisions use cases^{1,2} thoroughly examine various pieces of metadata that should be included with an artifact, as well as a standardized structure for packaging the information. Existing Draft Standards for Trial Use (DSTU), including FHIR, have created a “rule summary” that encompasses some metadata, although not all of the fields that Health eDecisions suggests. Sources also note that metadata is useful in promoting sharing across organizations. Providers often find it difficult to use CDS resources developed by providers at other organizations because CDS resources have built-in assumptions that are based on the institution in which they are authored, which could be made explicit in metadata.

1

http://wiki.siframework.org/file/view/SIFramework_HeD_UC1_CDSArtifactSharing_v1.0.docx/371583300/SIFramework_HeD_UC1_CDSArtifactSharing_v1.0.docx

2

http://wiki.siframework.org/file/view/SIFramework_HeD_UC2_CDSGuidanceService_v1.0.docx/420514032/SIFramework_HeD_UC2_CDSGuidanceService_v1.0.docx

Legal Clarity

Untested legal questions regarding intellectual property, liability, and data security impede CDS sharing. The proprietary nature of CDS production raises concerns regarding intellectual property. CDS producers and users want assurance that they will not be held liable if a CDS resource is found to be the reason for a poor patient outcome. Data security is a necessary yet expensive and time-consuming precaution that inhibits sharing. The lack of shared understanding around legal concerns results in reinventing solutions for similar transactions. However, stakeholder discussants were virtually unanimous in stating that legal issues are less of a barrier to the adoption of CDS resources than other factors.

Intellectual property

CDS producers are interested in protecting their intellectual property, but the proprietary nature of CDS resources that are embedded in EHRs is a barrier to sharing. Large provider organizations note that when they want to share their homegrown CDS solutions, there are often also significant legal hurdles to ensure that the intellectual property of the authoring institution is not at risk. Literature review sources point to previous work, such as the CDS Consortium, which imposed mandatory, legally binding agreements for CDS producers, sharers, and users that address how information can be shared and distributed, and how ownership of each resource is determined.

Liability

Both producers and users of CDS resources fear legal liability resulting from inaccurate, malfunctioning, or incorrectly used CDS. However, the specter of liability may be as much a myth as reality. Clinicians are ultimately responsible for their care decisions, whether informed by CDS or not. In addition, few literature review sources cite cases of harm from use of CDS. Nonetheless, the issue persists largely due to lack of legal test cases.

Data security

Stakeholder discussions and literature review sources agree that structures and processes for data security are necessary for the building, use, maintenance, and sharing of CDS resources. However, this requires significant expense and time-consuming precautions that inhibit sharing. HIPAA requirements for data security and the way patient information is stored in the cloud may be an issue for “CDS as a service” models.

Facilitators of CDS Sharing

Addressing the barriers outlined in this report will enable CDS resource sharing. In addition, the stakeholder discussants and literature review sources point out roles that the federal government could play in facilitating CDS development, sharing, and use.

Federal Government Role

Many sources believe that the federal government, and ONC in particular, should play a leadership role in stimulating CDS sharing. However, sources differ in their views of precisely what roles government should play, resulting in many different perspectives rather than consensus patterns. Some believe federal agencies should rely on their regulatory authority. Others preferred that the government sponsor convening activities to lay out a vision for the future, without mandating that businesses follow a specific path to achieve a desired future state. Virtually all discussants agree that it would be helpful for the federal government to create a public repository of interoperable, open source CDS resources.

Federal government as convener

Many sources believe that the ONC should serve as a convener of CDS stakeholders from the public and private sectors. Stakeholder discussants mentioned HIMSS, AMIA, and NQF as potential convening co-sponsors with ONC. In particular, discussants noted the opportunity to bring EHR developers and CDS content developers together to open up the possibility of real interoperability where third-party application developers create innovative CDS products that run on top of the large developers' EHR systems.

Federal government as regulator

While a few discussants preferred that the federal government play only a convening or facilitating role to help foster a healthy CDS market, the majority of discussants, including several representing private businesses, believe that government should go further. They noted the large uptake of health IT among providers in the past few years would not have happened without the meaningful use incentive programs and EHR certification regulations. In their view, government regulation is also required to move forward on CDS resource sharing.

In particular, some discussants indicated that government should play a larger role in encouraging data liquidity. Government could require that data be more easily exportable from and importable into EHRs, as a condition of certification. Further, EHRs should have open application programming interfaces (APIs) that allow third party developers to create innovative solutions that run on top of large enterprise EHRs. One discussant commented that to unlock data, "government needs to move beyond piloting to codifying."

Federal government role in creating a national repository

Discussants were virtually universal in their support for government taking the lead in creating and maintaining a national repository of CDS resources. They see government playing several roles regarding a national repository. First, discussants believe that government should produce CDS content, although not exclusively. Federal government agencies such as AHRQ and CDC that are already creating guidelines should also translate their guidelines so that they are consumable by providers' EHRs, and then make those translations available through a public repository.

Second, in creating a national repository, government would need to take the lead in coordinating policies for artifacts stored in the repository and processes for updating and validating them. Some discussants felt government should mandate standards for CDS resources stored in the repository. Others felt government should merely suggest what standards ought to be followed to avoid stifling innovation. Regardless, an open source national repository would stimulate private sector use of and possibly contribution to shared CDS resources. One discussant suggested that validation of materials in the public repository could be crowdsourced through a Yelp-like user rating system. While some private sector CDS-developers might see a public-sector repository as a threat, stakeholder discussants commented that they see government entering the market as a producer of high-quality CDS resources – especially generally applicable knowledge bases and trustworthy translations of clinical guidelines into knowledge artifacts – as priming the pump for a more efficient market for CDS resources and providing CDS developers an opportunity to offer more and better products to their customers.

CDS Resource Sharing Market

To illustrate current state barriers and preferred state opportunities for stimulating sharing CDS resources, particularly knowledge artifacts, Discern developed this market description. The CDS market is similar to other markets in that it requires regular and balanced contributions of supply and demand in terms of CDS production and use. Through the inherent features of market exchange, the best products rise to the top based on economic transactions and feedback loops between producers and users.

The CDS market can be divided into five functions. In addition, feedback loops affect each function of the market.

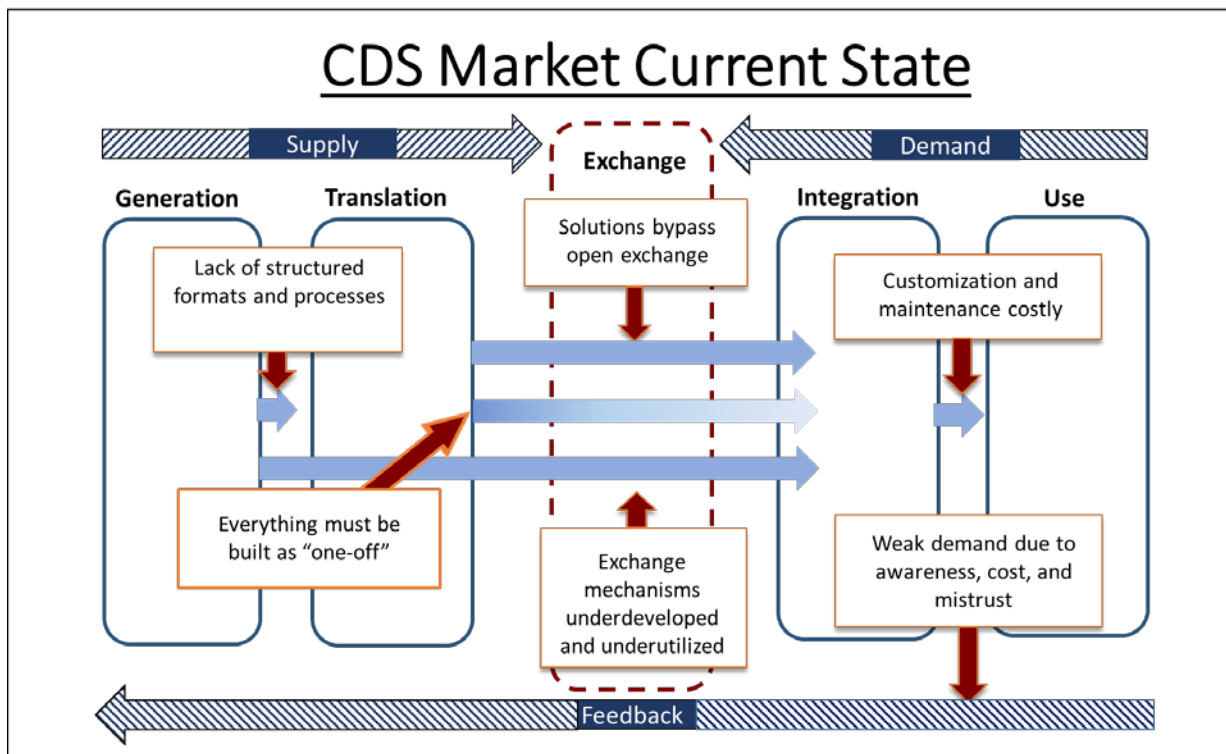
- **Generation:** Clinical guidelines and other knowledge created by professional societies, researchers, or other organizations
- **Translation:** Knowledge artifacts produced in structured format, usually by EHR or CDS developers
- **Exchange:** Artifacts made available in structured format for sharing, affecting all stakeholders
- **Integration:** Artifacts retrieved and customized for EHR/CDS system, usually by provider systems or health IT developers
- **Use:** Artifacts used in practice, by practitioners and sometimes patients

Each function of the market involves various stakeholder types, and the categories are not necessarily mutually exclusive. For example, professional societies, researchers, federal agencies, or other organizations may be involved in both knowledge generation and its translation into interoperable CDS resources; a large provider system may be involved in translating knowledge into interoperable artifacts, in addition to integrating and using them in CDS applications.

Current State Market

Through our stakeholder discussions and literature review, it is clear that the current state of CDS resource sharing is not optimal. Figure 4 illustrates the current state of the CDS market and identifies specific challenges that are discussed after the illustration.

Figure 4: Current State of the CDS Market



Lack of structured formats and processes

Challenges with CDS resource sharing begin when producers attempt to translate clinical practice guidelines or other clinical knowledge into computable artifacts. Producers are often frustrated by lack of defined, reliable, and repeatable processes and formats for supporting translation. Currently, there is no standardized approach for turning guidelines into artifacts, which leads to inefficiency and inconsistent products. Barriers to translation affect supply of CDS resources, which affects the ability to share and ultimately use them.

Everything must be built as “one-off”

The lack of standardized methods or best practices for producing CDS resources means that each development effort is typically unique. Technical barriers to interoperability and intellectual property issues of proprietary solutions constrain sharing and reuse of CDS resources among organizations. As a result, CDS resources are usually intended for only one organization or system, despite overlapping needs across users.

Solutions bypass open exchange; Exchange mechanisms underdeveloped and underused

Because CDS resources are produced for specific organizations or systems, there is little to no supply for a central library or open market of resources. At the same time, the lack of supply and market compels

organizations that would rather buy a high-quality product off the shelf to build their own, often at great expense.

Since the majority of CDS resources thus bypass exchange, both the supply and demand sides are underdeveloped. If a vibrant market existed, the quality of CDS resources would benefit from feedback about user experience, thereby increasing trust and demand. Currently, the CDS resource market faces a “chicken or egg” problem, in that the exchange and reuse of resources will likely remain underused until the market is further developed, and vice versa.

Customization and maintenance costly

Stakeholders involved in CDS resource integration and use experience challenges on the demand side of the market. While standardization is efficient for CDS production, it is also important that producers consider the local needs and unique workflows of organizations implementing CDS resources. Since every provider site has particular needs and different EHR/CDS systems, implementation of CDS requires thoughtful integration that will work for providers at the point of care. Customization to fit providers’ workflows is costly but is a necessary, and potentially ongoing, expense.

Once a CDS resource has been implemented, it requires regular monitoring and maintenance. CDS users criticize the lack of feedback loops to evaluate and improve the user interface and experience of use. In addition, the clinical evidence and guidelines from which CDS resources are derived often change. CDS implementations that are locally built are more resource-intensive to maintain than solutions based in the cloud that can be revised and automatically updated for multiple users at one time, unless they involve clinician workflow changes. Regardless of the model, updating and revising existing resources is costly for producers and users.

Weak demand due to awareness, cost, and mistrust

Demand for CDS resources is weakened by various factors, including lack of awareness of benefits, high cost, and uncertainty. Stakeholders note that small providers in particular see CDS primarily as a requirement of the Medicare and Medicaid EHR Incentive Programs, not as a tool to help them improve quality of care. Building awareness is difficult given many competing priorities for clinicians’ attention, and there has not been an obvious national champion touting the benefits of CDS.

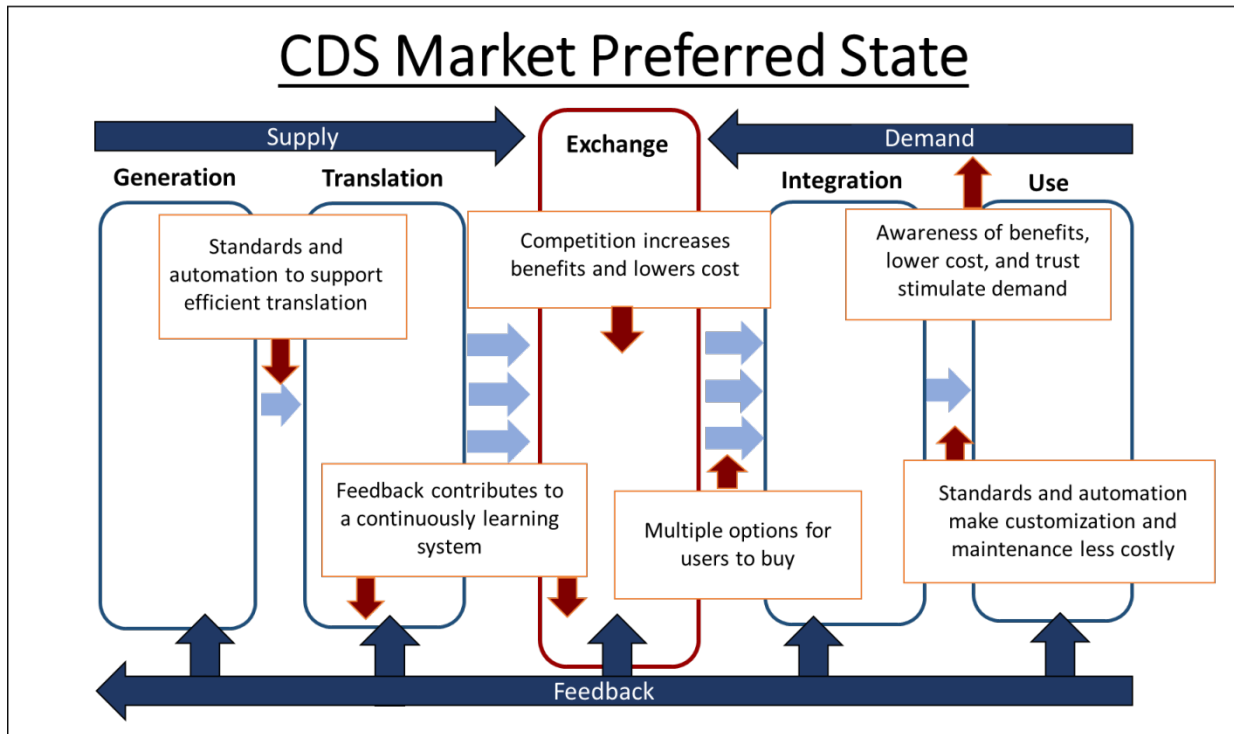
The high cost of CDS adoption and maintenance is a significant barrier that impacts demand, particularly for smaller providers. In addition to the cost of customization, high price tags may be due in part to the high barriers to entry and inefficiency in production, creating costs that producers pass along to users. As a result, CDS resources are less affordable to providers, decreasing demand.

Stakeholders and researchers also note that uncertainty regarding the validity and reliability of CDS resources is a major factor influencing demand. The translation and integration processes require a significant amount of judgment, and providers must be confident in the outputs of these processes. Providers tend to be skeptical of resources developed by others outside of their own organizations because they often contain built-in assumptions specific to the authoring organization. Currently, direct provider involvement in vetting CDS resources is the primary mechanism for ensuring integrity, which is costly and takes time away from direct patient care.

Preferred State: Robust Open Market

The preferred state of the CDS market conveys how an effective market can work when barriers are addressed. Figure 5 illustrates the preferred state and highlights opportunities that are discussed after the illustration.

Figure 5: Preferred State for the CDS Market: Robust Open Market



Standards and automation to support efficient translation

Standards for creation, sharing, and maintenance of CDS resources are needed for an efficient market. Although some standards are emerging, such as Health eDecisions and CQL for knowledge artifacts and FHIR profiles based on the Quality Information and Clinical Knowledge model for interoperable reference to clinical quality data, these are not yet completely developed, thorough, or used to the degree necessary to fully support CDS production. In the preferred state, generally accepted standards will be in place to identify needed data elements and express clinical logic uniformly so that artifacts can be shared and readily implemented across organizations. The preferred state also includes tools for CDS resource production that are capable of more efficiently translating clinical evidence into computable knowledge artifacts, including automated tools to format and test logic expressions against clinical intent.

Competition increases benefits and lowers cost; Multiple options for users to buy

In the preferred state, the CDS market is vibrant and the exchange function is extensively accessed by resource producers and users. Stakeholders involved in CDS resource production and use look to the open market as a primary way of sharing their CDS needs and products. Competition is an inherent

advantage of multiple options, and competition typically increases quality and lowers cost. Users can compare options to assess products on their effectiveness, levels of effort to implement, presentation interfaces, and prices to determine which CDS resources best suit their needs.

Standards and automation make customization and maintenance less costly

Standards and automation are needed for users, as well as producers, to decrease the cost of customization and maintenance of CDS resources. Implementing standards on the supply side also has advantages on the demand side for more efficient integration, use, and sharing across multiple users. Technical issues that influence the demand side of CDS sharing include standards for capturing and displaying data; modular, open-source formats to facilitate application across platforms; cloud-based connectivity; and the structure and content of relevant metadata. However, it is still important to recognize that virtually all CDS solutions will need to be customized to some extent to meet local needs and fit unique workflows.

Awareness of benefits, lower cost, and trust stimulate demand

Both our stakeholder discussions and literature review point out the need for a governmental entity, such as Health and Human Services (HHS), to take the lead on stimulating the market for CDS resources and making users aware of the benefits of CDS. In the preferred state, users view CDS as an essential quality improvement tool. When providers value CDS and invest in it, increased demand will stimulate supply and competition, leading to higher quality and lower cost CDS resources. The preferred state also assumes that mechanisms for evaluating the validity and reliability of CDS resources and legal guidelines are in place to decrease uncertainty, building trust and furthering use of CDS. Support for a CDS resource from a trusted government agency or medical specialty society tends to promote clinician trust in the resource.

Feedback contributes to a continuously learning system

The preferred state market includes feedback loops from CDS users to every other function. Understanding the users' experience allows producers and other users to learn how to make CDS resources more useful for meeting important needs. In addition, providers need feedback loops within their own systems so that the systems can learn to better tailor CDS to clinicians' practices and decrease alert fatigue.

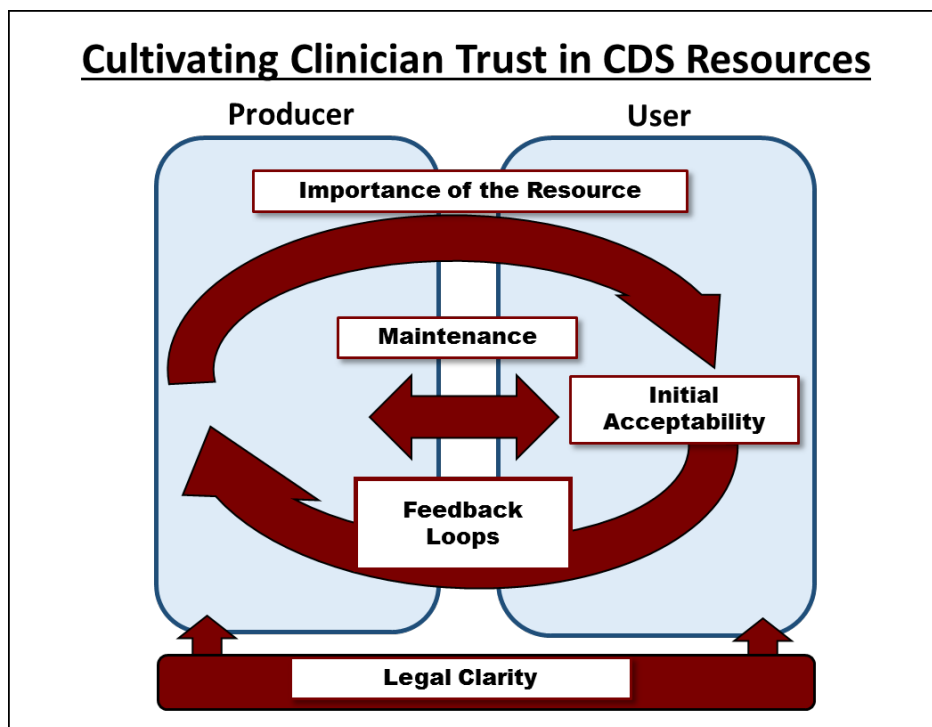
Conceptual Model for Cultivating Clinician Trust in CDS Resources

As noted above, there are various reasons that a robust market for CDS resources has not emerged. Our findings indicate that clinician trust in the processes for translating underlying knowledge into CDS resources, integrating resources into systems, and maintaining resources over time is necessary for a vibrant market. Based on our stakeholder discussions and literature review, Discern has identified five essential elements for instilling clinician confidence in CDS resources.

The essential elements of the conceptual model for cultivating clinician trust in CDS resources include:

- **Importance of the resource**- Assurance that clinicians have the CDS resources they need to address critical quality issues
- **Initial acceptability**- Assurance that CDS resources are valid, reliable, and relevant
- **Maintenance**- Assurance that CDS resources remain acceptable over time, in accordance with the evolving evidence
- **Feedback loops**- Assurance that we are learning about CDS resources and their contribution to quality of care over time
- **Legal clarity**- Assurance that users and producers of CDS resources will not suffer legal consequences for good faith actions

Figure 6: Trust Conceptual Model



Importance of the Resource

Clinicians must believe that CDS resources offer tangible value in terms of information they can act on to help them deliver higher quality care. Too many clinicians, particularly those in small practices, do not appreciate or are not aware of the value of CDS. What they currently experience that they can identify as CDS is often limited to a set of alerts that they experience as a nuisance. This leaves them adopting CDS resources grudgingly, only to comply with meaningful use requirements. Awareness of the full range of CDS types and their benefits – especially of non-interruptive, workflow-supporting presentation of the right information at the right time to the right person in the right format to improve care – would stimulate clinician trust and demand for CDS functionalities.

Initial Acceptability

To be confident adopting CDS resources, particularly resources developed by outside organizations, clinicians must be able to assess the validity and reliability of the resource and its relevance to the unique needs of their practices. First, criteria are needed for determining validity, reliability, and relevance of CDS resources. This includes criteria for assessing the characteristics of a resource, such as the qualifications of the content developer, the underlying clinical evidence used in development, the quality of the translation of that evidence into a computable format, testing that the resource has undergone, whether users have reviewed the product, and the relevance of a CDS resource for a particular clinician's needs. In addition, processes are needed to test, review, and/or certify against the criteria. Certification processes could be done formally through a certifying body or through less formal processes, such as crowdsourcing or producer attestation. Currently, information about the characteristics and processes important for determining initial acceptability of CDS resources is not readily available. This is one of the reasons that large organizations often opt to make large investments in building their own one-off resources, rather than buying them from outside CDS developers.

Maintenance

When clinicians are deciding whether to use a CDS resource, they need to know what processes the steward has in place to keep the resource fresh. A CDS resource that is valid and reliable at inception will not continue to be acceptable unless it is regularly updated based on the latest clinical evidence. Today, the roles of stewards and systems for stewardship of CDS resources are not well developed. Even large provider organizations find maintaining freshness of CDS resources challenging and costly.

Feedback Loops

Feedback loops are essential for a continuously learning health system. Clinicians want assurance that CDS resource developers are monitoring their products for unintended undesirable effects and for opportunities to improve their products. Clinicians ultimately want to know that use of CDS resources is moving the needle on improving quality of care. However, it is important to note that while quality measures are useful directional indicators of the effectiveness of CDS, many factors contribute to quality measurement. Thus, neither improvement nor lack of improvement on a particular quality measure is determinative of the value of a CDS resource. In addition, clinicians want feedback loops that allow CDS resources to learn their practice patterns and preferences over time to reduce repetitive nuisance alerts.

Legal Clarity

Enhanced clarity on several legal issues related to the production and use of CDS resources would increase both the supply of and the demand for resources. Clinicians are concerned about liability associated with relying on, or not complying with, care recommendations offered by CDS resources. They are also concerned that allowing cloud-based CDS systems access to confidential patient information could breach HIPAA requirements to protect patient privacy. The producers of CDS resources are concerned about protecting their intellectual property and about liability for harm that may be caused by their products. In addition, a lack of understanding about the implications of FDA's proposed risk-based regulatory framework for health IT³ for potential future treatment of CDS resources adds uncertainty to the business environment for CDS producers.

³ See US Food and Drug Administration, "FDASIA Health IT Report: Proposed Strategy for a Risk-Based Framework," April 2014, available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>.

Recommendations for Next Steps: Cultivating Clinician Trust in CDS Resources

A significant barrier to widespread adoption of CDS is the challenge clinicians face in evaluating the validity, reliability, relevance, and freshness of CDS resources developed outside their organizations. As an advocate for clinician use of health IT including CDS, ONC/OCQS is well positioned to sponsor a set of activities to clarify the challenges and identify solutions for cultivating clinician trust in CDS resources. Collaboration with AHRQ's health IT portfolio would be important to ensure synergy and optimize impact across HHS efforts to promote advancement of CDS availability and use to disseminate new clinical knowledge such as patient-centered outcomes research findings. To extend the breadth of engagement or to enhance credibility of this effort across all key stakeholders, ONC may want to consider partnering with the National Academy of Medicine/Institute of Medicine (IOM), National Quality Forum (NQF), or AMIA.

The goal of this set of recommended activities is to create voluntary practical guidance for the CDS developer community, so that developers are better able to build resources that clinicians will trust and use. Guidance materials would include a framework of characteristics (e.g., source and strength of the underlying evidence, maintenance schedule) and processes (e.g., testing methods, certification) for producing trusted CDS resources. As part of the process for developing the guidance materials, stakeholders in the CDS ecosystem should be given a variety of opportunities to provide input through virtual and in-person meetings, and possibly a public comment period on a request for information or other appropriate material such as a preliminary draft of the voluntary guidance.

Discern believes that the conditions are right for a conversation among CDS stakeholders that will lead to the identification of guidance for CDS developers. Both public and private payers are moving from paying for volume to paying for value, and clinicians need support for quality improvement to succeed in the value-based environment. The Medicare and Medicaid EHR Incentive Programs have achieved a critical mass of clinicians using EHRs that support use of CDS for quality improvement. Previous federally sponsored initiatives for promoting CDS and advances in technical standards have expanded the potential for development and delivery of more sophisticated, and more sharable, CDS that supports improvement on performance targets for value-based payment incentives. These developments are motivating clinicians who may have been skeptical about using CDS in the past to consider effective use of CDS resources in their practices.

The larger goal of producing voluntary practical guidance for CDS developers to accelerate the availability of trusted, interoperable CDS resources that support clinical quality improvement can be broken down into four objectives:

- Objective 1: Introduce and verify with stakeholders the Conceptual Model for Cultivating Clinician Trust in CDS Resources
- Objective 2: Determine critical information for decreasing uncertainty in adopting CDS resources
- Objective 3: Determine methods for assessing acceptability of CDS resources
- Objective 4: Determine next steps for stakeholders for cultivating clinician trust in CDS resources

This section presents a set of activities to achieve these objectives through stakeholder engagement, including circulating a white paper, holding an in-person meeting, and producing a report and an issue brief containing guidance for CDS developers.

Laying the Groundwork for Creating Guidance for CDS Developers

Discern recommends that OCQS distribute a white paper to stakeholders to notify the community of its intentions to create voluntary guidance for CDS developers. The white paper will serve as background for a real-time interaction of participating stakeholders, such as an in-person or web meeting giving participants opportunity to interact with one another as well as presentation materials in real time. If OCQS desires broader input, the white paper could also serve as the basis for obtaining public comments through a request for information or other appropriate process.

In anticipation of the real-time interaction amongst a select group of stakeholders that would inform OCQS/partner entity or support contractors' development of content for voluntary practical guidance, Discern also recommends preparatory activities to introduce the meeting participants to the trust conceptual model and orient them to the objectives of the meeting. The preparatory activities include an exercise and a pre-call. These activities will set context, gather knowledge from the participants, raise questions that will be addressed, and present desired outcomes for the meeting. Thorough preparation will allow attendees to move more quickly into addressing the meeting's key objectives, maximizing use of the real-time interaction. If feasible within budget and other applicable constraints, Discern would recommend at least a significant and focused period of real-time interaction among stakeholders occur in person. In-person interaction is a feature of effective multi-stakeholder collaborations such as NQF-convened partnerships and consensus projects, or IOM's Roundtable on Value and Science-Driven Health Care Innovation Collaboratives. Thus, the remainder of this recommendation describes the real-time interaction as an in-person meeting. However, recognizing this may not be feasible, the recommendation would be to adapt specific details of the recommended activities to fit with alternative modes of interaction.

White Paper

The white paper will present a conceptual model for cultivating trust in CDS, supported by findings from the literature and stakeholder views on issues related to uncertainty and clinician trust in CDS resources. In addition, the white paper will offer background and ideas tied to each of the objectives of the meeting to stimulate participant reaction. Specifically, the white paper will inform conversation regarding the meeting's second objective by describing the gaps in information about the characteristics of CDS resources that make it difficult for clinicians to evaluate the validity, reliability, relevance, and freshness of resources produced outside their organizations. To inform discussion regarding the third objective, the white paper will also describe the alternative vetting processes currently being used by organizations to validate CDS resources. Finally, the white paper will include draft guidance materials for CDS developers to elicit reaction from the stakeholder community.

Preparatory Exercise for In-Person Meeting

Meeting invitees will be given the opportunity to share their thinking about the essential characteristics and vetting processes necessary for clinician trust in CDS resources. This material will be compiled and summarized prior to the pre-meeting conference call, to support robust discussion and inform refinement of plans and materials for the in-person meeting.

Pre-Call for In-Person Meeting

A preparatory conference call will be held in advance of the in-person meeting to orient participants to the context and objectives of the meeting (see Objective 1 below).

Objectives and Issues to Consider in Creating Guidance for CDS Developers

To gather input on the four objectives and inform the report on guidance for CDS developers, Discern recommends an in-person meeting of national thought leaders representing various stakeholder interests and expertise.

Objective 1: Introduce the Conceptual Model for Cultivating Clinician Trust in CDS Resources

The first objective is to introduce the meeting participants to the conceptual model for cultivating clinician trust in CDS resources and obtain their reactions. The model and its components will be described in relation to key aspects of ONC's strategic vision as described in the *Federal Health IT Strategic Plan, Health IT Enabled Quality Improvement: A Vision for Better Health and Health Care*, and the shared national vision as described in *Connecting Health and Care for the Nation: a Shared Nationwide Interoperability Roadmap*.

The conceptual model will be introduced to the meeting participants via conference call prior to the in-person meeting. The call will also address scope and assumptions for the meeting and provide additional context for objectives 2 and 3. A summary of the pre-call discussion will be presented at the beginning of the in-person meeting.

Discussion Questions

- Does the conceptual model capture all of the critical elements required for clinicians to evaluate and trust CDS resources?
- Of the elements described, in what order should they be addressed?

Objective 2: Determine Critical Information for Decreasing Uncertainty in Adopting CDS Resources

The second objective for the meeting is to determine the critical information clinicians need to decrease uncertainty and promote adoption of CDS resources. Specifically, the group will explore the validity, reliability, relevance, and freshness of CDS resources. Validity is the accurate translation of underlying clinical evidence and/or best practice guidelines into computable representation. Reliability is whether CDS resources perform consistently over time. Determining validity and reliability requires an initial evaluation, but also processes to refresh, or update and re-evaluate resources, when new evidence emerges. Relevance is the extent to which CDS resources meet clinician needs, which includes the ability to integrate CDS into local workflows and customize it to minimize nuisance alerts.

Discussion Questions

- What information do clinicians need about the underlying evidence, practice guidelines, or alternative sources of clinical logic?

- What do clinicians need to know about the stewardship of the underlying clinical logic, and the stewards' processes for updating resources based on changing evidence?
- What do clinicians need to know about the translation of clinical knowledge into structured and computable representations?
- How can we assess whether clinicians have adequate information to judge the validity and reliability of CDS resources?
- What information do clinicians need about the assumptions that are built into CDS resources because of their development by providers in organizations with unique characteristics?
- What do clinicians need to know about how a CDS resource determines what information is relevant to deliver during a clinical encounter?
- How should CDS resources be customized to a particular clinician's needs? How can resources learn the unique circumstances of a clinician's practice so that it will provide the clinician with high-value information, as opposed to nuisance alerts?
- How can the information needed to decrease uncertainty be translated into metadata that travels with CDS resources to provide transparency about validity and reliability?
- How do the information needs about CDS resources vary between clinicians making decisions about incorporating CDS resources into their EHRs and CDS service providers determining whether to add resources to their platforms?
- Are there specific metadata elements that were not included in the Health eDecisions Knowledge Artifact standard that clinicians need to assess the validity and reliability of CDS resources? If so, which metadata elements should be prioritized for development?

Objective 3: Determine Methods for Assessing Acceptability of CDS Resources

The third objective of the meeting is to determine the strengths and weaknesses of alternative methods for assessing the validity, reliability, relevance, and freshness of CDS resources. For various types of resources, processes could include testing, review, and/or certification or endorsement. The meeting participants will also consider the roles of various entities in establishing and maintaining those processes.

Discussion Questions

- What are examples of emerging approaches to assuring validity, reliability, relevance, and freshness of CDS resources?
- What processes are large provider organizations (e.g., VA, Kaiser) that produce CDS resources centrally and then diffuse them within their systems using? What processes are medical specialty societies (e.g., ACC) using?
- Would testing, review, and/or certification or endorsement by widely trusted entities, such as ONC-authorized certification bodies or voluntary consensus bodies, be helpful?
- What role should government play in validating CDS resources? Should government adopt criteria for validating CDS resources it creates? Should government be involved in validating CDS resources created outside government?
- What role should professional societies play in validating CDS resources?
- What role should local vetting or crowdsourcing (e.g., Yelp-like websites) play in validating CDS resources?
- What processes are intermediaries, such as CDS and EHR developers, using to assess the validity and reliability of CDS resources before providing them to small practice customers? How do these methods for establishing validity and reliability of CDS resources differ from the processes

used by large practices? Are there particular needs of small practices that need to be addressed separately from the needs of providers who are part of larger practices?

- What processes should be adopted to assure timely updating of CDS resources based on evolving clinical evidence?
- What level of formality is needed in the methods for determining the validity, reliability, and relevance of CDS resources?

Objective 4: Determine Next Steps for Stakeholders for Cultivating Clinician Trust in CDS Resources

The fourth objective for the meeting is to identify key learning and next steps that stakeholders can take to cultivate clinician trust in CDS resources. This objective would be partially addressed during an agenda item at the close of the in-person meeting, but the majority of the discussion and conclusions would occur during post-meeting interaction with and discussion among the stakeholder participants.

Developing and Disseminating Guidance for CDS Developers

To build on the momentum from the series of activities and maximize impact, Discern recommends developing a report and an issue brief that include guidance materials for CDS developers as well as recommendations for next steps and potential related activities.

Post-Meeting Conference Call(s) or Similar Interactive Activities

The purpose of the post-meeting call(s) will be to solidify key learning from the meeting, obtain buy-in from the participants regarding solutions, and identify next steps for various stakeholders.

Report and Issue Brief

A report will be prepared that captures the learning from the full series of activities. The report will present voluntary guidance for CDS developers and the rationale behind the guidance. In addition, an issue brief intended for broader dissemination will be prepared. The issue brief will present the conclusions from the series of activities in a manner that is accessible to a larger audience.

Potential Related Activities

The following activities that are also important to cultivating clinician trust in CDS resources should be considered. First, there are a number of legal issues that could be addressed through a parallel set of activities. The objective would be to identify best practices to address legal impediments to CDS resource sharing such as intellectual property and liability concerns. Learning from the parallel activities would be mutually reinforcing.

Another set of issues that could be explored is the broader motivations for CDS resource sharing and use by clinicians. Beyond challenges with assessing the validity and reliability of CDS resources, many providers are not taking maximum advantage of what CDS has to offer because they see CDS as a requirement of federal regulations with which they must comply, as opposed to a tool that can help them improve the quality of care they deliver. The overall objective for this work would be determining how to best demonstrate the value of CDS resources to clinicians. Again, learning from the related activities would be mutually reinforcing, as all relate to effectively communicating information about the value of CDS resources to clinicians.

Conclusion

Increasing clinician trust in CDS resources will have significant impact on the development, sharing, and use of CDS. The findings of this project revealed that one of the primary impediments to the availability of CDS resources is a lack of demand from clinicians as end users, and uncertainty about the trustworthiness and value of CDS decreases demand. Clarifying the value of CDS for clinicians will increase demand and providing guidance for CDS developers will enhance the supply of trustworthy, interoperable resources, which will stimulate a robust market for high-quality CDS resources.

Appendix A

Clinical Decision Support Resource Sharing Stakeholder Discussions Synthesis and Methodology

Introduction

As part of the CDS resource sharing project, Discern Health has conducted informal conversations with stakeholders to inform the findings for the report. We completed discussions with more than 15 informants, though the topics and focus varied across stakeholder groups and it should be recognized that methodology was not designed or implemented to gather the same information across all discussants. To the extent stakeholders within a given group, as identified below, provided similar information or expressed views in alignment with one another, the sample sizes were small (<10) in all groups and the findings should be interpreted with this in mind. This document provides a synthesis of findings from the discussions.

In collaboration with the ONC team, the Discern team first developed criteria for selecting discussants. We identified the following stakeholder groups as the most relevant to resource sharing across the CDS ecosystem:

- Health IT Developers, including EHR and CDS content developers
- Providers
- Researchers
- Federal Health Agencies
- Implementation Support

Second, we selected individual discussants to represent each of these stakeholder groups based on the following criteria (see table below):

- Affiliation with a prominent organization in a given stakeholder community
- Participation in ONC-sponsored projects
- Authoring significant publications about CDS
- ONC team's recommendations
- Recommendations from other discussants

Third, in collaboration with the ONC team, we developed a discussion support document for our conversations, to ensure that we were transparent about our key questions while remaining flexible (see Addendum: Stakeholder Discussion Support Document). Finally, we conducted the conversations with stakeholders via teleconference, reviewed our notes from each discussion, and prepared the summary below.

Table. Stakeholder Discussants

Stakeholder Role		Names	Affiliation
Health IT Developers	EHRs	Richard Loomis	Practice Fusion
	Knowledge Bases & CDS Delivery Mechanisms	Adam Wright	Partners HealthCare
		Nate Weiner	Avhana
		Jonathan Teich	Elsevier
		Victor Lee	Zynx Health
		Paul Magelli	Apervita
Providers		Blackford Middleton	Vanderbilt
		Various	American College of Cardiology (ACC)
		Various	ONC Health IT Fellows
		Scott Young, Bill Marsh, Craig Robbins, Carol Cain, Amy Lou	Kaiser
		Andrew Rosenberg	University of Michigan
Research Organizations	Jean Slutsky	PCORI	
Federal Agencies		Ed Lomotan	AHRQ
		Paul Nichol	VA
		Nedra Garret	CDC
Implementation Support		Jerry Osheroff	TMIT Consulting
		Beth Schindele	REC

Preliminary Findings from Stakeholder Discussions

The Need for CDS Sharing, Particularly for Small Practices

The stakeholder discussants generally agreed that providers in large organizations have more CDS resources available to them than providers in small practices (1-10 physicians). In our conversations, we found that large provider organizations are concerned about the amount of resources they have to put into creating CDS systems. They note that duplication of efforts among large provider organizations leads to continuous reinvention, rather than efficient reuse.

A sizable number of discussants stated that when it comes to realizing the promise of CDS as a tool to improve health care quality, the biggest need is not that large organizations develop better CDS, rather that small practices with limited resources have access to high-quality CDS. Providers in small practices do not have the resources to build complex CDS systems. As a result, they are often limited to using the CDS systems or features that are packaged within their EHR software. Discussants agreed that small provider access to CDS would be facilitated by a more robust market where CDS resources are exchanged for a competitive fee or made available for free by their producers.

Barriers to CDS Sharing

Barriers for Producers

Lack of standards for CDS resources; common models for CDS sharing

Almost universally, discussants saw a lack of mature standards for CDS resources as a major barrier to CDS resource sharing across organizations, for several reasons:

- EHR developers and other users are reluctant to license CDS content that is proprietary and non-standardized. Users want to be able to continually assess third-party solutions and switch to a better product when/if one appears in the market. Purchasing non-standardized resources makes it difficult to switch to a different/better resource because of the costs involved in customizing third party, non-standardized resources to run on a host EHR system.
- Discussants see the Health eDecision standards as a good first step, but believe that these standards are not yet mature. They have found them to not be precise enough to make artifacts plug-and-play. Significant manual work is required to import artifacts built to Health eDecision specifications into an EHR system.
- In particular, discussants noted a need for standardized order sets and standardized processes for prioritizing which alerts are delivered to the provider. Discussants noted that standards in other areas that are helpful for both diagnosis and CDS applications, such as standardized ways of representing the clinical history of a patient, have emerged, but standards for order sets and schema for prioritizing alerts, which are specifically needed for CDS applications, have been slower to mature.
- Given that standards will change over time, discussants suggested that there needs to be a system for coordinated change. CDS programs, which by their nature depend on interoperability across different systems to integrate the information needed to provide high quality CDS, should not be disrupted by an update in one system but not another.

Sustainable business models for producers

Presently, there is not a clear business model for content producers looking to create and sell CDS resources on an open market. First, creating CDS resources that can be used by providers across a majority of the EHRs now in operation requires multiple translations. Even then, users purchasing third-party CDS resources must invest significant time and effort to customize resources to operate effectively with their local systems.

Today, the CDS resources that do exist come from two main sources: EHR developers that have proprietary CDS resources that are built to work with their systems, and large providers that are building customized CDS resources to meet their unique needs. There is no robust market in which third party (non-EHR developers) can build and sell products that are usable by many providers.

Barriers for Users

Awareness of benefits, competing priorities, and focus on regulation rather than quality improvement

Discussants noted that many providers, particularly those in small practices, see CDS as a requirement of the EHR incentive programs, not as a tool to help them improve quality of care. They suggested that for the necessary steps toward effective CDS sharing to occur, providers must see the value of CDS and demand it from EHR developers. Given numerous competing priorities for providers, they will not demand high quality CDS unless they believe it can help them improve quality of care.

Solutions that fit user workflow

Unlike providers in small practices, providers in larger organizations do see value in CDS. They are buying some CDS resources from content developers. However, they are still building a significant proportion of their CDS resources on their own and investing significant resources in customizing the third-party resources they purchase to fit their specific needs. Even within large organizations, users find that CDS created centrally cannot be disseminated and used in a plug-and-play manner. It must be customized to fit into the workflow of providers and the specific circumstances of each facility. Part of the reason there is little demand for CDS resources from third parties is that providers in small practices do not see the value of CDS, and providers in large practices see the value but have the resources to build customized CDS resources on their own.

Low cost options for users

The high cost of CDS adoption is a barrier, particularly for small- and medium-size practices. Currently CDS adoption is particularly costly due to expenses associated with customization to fit local needs and ongoing maintenance to assure that resources remain up to date. CDS resources that are pre-packaged with the EHRs that practices buy offer the potential for a lower cost solution, but often the pre-packaged resources are limited to the simplest forms of CDS, such as drug-drug interactions.

Lack of CDS Infrastructure

Feedback loops for a continuously learning system

CDS users at large, sophisticated organizations criticized the lack of feedback loops to evaluate and improve how CDS is being implemented in their organizations. They cite a need to understand what information providers find valuable and what information is a nuisance. Information that is helpful for

improvement would include recommendations generated by CDS systems that clinicians respond to, not the ones that are routinely dismissed. In addition, feedback loops from users to content producers would help to improve the quality of CDS resources.

Processes to ensure integrity of CDS resources

CDS developers noted that a stamp of approval by a government agency or a medical specialty society for a clinical practice guideline gives it legitimacy. However, there are many steps to translate that guideline into a CDS resource that can provide valuable information to the clinician at the bedside. The translation and integration processes require a significant amount of judgement, and providers must be confident in the results of these processes. Currently, direct provider involvement in vetting CDS resources is the primary mechanism for ensuring integrity.

Discussants from one medical specialty society described how their organization is actively involved in translating the latest clinically relevant information into formats that can be made available to clinicians through their EHRs or other channels, such as a smart phone. For this specialty society, making clinically relevant information available to their members in new formats is a natural extension of what they see as their core mission, which is to develop and disseminate information that is scientifically sound and helpful to their members.

Providers often find it difficult to use CDS resources developed by providers at another organization because CDS resources have built-in assumptions that are based on the institution in which they are authored. To address this challenge, one discussant recommended that authors of CDS resources include more information about the assumptions that have been built into the resources they have created. Several discussants identified transparency as a major factor in building provider trust in CDS resources.

Legal certainty for intellectual property, liability, and data security

Discussants expressed that lack of clarity about legal issues related to resource sharing is a drag on CDS innovation. HIPAA requirements for data security and the way patient information is stored in the cloud is an issue for CDS as a service. Discussants also noted concerns that CDS systems could subject providers to malpractice claims if they fail to follow treatment recommendations offered by the system. However, discussants were virtually unanimous in noting that legal issues, including intellectual property and licensing issues, are not a primary barrier to the development of a strong market for CDS resources. All agreed that legal challenges can be handled if larger problems are addressed.

Facilitators of CDS Sharing

Federal Government Role

Many discussants believe that the federal government, and the ONC in particular, should play a leadership role in moving CDS sharing forward. However, they differ in their views of precisely what role government should play. Some believe government should rely on its regulatory authority. Others preferred that the federal government stick to a convening role and laying out a vision for the future, without mandating that businesses follow a specific path to achieve a desired future state. Virtually every discussant believed that it would be helpful if government created a public repository of open source CDS resources.

Federal Government as Convener

Many discussants believe that the ONC should serve as a convener of CDS stakeholders from the public and private sectors. Discussants mentioned HIMSS, AMIA, and NQF as potential partners with ONC for convening. In particular, discussants noted a big need to bring together EHR developers and CDS content developers. The goal of such a convening would be to open up the possibility of real interoperability where third party application developers can create innovative CDS products that run on top of the large developers' EHR systems and better meet the needs of both providers and patients.

Federal Government as Regulator

While some discussants preferred that the federal government play a convening/facilitating role to help foster a healthy CDS market, many discussants, including several representing private businesses, believe that government must go further. They noted that we would not have seen the large uptake of health IT among providers in the past few years had it not been for meaningful use and EHR certification regulations. Similarly, government regulation is required to move forward on interoperability and creating a more robust market for CDS resources.

In particular, some discussants indicated that government should play a role in encouraging data liquidity. Government could require that data be exportable from and importable into EHRs, as a condition of certification. Further, EHRs should have open application programming interfaces (APIs) that allow third party developers to create innovative solutions that run on top of large enterprise EHRs. One discussant commented that to unlock data, "government needs to move beyond piloting to codifying."

Federal Government Role in Creating a National Repository

Discussants were virtually universal in their support for government taking the lead in creating and maintaining a national repository of CDS resources. They see government playing several roles in regard to a national repository.

First, government should be a creator of content. Government agencies such as AHRQ and CDC that are already creating guidelines should go the next step and translate their guidelines so they are consumable by providers' EHRs and then make those translations available through a public repository.

Second, in creating a national repository, government would need to take the lead in coordinating policies for artifacts stored in the repository and processes for updating and validating them. Some felt government should mandate standards for CDS resources stored in the repository. Others felt government should merely suggest what standards ought to be followed. One discussant suggested that validation of materials in the public repository could be crowdsourced through a Yelp-like user rating system.

Discussants stated that by making high-quality translations available through a public repository, the federal government would be creating a high baseline for CDS resources. This would not eliminate the need for private-sector developers. Indeed, there would be an expansion of the need for developers specializing in improving the delivery and presentation of information to providers. Many EHR developers in particular do not see the updating and maintenance of complex clinical content as central to their business and would be pleased to see this taken on by government or some other entity.

Some private CDS developers may feel threatened by government engaging in translation work, but the companies we spoke with who are involved in producing CDS content stated that they would not view a government-sponsored repository as a threat. Many companies in Health IT, particularly newer smaller companies, believe that what they are selling to their customers is their ability to be nimble and respond quickly to changes in the market. They see change not as a threat but as an opportunity to grow the market. As such, they see government entering the market as a producer of high quality CDS translations as an opportunity to offer more and better products to their customers, and to prime the pump for the development of a more effective market for CDS resources.

Many large provider organizations that are currently producing their own CDS resources would also welcome the creation of a national repository for CDS resources. They are interested in sharing their CDS resources for use by other organizations, and see the content they have created primarily as a public good that should be widely available. These organizations are less motivated by a business interest in selling their CDS resources and would be willing to make them available for free.

Addendum: Stakeholder Discussion Support Document

Thank you for agreeing to participate in this discussion. We appreciate your willingness to share your perspectives with us.

Background

In 2014, the Office of the National Coordinator for Health Information Technology described a vision for an “electronically enabled QI ecosystem that promotes better health and care, improved communication and transparency, rapid translation of knowledge for all stakeholders and reduction in the burden of data collection and reporting for providers.” ONC has engaged Discern Health to assist ONC staff in assessing where we stand in our shared journey to that ideal state, specifically for clinical decision support (CDS). In addition to assessing the current state of sharing clinical decision support resources based on stakeholder interviews and a literature review, Discern will be recommending steps that ONC could take in the near- and mid-term to accelerate the sharing of high-quality CDS resources.

Points of Interest, for Potential Discussion

1. Please introduce yourself. Briefly, how does your organization approach clinical quality improvement using health IT? What work have you done related to CDS? How does your current role and organization relate to CDS?
2. Have you ever used a CDS tool or artifact developed by someone else and shared with you? Would having access to shared CDS resources interest you? Why or why not?
3. We are interested in exploring the enablers and barriers to organizations using CDS resources created by another organization. What do you believe are the most important accelerators and challenges? For example:
 - Standards?
 - Integration into workflow?
 - Ability to customize?
 - Regulations/Meaningful Use?
 - Business model/sustainability?
 - Confidence in the quality of the resource?
 - Legal issues?
 - Other?
4. What role should government play in encouraging CDS resource creators to share them, and for CDS resource users/implementers to use them?
5. What practical steps could a federal entity such as ONC take to accelerate CDS resource sharing? For example:
 - Pursue a national framework to encourage CDS resource sharing?
 - Support development and/or maintenance of a publicly available repository/library of CDS resources?
 - Other?

6. What is the value proposition and motivation for CDS resource sharing for your organization under current circumstances? How would the creation of a public repository/library of CDS resources that organizations could freely contribute to and use impact your organization's business plans? How could a public library be structured to motivate organizations such as yours to contribute to and use its resources?
7. What other advice do you have for ONC regarding this topic? For the Discern team? Please suggest additional stakeholders Discern should consider talking with and any specific literature we should review.

Appendix B

Clinical Decision Support Resource Sharing Literature Review Synthesis and Methodology

Introduction

As part of the CDS resource sharing project, Discern Health conducted a literature review to inform understanding of the current state. We have completed searching, reviewing, and inputting results from the pertinent literature into a data collection tool. This document presents the literature review methodology and a synthesis of the review results.

The subjects of interest for our review were the current, non-technical barriers and accelerators of CDS resource sharing, particularly those factors that impact a CDS user’s ability to differentiate high-quality resources. We selected search terms and inclusion criteria to gather sources that would best address those subjects. We acknowledge that there is a range of other CDS-related topics that were not within the focus of this search.

Methodology

Search Terms and Inclusion Criteria

We developed a list of 27 search terms that we used in combination with the terms “clinical decision support” or “CDS.” The terms addressed the range of potential barriers and accelerators that the Discern and ONC teams identified in the initial stages of the project.

Search Terms			
• Sharing	• User	• Business model	• Open source
• Framework	• Patient	• Liability	• Return on investment
• Future	• Barrier	• Intellectual property	• Producer
• Artifact	• Challenge	• Licensing	• Resource
• Tool	• Workflow	• Integrity	• Value proposition
• Vendor	• Customize	• Confidence	• Validity
• Repository	• Sustainability	• Trust	

We applied the terms to multiple search engines, including general search engines (i.e., Google, Bing), NLM’s PubMed, and intra-site searches of websites from organizations such as the Institute of Medicine, Kaiser Health, and Modern Healthcare. Some sources were provided directly by ONC.

We used the following criteria for including sources:

- Published after January 1, 2009;

- Peer-reviewed articles or authoritative white papers and reports preferred (others were evaluated subjectively for authoritativeness); and
- Primary sources preferred (i.e., editorials on primary articles in the same journal or slide presentations that paralleled reports were not included).

Sources that were not included typically focused exclusively on the following subjects:

- General descriptions of what CDS is;
- The effectiveness of a particular CDS intervention for quality improvement, or reviews of such interventions; or
- Technical details of CDS development (e.g., coding languages and logic structures).

An illustrative list of unused sources is provided under the Unused Sources tab in the data collection tool.

We executed the literature search in two rounds. In the first round, we downloaded sources that met the inclusion criteria. We then read and assessed the sources for relevance. We entered relevant information from the sources into a custom data collection tool that enabled capture and sorting of information on subjects of interest.

We evaluated the results from the first round of review for subjects that were either under-represented or of greater interest. We carried out a second round of searching and recording, focused on filling gaps and assuring capture of more recent sources.

Data Collection Tool

We used a custom tool to capture information from relevant documents, including:

- Bibliographic information, such as title, author, date, source, and primary stakeholder perspective;
- Statements on the current and future status of CDS resource sharing and statements on CDS producer, user, and government roles; and
- Points related to specific barriers and accelerators of CDS resource sharing, with a + or – sign placed next to the information to designate it as a barrier, accelerator, or both.

We sorted information in the tool by topic and synthesized the results for this report.

Search Results

Searches for “clinical decision support” yielded a large number of hits in most search engines (for example, “clinical decision support” after 2009 yielded 16,861 hits in PubMed). Many of the hits were not directly relevant to our project. The inclusion criteria yielded more manageable, and often reinforcing, results (for example, adding “sharing” to “clinical decision support” after 2009 yielded 188 hits, adding “validity” yielded 495 hits, and adding “value proposition” yielded 3 hits.).

Excluded results addressed subjects such as analyses of how clinicians make decisions, condition-specific treatment and diagnostic decisions, health IT reports that mention CDS only in passing, and other articles that did not meet the inclusion criteria. After filtering, 50 public sources and 2 non-public sources were entered in the recording tool.

The tables below present counts of cells for that were filled by content from the examined sources:

Category	Article Count
Statements on Current Status of CDS Sharing	30
Statements on Future Directions	10
Statements on Government Role	9
Knowledge Producer Perspectives/Motivation	10
Knowledge User Perspectives/Motivation	11

Category	Counts (+)	Counts (-)
Technical Standards	9	8
Accessibility	2	2
Usability/Integration in Workflow	8	11
Customizable to Local Needs	8	11
Patient-Sensitive	3	2
Sustainability/Value Proposition	7	6
Regulatory/Meaningful Use	7	2
Legal	4	6
Information Integrity	8	13

Review Findings

In this section, we synthesize the major points across categories into a comprehensive picture of the various challenges for CDS resource sharing and trustworthiness. We found that statements entered under the categories of the data collection tool often overlap with or are related to other categories.

Statements on Current Status

The sources reviewed describe the widespread use of different types of CDS, including electronic and manual forms that have been available for many years. Types of CDS vary across a spectrum of subjects, settings, providers, devices, content, and methods of presentation. Many EHRs include CDS that originates either from third-party developers or from EHR developers' CDS products. The sources state that CDS is important and useful for quality improvement in the value-based healthcare environment, and that CDS is sought after by administrators and clinicians.

Sources further acknowledge that development of CDS has been siloed, and that the mechanisms for sharing CDS among users and health IT developers is currently limited. Several sources discuss the need for pilot programs, such as those that have been sponsored by the federal government in the past, to identify ways to encourage CDS resource sharing. While these programs have resulted in recommendations for consistent technical standards and legal protections, national consensus has not yet emerged. Some sources promote approaches that would increase use and trust in CDS, including the “Five Rights” of CDS delivery: right information, right person, right format, right channel, and right time in workflow.

Select Quotations:

“Despite significant evidence of their clinical utility...CDS capabilities are not widely available.... [A]n important factor is the lack of a framework for sharing CDS resources and capabilities nationally.”- Kawomoto 2013

"We have...argued for the need to integrate the three essential components of CDS—information management, knowledge management, and data analytics—and we found ample evidence that the CDS area is moving towards integration.... Even though integration [of CDS with other clinical systems] is a goal of many, it is still complicated at the technology level, at the data level, and at understanding clinical work." –Sen 2012

Statements on Future Directions

Sources that recommend future directions suggest that CDS will become ubiquitous and advanced, particularly as health IT systems become more interoperable and as the role of quality measurement becomes more important to demonstrating value of care. However, they note that significant barriers remain to making CDS more accessible. Several sources call for improvements to standards for CDS resources, while others call for infrastructure and market-based improvements. They suggest improvements to make development easier and to reduce barriers at the developer and clinician levels. Some sources call for development of repositories to facilitate sharing of guidelines and tools and to promote standardization of CDS resources.

Select Quotations:

"...impressive new software tools may help providers personalize patient care. The big point of change is the data supply: there's now a vast and growing collection of digital patient data in [EHRs] to tap in search of individualized clinical guidelines. The pressure to use that data horde to help clinicians make better decisions is growing." –Fluckinger 2012

Statements on Government Roles

Statements related to government roles acknowledge that federal entities have the size and scope necessary to strongly influence standard setting and infrastructure development. Several sources specifically call for a CDS repository or repositories hosted by the federal government that would include, among other things, national databases to inform CDS tools such as drug-drug interaction alerts. Sources also note that national leaders could be apply influence to reduce barriers to CDS resource development and stimulate the market.

Select Quotations:

"In general, the federal government has an important, but limited, role in influencing the market, and acts when there is a legitimate public purpose and authority for doing so." –Daniel 2014

"...the local and national bodies responsible for creating and maintaining the rules and regulations that govern the operation of the healthcare facilities and their workers must be updated to take into account the new capabilities of...CDS-enabled EHR systems." –Sittig 2011

Knowledge Producers Perspectives/Motivation

Sources note that knowledge producers and CDS developers have typically produced content for individual user clients. Developers include providers who have invested in their own internal CDS development teams and procedures. Sources further note the necessity of a strong business case for producers to generate CDS at all. Producers have generally taken responsibility for their products and have worked with clients to update CDS over time, but this is not always the case.

Sources comment that many CDS developers are innovating to make use of new technologies and platforms. Producers recognize the utility of current standards for coding (HL7) and guideline-based content authoring (GRADE/MAGIC) for their development processes, though they do not consider these tools fully mature, and adoption of the tools is not universal.

Knowledge Users Perspectives/Motivation

Sources reference multiple types of uses and users of CDS resources and their clinical environments, ranging from pediatric offices to emergency rooms to battlefield medic scenarios. In each case, discussions about CDS include issues of the usefulness, trustworthiness, and compatibility of resources with clinician workflow.

Sources note that whether a CDS resource is accepted and used by clinicians depends on multiple factors, including underlying evidence, source of the resource, perception of usefulness, quality of presentation, availability of metadata about validity and reliability, assurance of currency, and ability to provide feedback to the developer. Because customization and testing at a local level are important to implementation, many provider organizations have their own internal vetting processes, which is expensive because it necessarily includes allotment of clinician time. Some sources discuss crowdsourcing using the clinician community for including local considerations into the development process.

Many clinicians identify and access CDS resources through their EHR systems. Thus, health IT developers strongly influence whether a clinician has access to a specific resource, whether that resource is customized and usable in the system, and whether maintenance and feedback mechanisms are available. Sources note that many EHR developers have exclusive CDS resources that they have created themselves or in collaboration with clients, or that they have obtained through contracts with outside resource producers. As a result, health IT developers have CDS resources that are not easily shared outside their systems.

Technical Standards

Sources identify a broad range of technical issues that might influence CDS sharing and validity. Issues include: standards for capturing and displaying data; modular, open-source formats to facilitate application across platforms; cloud-based connectivity; and the structure and content of relevant metadata. Most sources recognize lack of technical standards as a barrier, but where standards do exist and have been applied, they are typically described as useful solutions.

Availability

References to availability of CDS resources in the sources reviewed are closely aligned with statements about customization and the siloed nature of the market. Some types of CDS are not in use because they are not easily available to clinicians, or because the technological requirements to implement them are not available locally. Other statements about availability discuss the need to make information necessary to evaluate validity and alignment with guidelines public, noting that resources needed to implement common standards of care should not be a basis for competitive differentiation.

Usability/Integration into Workflow

Sources acknowledge that workflow integration is a primary concern. They note that all new CDS interventions will need to be coordinated at the appropriate point in the workflow of the local providers—physicians, nurses, pharmacists, and others who deliver care. Ideally, workflow considerations are part of the development of the resource itself. A description of the intended insertion into the workflow may be a key piece of metadata for clinicians to determine the usefulness of a resource. However, sources indicate that the customization needed for local implementation and the increasing amount of data integration that some resources require (e.g., patient data from multiple sources) make sharing a resource with others more difficult.

Customizable to Local Needs

Customization by the user is generally required for CDS implementation. Sources indicate that there are currently no common methods for tracking custom modifications that providers make to CDS developed by other entities. While system administrators can track customizations within a hospital, that information is not typically available to the developer. Customization may affect how the CDS is presented on the screen across multiple devices, whether alerts or downloads are available in different settings, and how the programs check for human errors. How CDS is customized may affect the outcomes of its use and make it harder to compare experience with CDS resources across providers.

Patient-Sensitive

Sources reviewed made few direct statements about patients and their use of CDS resources. This is, in part, because patient concerns are implicit in statements about usability and trustworthiness. For example, concerns about the accuracy of drug-drug interaction alerts are clearly patient safety issues. In addition, sources typically describe CDS resources, such as checklists, as tools for clinicians, rather than as tools for shared decision-making. If the search terms had included shared decision-making terminology, more patient-focused sources may have been identified, but discussion of CDS resources for patients appears to be under-represented in the literature.

Sustainability/Value Proposition

The most often-cited barrier to sustainability in the sources reviewed is the need to maintain and update CDS resources to keep up with the rapid evolution of medical evidence. Keeping up with this pace is resource-intensive for both CDS developers and users, particularly for smaller organizations.

Factors for the value proposition of a CDS resource include the costs of the resource, maintenance, and integration, weighed against the benefits of improvement in health, care experience, or cost reduction. Where CDS supports quality measures that help to prevent harm, reduce liability, and increase performance-based payment, then the value proposition increases. Conversely, where CDS is not aligned with measures or does not improve care, then the value proposition is diminished.

Regulatory/Meaningful Use

The Medicare and Medicaid Electronic Health Record Incentive Programs were in different stages of development and implementation during the range of the search (2009-present), and so references to them are often stage-specific. Many sources cite the incentive programs and corresponding EHR certification criteria as drivers of CDS development and use. These statements often appeared with others about the use of CDS to facilitate quality measure requirements from various sources, including the electronic clinical quality measures (eCQMs) that are part of “meaningful use” requirements of the incentive programs.

Though many sources cite the need for technical and procedural standards for CDS, most do not advocate for federal regulation of standards. One author notes that regulation of CDS could stifle innovation. A few sources discuss the possibility of FDA regulation, but there is no general agreement on FDA’s appropriate role.

Legal Issues

Statements about legal issues related to CDS in the sources reviewed generally fall into two categories: medico-legal liability and intellectual property. Medico-legal liability in the literature primarily addresses who is accountable if use of CDS is found to cause harm to a patient. Sources note that physicians are ultimately accountable for the care they provide regardless of what literature, recommendations, or decision support they rely on. The interest of all stakeholders in avoiding liability drives their interest in ensuring the trustworthiness of the CDS.

A few sources cite cases of harm from use of CDS. An Institute of Medicine 2012 report provides an example of a pediatric ICU in Pittsburgh that implemented a computerized physician order entry (CPOE) system and subsequently observed a significant increase in mortality that other providers implementing the same system did not observe. An analysis of why the CPOE system had a different effect in the Pittsburgh hospital found inefficient integration into the clinical workflow and administrative and logistical problems. The authors indicate that quantifying the potential harms of CDS is complicated by many variables. Another source notes that developer non-disclosure agreements may interfere with clinicians’ ability to share information about adverse events associated with use of CDS resources.

The sources reviewed that address intellectual property rights primarily discuss approaches taken by previous initiatives such as the CDS Consortium, which imposed mandatory, legally binding agreements

for CDS producers, sharers, and users. The intellectual property agreements address how information can be shared and distributed, and how ownership of each resource is determined. This initiative set a precedent that could help inform similar market structures that may be established in the future.

Integrity of CDS Resources

Sources emphasize that integrity of CDS resources is critical for all stakeholders, and we found that need to ensure integrity is related to all of the other categories of this review. Sources note the importance of metadata for providing transparency to clinicians about CDS resources, including the underlying guidelines and evidence, validity and reliability testing, and methods for maintaining currency. Peer experience is also important for clinician acceptance and adoption of CDS resources. In addition, clinicians need to be able to provide feedback to CDS developers about their experience using resources, particularly to report the occurrence of undesirable, unintended effects.

Select Quotations:

"Although it may seem self-evident that the core of good CDS intervention is providing the right information, many CDS interventions fail because this element isn't addressed appropriately.... All information provided to practitioners and patients should be current, relevant to the patient, evidence-based and from trusted sources." –Sirajuddin 2009

"Some experts recommend that healthcare organizations and practitioners who find themselves in the early stages of CDS intervention development refrain from basing interventions solely on expert opinion. In some cases, expert opinion can be contentious. Because it may not be universally agreed upon as best practice, it may negatively influence whether an end user complies with the recommended actions forming the basis of the CDS intervention." –Campbell 2013

"When physicians can generate, validate, and reuse information from themselves and their peers, information is likely to be accurate and used." –Allison 2012.

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