DESIGN AND IMPLEMENTATION CONSIDERATIONS FOR A CLINICAL DECISION SUPPORT KNOWLEDGE MANAGEMENT REPOSITORY

By

Kevin M. Heard, B.S.

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CERTIFICATE OF APPROVAL

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Kevin M. Heard

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Joan S. Ash, Ph.D.

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ABSTRACT

Maintaining and governing a clinical decision support system is an extremely time consuming and daunting task. Common challenges that health care organizations face when managing clinical decision support include: maintaining a comprehensive listing of all clinical decision support artifacts that are being developed or are live in production; identifying interdependencies between clinical decision support artifacts and other artifacts, guidelines, terminologies, value sets, and other electronic health record build artifacts; tracking changes to decision support; and knowing when an artifact needs to be reviewed. A centralized clinical knowledge management system which catalogs clinical decision support artifacts is essential to successful clinical decision support governance and implementation, providing economies of scale, levels of abstraction, relationships, and processes which are difficult or impossible to accomplish using traditional content management and documentation tools.

INTRODUCTION

Clinical decision support (CDS) provides person- and context-specific guidance and knowledge to clinicians and patients for the purpose of improving health and health care. One of the primary deployment models for CDS is within the electronic health record (EHR) during patient care. Types of CDS include alerts and reminders, order sets, guidelines or clinical pathways, documentation templates, and prompts to ensure appropriate actions are taken[1]. The CDS artifacts built within the EHR are driven by clinical content—guidelines, best practices, quality measures, policies, and procedures which provide the context and background for the CDS.

Often, this clinical content is managed in one place and CDS requests and implementation details are managed in another, and the two repositories remain siloed. Consequently, identifying what CDS is in place for a specific clinical domain or problem is often difficult. These linkages between clinical knowledge and CDS artifacts are critical when clinical content needs to be updated due to regulation changes, updated evidence, or changes in practice, so that the related CDS can be updated in turn[2].

We will explore best practices, standards, and frameworks for implementing a clinical knowledge management (KM) repository for clinical decision support that will enable viewing and maintaining key information related to CDS artifacts, linking artifacts to clinical content, and performing impact and dependency analysis for CDS artifacts both native and external to the EHR. The establishment of a CDS knowledge management repository within a healthcare organization will provide transparency, allow for dissemination and sharing of CDS artifacts and services, and assist stakeholders in managing current and future CDS work.

METHODS

Literature Review

We performed a literature review of 42 journal articles, professional organizations' reports, and conference proceedings to identify common definitions, themes, best practices, and standards related to knowledge management for clinical decision support (CDS). We searched PubMed for relevant material using the following search terms: "cds", "clinical decision support", "decision support", "knowledge management", "clinical knowledge management", and "clinical guidelines." Additionally, citations within the search results were reviewed for inclusion in the literature review. We narrowed the literature down to sources that provided background/foundational information, case studies, system architecture or implementation details, reviews of common practices and standards, or recommendations for best practices. The filtered set of literature amounted to 23 sources published from 2007 to 2018.

Extracting Best Practices

The resulting body of literature was used to distill a set of overarching recommendations for implementing a CDS knowledge management repository. We also identified benefits and challenges related to a clinical knowledge management program. The recommendations, benefits, and challenges will help lay the groundwork for establishing a clinical knowledge management program out our institution.

Survey Development

Lastly, we used the insights gained from the literature review to develop survey questions for identifying CDS knowledge management requirements within our organization. In order to identify which data elements, functionality, and general requirements should be given priority in our knowledge management journey, we administered the survey to key CDS stakeholders within our institution. The survey was developed in Google Forms and sent to approximately 80 individuals belonging to the following stakeholder groups:

- CDS Steering Committee
    - Chief Medical Information Officers (CMIOs)
    - Clinical leaders with an interest in CDS
    - Clinical domain subject matter experts (SMEs)
- CDS Operations
- CDS Development
- Academic Informatics Leaders

Recipients were given two weeks to complete the survey and were given two follow-up reminders via-email. The survey consisted of the 28 questions broken into 3 sections: Key Data Elements, Key Functionality, and General Questions. The questions and response choices for each section are outlined below.

A. Key Data Elements to be Included in the Knowledge Repository

Response choices for each data element item are a 1-5 Likert scale where 1 is Not at all important and 5 is Extremely Important.

1. Last time of update
2. Last time reviewed
3. Detailed rule logic
4. Inclusion/exclusion criteria
5. Trigger points
6. Specific clinical concepts and value sets used by the rule
7. Original requester of the CDS artifact
8. Owner of the CDS
9. Follow-up actions suggested by the HER
10. Acknowledgment options/reasons
11. Summary of performance (overridden vs. accepted)
12. Disruptive/popup vs. inline
13. Targeted locations and providers
14. Supporting evidence
15. *Additional data elements – free text field

B. Key Functionality

Response choices for each functionality item are a 1-5 Likert scale where 1 is Not at all important and 5 is Extremely Important.

1. Search by clinical concept
2. Search by targeted provider type
3. Provide comments/feedback about a rule
4. See others' comments about a rule
5. Search/filter by clinical service/domain
6. *Additional features – free text field

C. General Questions

1. Who should have view access to the repository? Choose all that are applicable:
    a. *All clinicians*
    b. *Quality/process improvement*
    c. *Clinical leaders*
    d. *CDS stakeholders/decision makers*
    e. *Anyone with EHR access*
    f. *Other*
2. Who should be able to modify content?
    a. *All clinicians*
    b. *Quality/process improvement*
    c. *Clinical leaders*
    d. *CDS stakeholders/decision makers*

e. *Anyone with EHR access*

f. *Other*

3. Who should be able to provide feedback/comment on a rule?

    a. *All clinicians*

    b. *Quality/process improvement*

    c. *Clinical leaders*

    d. *CDS stakeholders/decision makers*

    e. *Anyone with EHR access*

    f. *Other*

4. How often do you think you would use the repository? Choose one:

    a. *Once a month*

    b. *Once a week*

    c. *Several times a week*

    d. *Once a day*

    e. *Several times a day*

    f. *Other*

5. How important is it to have a knowledge management repository for CDS?

    Response choices are 1-5 where 1 is Not at all important and 5 is Extremely Important.

6. Select the 3 data elements that are most important to you:
    a. *Last updated time*
    b. *Last reviewed time*
    c. *Rule logic*
    d. *Inclusion/Exclusion criteria*
    e. *Targeted locations/providers*
    f. *Trigger points*
    g. *Clinical concepts*
    h. *Acknowledgement options*
    i. *Follow-up actions*
    j. *Disruptive or not*
    k. *High level performance metric*
    l. *Requester*
    m. *Owner*
    n. *Supporting evidence*
    o. *Other*
7. Additional feedback about Knowledge Management Repository (free text)

RESULTS

History of Knowledge Management

The discipline of knowledge management was established in the early 1990s, and was embraced by multiple domains, including library and information management, information systems, and business administration. Not long after, it became a key concept when discussing healthcare information technology and electronic health records.

Numerous definitions of knowledge management exist. One of the earlier and most terse definitions was by Davenport, who stated knowledge management is “the process of capturing, developing, sharing, and effectively using organizational knowledge[3].” Duhon of the Gartner Group proposed “knowledge management is a discipline that promotes an integrated approach to identifying, capturing, evaluating, retrieving, and sharing all of an enterprise's information assets. These assets may include databases, documents, policies, procedures, and previously un-captured expertise and experience in individual workers[4].” The American Productivity and Quality Center (APQC) defines knowledge management as “a collection of systematic approaches to help information and knowledge flow to and between the right people at the right time (in the right format at the right cost) so they can act more efficiently and effectively to create value for the organization[5].” All of these definitions share one common goal of sharing knowledge across the organization.

Clinical Knowledge Management and its Role in CDS

The subdomain of clinical knowledge management has been defined as “the entire process by which clinical knowledge is created, made available, and maintained within an

EHR system. This includes the software tools necessary to organize and define knowledge, along with the organizational procedures necessary to manage this knowledge.[6]" While much of the clinical knowledge generated resides in one shape or form within the EHR, there is still much knowledge that exists outside the EHR, or cannot be fully represented using the EHR's tools. Also, many EHR's knowledge management tools are limited in scope and functionality, and are primarily targeted to CDS implementers/builders and no one else[2,6–8]. Knowledge management requires multiple roles to ensure quality and allow for checks and balances. Ideally these roles should consist of content writers, knowledge engineers, clinical subject matter experts, and CDS implementers, all distinct roles with different individuals and skillsets filling them[8,9].

We know that CDS malfunctions occur, and are probably underreported[10,11]. Errors where CDS artifacts fail to run are probably largely unknown until a serious event occurs or someone notices a decline in execution rates through manual report review. Failures to execute can be caused by a number of situations, but some common causes have been identified as: accidentally turning a CDS artifact off during build migrations, breaking the CDS artifact during an upgrade, updating terminologies or EHR master data (e.g. lab test/result codes or medication concepts), and failure of an external CDS service[10]. A knowledge management program and platform can help catalog and identify some of these interdependencies and facilitate impact analysis to determine what CDS is impacted by a change in another area of the EHR[11].

Knowledge Representation

There are many ways knowledge can be represented. A common framework for representing clinical knowledge, particularly CDS, was proposed by Boxwala in 2011[12]. This framework consists of four layers or levels of knowledge representation (Table 1). Level 1 is a narrative, human readable version of the guideline, policy, and/or evidence that informs the CDS intervention. Level 2 is a semi-structured, organized text representation that includes recommendations for CDS implementation. Level 3 is a structured, generalizable format using standard terminologies and representation enabling the CDS artifact to be shared and interpreted by a computer. Lastly, Level 4 is the localized, coded and interpretable representation which is specific to a single organization and EHR[12,13].

The multi-level representation has been recommended and used by the CDS Consortium, an AHRQ-funded project aimed at creating shareable, re-usable CDS interventions, both implemented locally in the EHR, as well as through published external CDS services that other organizations can consume in their EHRs[14]. Having shareable and service-oriented CDS are two foundational CDS capabilities that have become incorporated into the ONC (Office of the National Coordinator) and AHRQ's (Agency for Healthcare Research and Quality's) efforts to improve adoption and implementation of CDS, by providing standards, frameworks, and tools for creating a national CDS knowledge sharing platform[15].

	L1 (Narrative)	L2 (Semi-structured)	L3 (Structured)	L4 (Executable)
Format	Narrative text	Organized text, logic flow diagram	Fully specified knowledge representation (e.g. Clinical Quality Language)	Code and implemented in an execution environment (e.g. Python)
Modality and Tool Independent	Yes	Yes	Yes	No
Site Independent	Yes	Yes	Yes	No
Author	Guideline developer	Clinical domain expert	Knowledge engineer	CDS implementer
Purpose	Communication of policy; synthesis of evidence	Recommendations for implementation in CDS	Precise communication; validation	Implementation for a particular site

Table 1. Four levels of the knowledge representation framework.

Implications of Knowledge Management on CDS Interoperability and Shareability

The convergence of several standards for sharing CDS have broad implications for knowledge management. With CDS Connect, AHRQ has established a national repository of CDS artifacts, including a rule authoring environment[16]. CDS Connect utilizes the Clinical Quality Language (CQL), first established for encoding Electronic Clinical Quality Measures, to express the logic of the CDS artifact. FHIR (Fast Healthcare Interoperability Resources) is used as the data model to represent the clinical

data on which the CQL expressions will be evaluated. This new platform enables institutions to download CDS artifacts that have been made public as CQL files, which can then be imported into the EHR. A user interface enables end users to see and edit the criteria and logic for the artifacts in a user-friendly manner.

CDS Hooks is a complementary framework for deploying CDS services external to the EHR, which can then be consumed in real-time by any EHR which supports the CDS Hooks standards[16–18]. Transparent to the clinician is the fact that the CDS intervention is being evaluated remotely and not within the EHR. Included in the standard are elements that control how the CDS intervention is presented and that enable the launching of a SMART on FHIR app within the EHR as well. The backend implementation of the CDS Hooks service can be any programming language or technology, but one option is to utilize FHIR and CQL so that CDS Hooks artifacts are easily shareable and implemented. For example, if the CDC publishes a new guideline for opioid prescribing, and that guideline is implemented as a CDS intervention using AHRQ's CDS Connect, then all that remains is publishing that artifact in a CDS Hooks environment and making it available for EHRs to consume.

While most informatics experts agree that having shareable CDS artifacts will improve time to adoption and reduce implementation costs[15,19–22], there are still important factors to consider. There must be mechanisms in place to communicate when updates are made to external CDS artifacts. Also, for remote CDS services, any planned outages or maintenance will need to be communicated to the consuming organizations. Consequently, even though the knowledge artifact may not be owned by or reside within an organization, that organization will still need to be able to manage that artifact. A

knowledge management repository should not only be able to catalog internal CDS artifacts, but also external artifacts. Furthermore, a mechanism for pushing updates and notifications from a central repository to an organizational repository should exist so that an institution's knowledge management processes can identify and triage any changes that may impact their EHR. In order to establish trust in CDS knowledge artifacts, metadata capturing the provenance and version history of an artifact must be maintained. There is also a social aspect to knowledge management, in which publishers and consumers should be able to interact with one another to question or comment on an artifact. Links to supporting evidence are also key to establishing and maintaining trust in CDS[13].

Terminologies and Value Sets

Another requirement for a knowledge management program is to link to terminologies and value sets that are used in the criteria for a CDS artifact. CDS artifacts should identify clinical concepts through standard terminologies such as SNOMED-CT, RxNorm, and LOINC. It is critical a knowledge management repository be able to import terminologies, identify changes from one update to the next, and identify where a concept is being used. In addition to terminologies, value sets which group similar concepts together for use in CDS artifacts are a key asset that needs to be accounted for in a knowledge management program. Clearinghouses like the Value Set Authority Center (VSAC), provide shareable, terminology-based value sets that can be published by domain experts and quality organizations. A knowledge management platform should be able to link to services such as the VSAC when representing the CDS logic and allow for updates to a value set to be incorporated into the CDS[11,23]. For example, let's assume

there is a LOINC value set which collects all possible hemoglobin A1c tests which can be performed. Then, suppose a new HbA1c test is made available to the lab. Not only would the new LOINC concept need to be added in the knowledge repository, but the value set will also need to be updated to include the new HbA1c. These updates should be easy to review and accept into the knowledge repository and subsequently apply to the EHR environments.

Survey Responses

Out of the 80 recipients of the survey, 24 (30%) responded. All responders answered all questions. The Likert scale questions are summarized below in a divergent stacked bar chart (Figure 1). The divergent stacked bar chart indicates which proportion of responders leaned toward either end of the Likert scale. In this case, the items with more of the bar to the right indicates that item was deemed more important by the majority of the responders, while those items where the bar is mostly on the left are those items that were less important or not needed. Five data elements were considered important by 90% of the responders. Those 5 most important data elements were:

- Trigger points (100%)
- Detailed rule logic (98%)
- Inclusion/exclusion criteria (98%)
- Follow-up actions (96%)
- Clinical concepts (93%)

The least important data elements were:

- Original requester (46%)
- Last time reviewed (30%)

- Supporting evidence (25%)

It is important to note that none of the “less important” data elements had a strong inclination toward not being needed. Even the least important element, “original requester”, was only considered not important by 46% of respondents.

The important features were:

- Search by clinical concept (86%)
- Search by targeted provider type (80%)
- Search by clinical service/domain (78%)

While the least important features were:

- Provide comments/feedback (55%)
- See others’ comments (47%)

Lastly, 90% of respondents indicated the knowledge management repository was important to have in our organization. One individual commented that an organizational mechanism for managing institutional policies and guidelines was more important than a tool for managing only CDS knowledge.

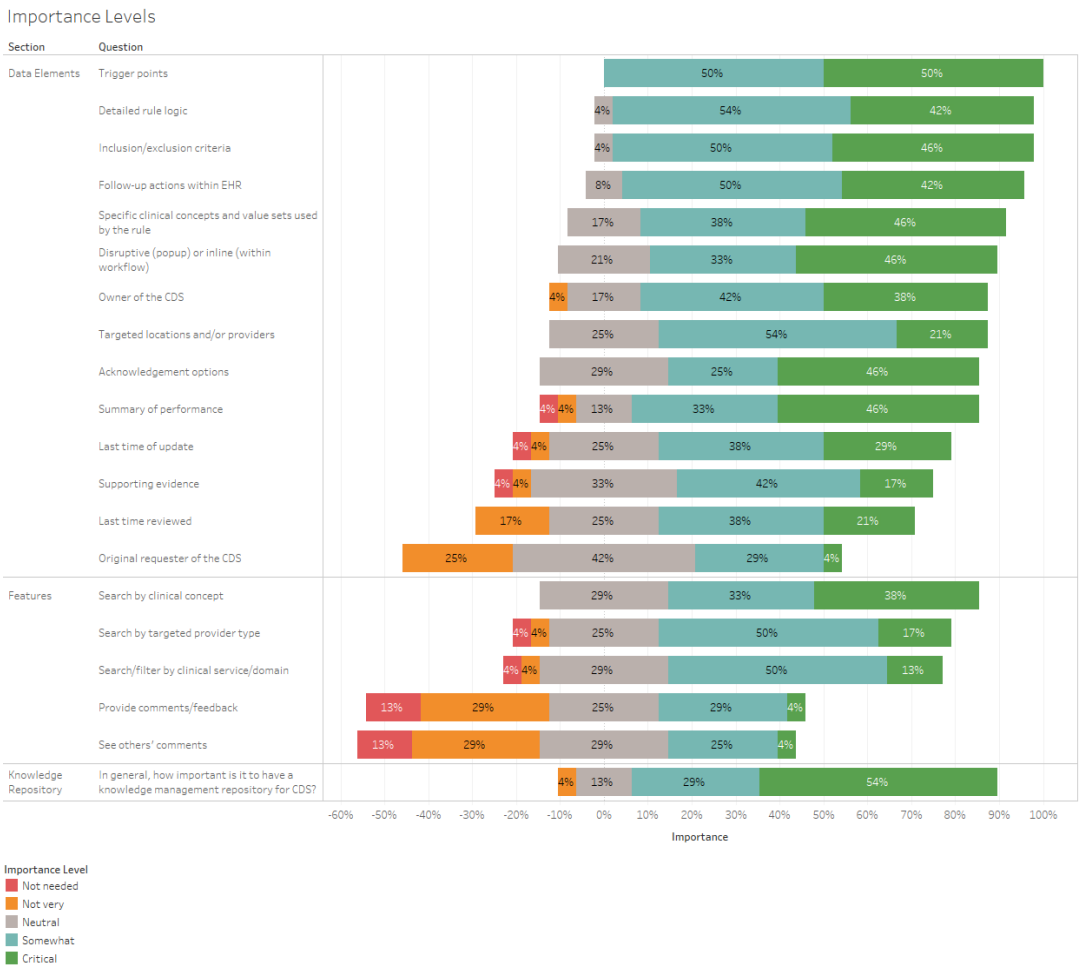

Figure 1. Importance of Data Elements and Features.

When asked what the 3 most important data elements to include in a knowledge repository were, respondents indicated rule logic (79%), inclusion exclusion criteria (38%), and high level performance metrics (33%) were the most important data elements that should be captured (Figure 2). While the rule logic and inclusion exclusion items ranked similarly in both the Likert and "top 3" questions, CDS performance was ranked slightly more important in the "top 3" question than it was assessed on the Likert scale of importance. However, this difference is probably explained by the fact that several data elements were all clustered together with similar importance levels. When asked to choose only 3 data elements, the performance measurement bubbled to the top. It's also

interesting to note that one commenter indicated they felt performance could be provided in another tool or report and not necessary for the knowledge management repository. We will need to assess whether it makes sense to link to dashboards that provide performance information or whether showing some performance metrics inline with the CDS repository is more beneficial.

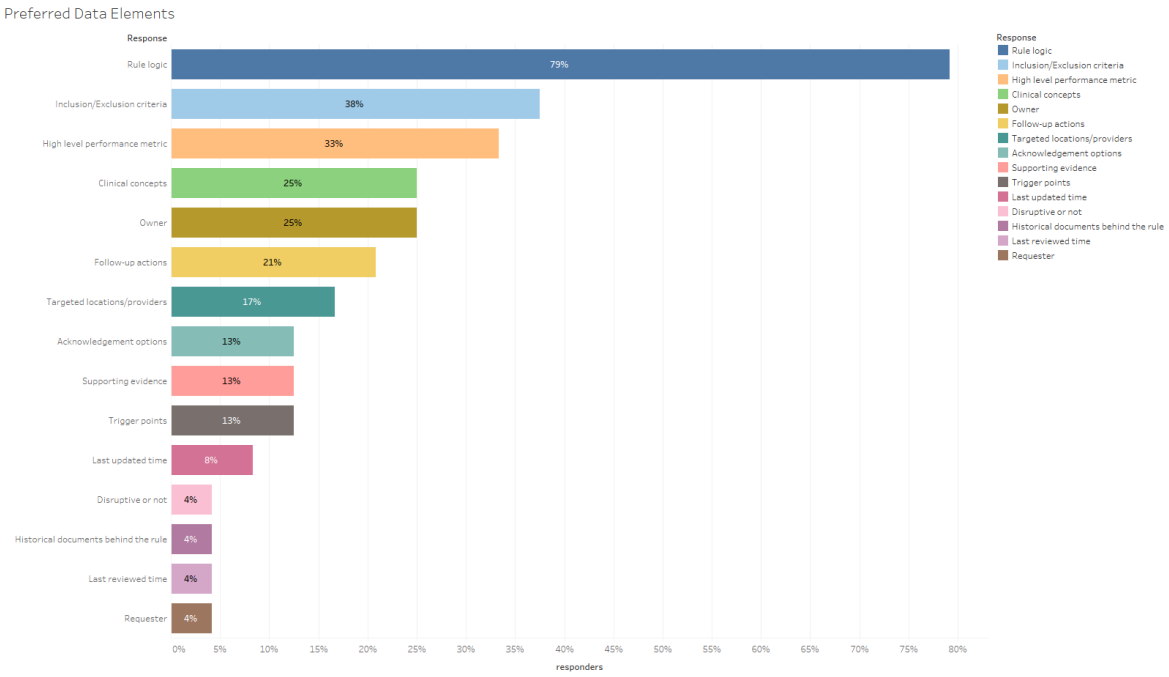

Figure 2. Preferred data elements, top 3 ranking.

Questions related to user roles and what permissions they should have in the repository indicated CDS stakeholders and decision makers should largely be able to view (88%) and modify (96%) content in the repository. Providing feedback was considered equally applicable for all roles. Responders felt clinical leaders should be able to view content (83%), but few thought they should have edit privileges (21%) (Figure 3).

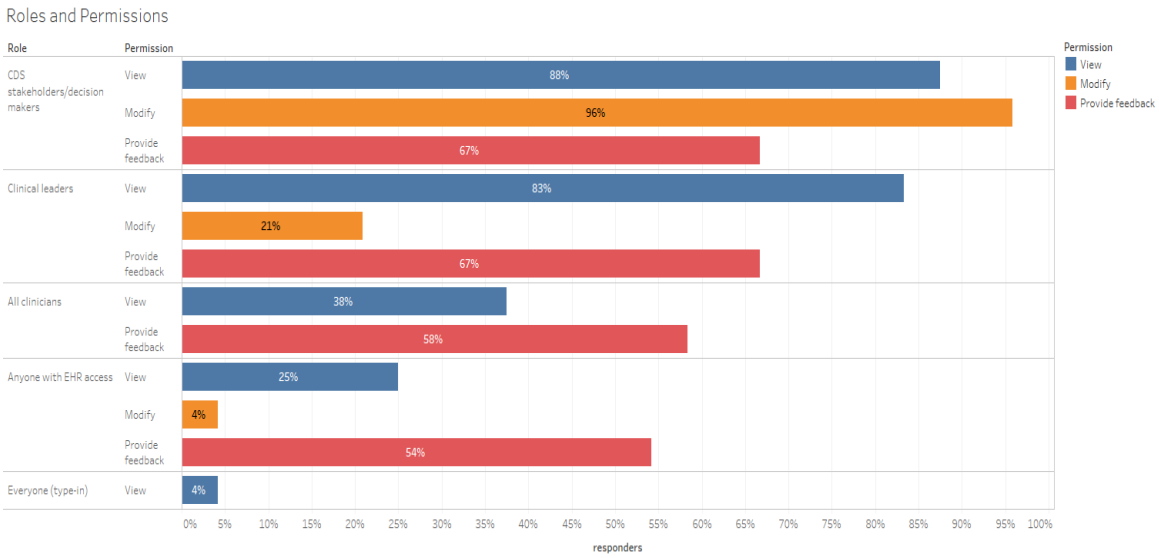

Figure 3. Perspectives on roles and permissions.

While the sample size is somewhat small, the survey results do confirm a few assumptions regarding what data elements and functionality are important and help focus the scope of our project as we begin to design and build the repository.

DISCUSSION

The best practices, standards, and frameworks presented in the results section help provide a justification and foundation for implementing a clinical knowledge management program at our institution. Here we discuss the benefits we predict will be gained from having our CDS assets catalogued in the repository, as well as the rationale for establishing such a repository.

Benefits of Clinical Knowledge Management

A knowledge repository for managing clinical content related to CDS artifacts will enable decision makers to easily identify CDS related to specific disease states, adverse events, quality measures, process improvement initiatives, and similar

categorizations that would be useful to stakeholders. Such a CDS knowledge management repository will allow users to view detailed information about the CDS artifact, both manually curated and electronically imported data elements from the EHR.

Successful implementation of the knowledge repository will provide stakeholders with transparency into the CDS implemented in the EHR and the related clinical content. We expect significant savings in time and resources by allowing analysts to quickly and easily identify the impact of a change in clinical protocol or related content on existing CDS artifacts. Patient safety and quality can also be enhanced by being able to more rapidly identify and update dependent CDS when recommendations change, as well as being able to identify when CDS recommendations may be out of date or no longer valid. Stakeholders such as quality or performance improvement consultants will be able to use the repository to identify gaps in available CDS for specific initiatives.

Why Knowledge Management?

Institutions such as Partners HealthCare, Intermountain Healthcare, Mayo Clinic, and Vanderbilt have well-established, mature knowledge management programs. However, they were early adopters, innovators, and most importantly, had resources to devote to knowledge management, which they've had many years to iterate on and refine.

Our assumption based on the literature and discussions with colleagues is most healthcare organizations do not have a comprehensive clinical knowledge management strategy, aside from what's maintained in external knowledge bases (e.g. radiology and pharmacy) and what is built in the EHR. However, it seems clear trying to manage all clinical knowledge within the EHR alone is not practical, at least with the current state of EHR knowledge management capabilities. Additionally, the expansion of service-

oriented and shareable CDS artifacts provide the case for a separate, purely knowledge management focused tool for managing clinical knowledge, CDS artifacts, terminologies, and value sets.

Desired Features

Critical interoperability features will be required to extract existing knowledge from the EHR and/or enable creating the knowledge within the tool and pushing it into the EHR. These capabilities will require the use of Clinical Quality Language (CQL) and Fast Healthcare Interoperability Resources (FHIR) in order to import and export shareable CDS artifacts to/from the EHR. The knowledge management repository will need to be a combination of social networking, discussion forum, content management, and metadata management with powerful query and reporting tools to support all facets of knowledge management.

Potential Tools

It appears most institutions that perform knowledge management activities well have developed a knowledge management tool internally or combined several tools together (e.g. SharePoint, eRooms, JIRA, Confluence, Business Process Model and Notation) to accomplish their goals. Up until very recently, there did not seem to be a commercial product available which was targeted toward clinical knowledge management that supported the entire knowledge management lifecycle. A recent entry to the space is Semedy, a German ontology and semantic tools vendor that is actively engaged in partnerships with Partners HealthCare and Vanderbilt University Medical Center to catalog and manage portions of their clinical knowledge assets. It will be interesting to see how Semedy's Clinical Knowledge Management System matures over

time and whether there will be any meaningful competition in the near future. Products such as Collibra which facilitate data governance overlap quite a bit with knowledge management practices, so that may be another option as far as a vended solution is concerned. Whether a robust knowledge management system is employed, or simpler content management and documentation tools are used, cataloguing all CDS artifacts is a necessary first step before moving on to a more mature knowledge management process.

CONCLUSION

Multiple initiatives and standards around CDS implementation, sharing, consumption, and knowledge management make it an ideal time to begin deploying an enterprise-wide clinical knowledge management at our organization and others like ours that are lagging in the knowledge management arena. The move toward learning health systems and personalized medicine only means the amount of CDS artifacts, and the level of complexity of those artifacts, will continue to increase. The only way to successfully manage this growing clinical knowledge is to catalog the knowledge assets appropriately and establish processes around the management of those assets. Next logical steps in this endeavor are to identify how and where we want to catalog our CDS artifacts and begin working on a proof of concept where we can validate we are capturing the correct information in the best possible way for it to be useful to our CDS builders, SMEs, clinical champions, and other CDS stakeholders. We will also want to investigate how clinical protocols, standard operating procedures, guidelines, and other knowledge not directly related to CDS should be managed, as that is another critical component of organizational clinical knowledge.

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