Patient-Centered
Clinical Decision Support
Learning Network

Recommendations for Building and Maintaining Trust in Clinical Decision Support Knowledge Artifacts

Blackford Middleton, MD, MPH, MSc
Jodyn Platt, PhD, MPH
Joshua E. Richardson, PhD, MS, MLIS
Barry H. Blumenfeld, MD, MS

On behalf of the Patient-Centered Clinical Decision Support Learning Network

September 21, 2018

Contributors

We would like to thank the contributions from each member of the Trust Framework Working Group (TFWG) and for volunteering their valuable time and expertise to make this report possible.

Member	Organization
Shafa Al-Showk, MPH, CHES	AHRQ/CEPI
Noam H. Arzt, PhD	HLN Consulting, LLC
Barry H. Blumenfeld, MD, MS	RTI, Patient-Centered CDS Learning Network
Lorraine Doo, MSWA, MPH	Centers for Medicare & Medicaid Services
Andrew Hamilton, RN, BSN, MS	AllianceChicago
Vojtech Huser, MD, PhD	NIH, National Library of Medicine (Lister Hill Center)
Edwin Lomotan, MD	AHRQ/CEPI
Ginny Meadows, MSHI, RN-BC	MITRE Corp.
Blackford Middleton, MD, MPH, MSc	Apervita, Inc.
Jodyn Platt, PhD, MPH	University of Michigan Department of Learning Health Sciences
Joshua E. Richardson, PhD, MS, MLIS	RTI, Patient-Centered CDS Learning Network
Marc Sainvil, MS	Mayo Clinic-Center for Translational Informatics and Knowledge Management
Sharon M. Sebastian, MS, RN-BC, PDMP	MITRE Corp.
Christopher W. Shanahan, MD, MPH, FACP	Boston University School of Medicine
Julia Skapik, MD, MPH	Cognitive Medical Systems
Danny van Leeuwen, MPH, RN	Health Hats
Michael A. Witte, MPH	Office of the National Coordinator for Health Information Technology

Preferred Citation:

Middleton B, Platt JE, Richardson JE, Blumenfeld BH. Recommendations for Building and Maintaining Trust in Clinical Decision Support Knowledge Artifacts. Research Triangle Park, NC: Patient-Centered Clinical Decision Support Learning Network; 2018 Sep p. 21.

Acronyms

AFA — Analytical Framework for Action

AHRQ — Agency for Healthcare Research and Quality

CDS — Clinical Decision Support

L1, L2, L3, L4 — Layers 1 through 4 for CDS knowledge abstraction, translation, and specification

TFWG — Trust Framework Working Group

Introduction

The United States healthcare system has widely adopted electronic health record (EHR) technology that includes clinical decision support (CDS). CDS, integrated at the point of care, aims to inform clinicians about recommended evidence-based care, such as clinician reminders for needed health screenings, advice on medication use, or other suggested interventions. CDS is increasingly being developed in the form of discrete tools, or knowledge artifacts, external to EHRs.

We referred to Cabitza et al. [1]who described knowledge artifacts as objects that people within an organization or community use to capture and organize memories. From a health informatics perspective, knowledge artifacts are objects consisting of health-related knowledge as logic expressions, triggers, data requirements, and outputs that become CDS interventions in practice.[2]

Modern approaches to creating and defining knowledge artifacts enable specific users, clinical practices, or health delivery organizations to choose CDS that best supports their needs. Delivering CDS via web-based platforms makes it possible to provide decision support directly to people, including patients and their caregivers, who simply have access to the internet via web browsers and/or smartphones.

A long-term goal of informatics has been to make such knowledge artifacts shareable because they are expensive and difficult to create and maintain. CDS Connect, funded by the Agency for Healthcare Research and Quality (AHRQ), is a platform that has been built to support authoring, archiving, curating, and disseminating knowledge artifacts for CDS.

CDS relies on a complex and dynamic ecosystem made up of actors (people who perform certain roles) who identify, build, implement, and assess knowledge that CDS artifacts deliver as interventions applicable to patients and clinicians when executed at the point of care. That ecosystem contains points of "friction" that limit the flow of research evidence among actors (e.g. publishers, providers, and patients, etc.) due to numerous known challenges and causes. The known challenges include: 1) lack of interoperability that limits the exchange of knowledge between systems; 2) difficulties translating knowledge from human readable forms into forms that computers can interpret; and 3) difficulties that humans have with using computer-delivered knowledge in real-world patient care. These challenges often stem from multiple causes such as: 1) lack of robust standards for encoding clinical knowledge); 2) insufficient methods to implement standards-based artifacts across disparate EHRs and care settings; and 3) concerns about how knowledge may be used, misused, or misappropriated, e.g., in violation of intellectual property laws. Friction can be attenuated in a CDS ecosystem where the involved actors may be trusted and are trustworthy, and where enabling technologies facilitate knowledge sharing across disparate EHRs and care settings.

CDS Challenges: *lack of interoperability, knowledge translation, and human-computer interaction issues.*

Causes include: *lack of robust standards, limited implementation method choices, and concerns about knowledge use and management.*

The Patient-Centered Clinical Decision Support Learning Network (Patient-Centered CDS Learning Network) is funded by AHRQ through a cooperative agreement to promote the implementation of CDS derived from patient-centered outcomes research to improve care [3]. Given this charge, the Patient-Centered CDS Learning Network chartered the Trust Framework Working Group (TFWG), made up of volunteers, to make recommendations for trust among actors in a CDS ecosystem. The TFWG considered CDS Connect-provided scenarios to identify and describe the roles of relevant actors and the relationships in the CDS ecosystem—actors who play active roles in the ecosystem—creating, managing, encoding, distributing, implementing, monitoring CDS in use, etc. The TFWG then identified core attributes for trust ("trust attributes") based on written descriptions of relationships among those actors. The TFWG used an iterative process to then recommend how each trust attribute can build and maintain trust in knowledge artifacts used in practice and within emerging systems such as CDS Connect.

The TFWG recommendations are not intended to be a set of top-down requirements; they are instead to be used as starting points that stakeholders can use to discuss using, reusing, and sharing CDS knowledge artifacts.

CDS Connect provided real-world scenarios for which the TFWG could consider issues of trust.

CDS Connect offers an online repository and authoring environment for shareable CDS (see https://cds.ahrq.gov/cdsconnect).

Background

Trust is a multidimensional area for evaluation, particularly in an ecosystem early in its development like CDS, but early evidence suggests it is important to study. Research shows trust is a critical consideration for complex information systems [4], and numerous examples in today's national discourse and popular press support the need to promote trust [5-7]. Trust in CDS and health information technology (IT) is no different, especially given the potential for patient harm from healthcare that is not evidence-based and the risks to patient privacy and security.

When addressing trust for a CDS ecosystem and its actors, we relied on Hall et al.'s definition of trust that is:

1. *a relationship between two or more entities or actors;*
2. *a condition, i.e., a set of roles and responsibilities, on which the relationship is based; and*
3. *a rationale for entering [an] implicit contract… that represents a "willingness [for one stakeholder] to be vulnerable to another for a given set of tasks."* [8]

We found this definition appropriate given the variety of roles and types of relationships in a CDS ecosystem.

To further address trust we sought to leverage a framework, as a framework could provide structure for analyzing roles and types of relationships in a CDS ecosystem. The Patient-Centered CDS Learning Network previously developed the Analytical Framework for Action (AFA), which depicts a lifecycle of interacting components for developing and disseminating evidence-based research findings via CDS (see Figure 1). We generally use the AFA to orient discussions with stakeholders, determine where past work has been carried out, identify gaps in the development of CDS activities, and propose opportunities for further work. Key factors of the AFA include:

- Prioritizing: Applying objective measures of evidence for identifying and prioritizing findings that are to be transformed and disseminated via CDS, assessing or defining their implementability, and defining stewardship and governance requirements.
- Authoring: Applying accepted data and knowledge standards for translating findings into one or more CDS intervention types that support key decisions, actions, and communications that are essential to ensure that the finding improves care and outcomes.
- Implementing: Applying standardized, best practice methods and architectures to operationalize CDS interventions into clinical workflows that deliver the right information to the right people in the right formats through the right channels at the right times to improve care processes and outcomes (Five Rights for CDS Implementation) [9].

The Patient-Centered CDS Learning Network's TFWG was chartered to recommend ways that trust may reduce friction among components in a CDS ecosystem and promote sharing of knowledge artifacts.

- Measuring: Ensuring that CDS interventions measurably improve clinician and patient decision making, care processes, and outcomes.
- Learning: Aggregating local CDS-related outcomes and effectiveness measures to facilitate both local and system-level learning from identified gaps in patient-centered outcomes research knowledge, and lessons learned from authoring, implementing, and using CDS in clinical practice to enhance care and outcomes.
- External Factors: External factors including the marketplace, policy, legal, and governance issues that impact development, dissemination, and implementation processes for CDS.

As it relates to trust, the AFA visualizes potential points of friction (e.g., resistance to effective collaboration) among components that can affect trust in a CDS ecosystem.

The Patient-Centered CDS Learning Network's TFWG was chartered to present a report that recommends ways that trust may reduce friction among components in a CDS ecosystem and promote more effective knowledge sharing within a Learning Health System. This technical report provides a summary review of the TFWG's methods, recommendations, and potential implications.

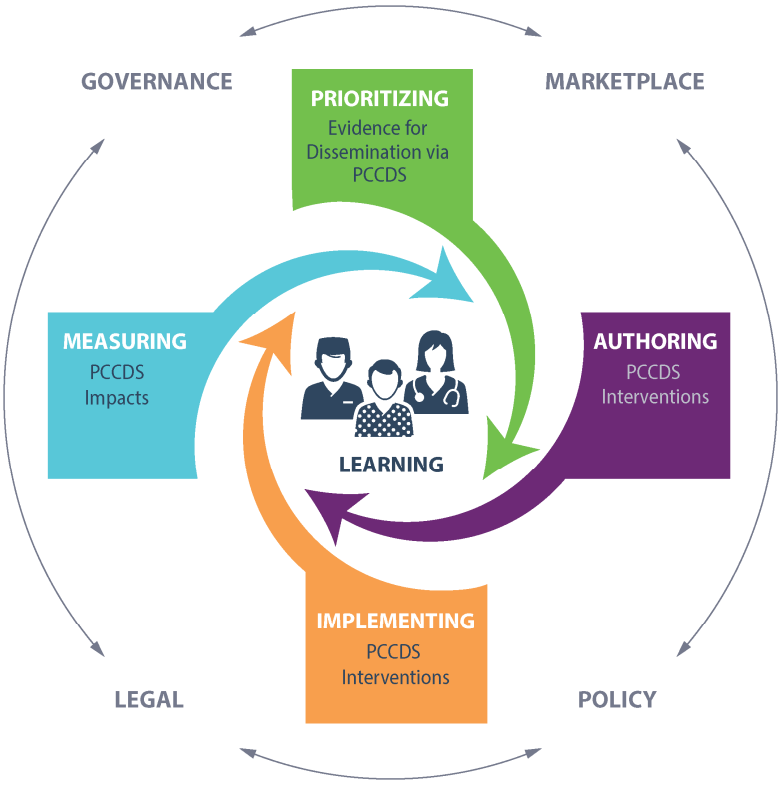

Figure 1: Analytical Framework for Action

Methods

We provide a summary review of the methods used to develop trust-related recommendations that inform both AHRQ's CDS Connect and the CDS field.

The TFWG was chartered in January 2018 to develop recommendations for building trust in a CDS ecosystem ("a trust framework"). We convened members from various backgrounds who met regularly between February and August 2018 for discussions, collaborative work, and review of ongoing findings. The TFWG carried out its work in the six stages summarized in ***Table 1***.

The TFWG developed a shared understanding of key issues in trust and previous research within that field and reviewed past work in CDS (Stage 1). Importantly, the TFWG considered Boxwala et al.'s work that describes four "layers" of knowledge representation in CDS development (see ***Table 2***).

Table 1: TFWG Activities in Six Stages

Stage	Description	Activity
1	Develop a shared understanding in trust and CDS	▪ Background webinar (Dr. Platt) ▪ Online bibliography
2	Define actors within a trust ecosystem	▪ Determination of stakeholders for scenarios ▪ Presentation to CDS Connect WG
3	Describe trust relationships between actors	▪ Group discussions ▪ Matrix exercise
4	Define key trust attributes among actors	▪ Group discussions ▪ Content analyses
5	Develop recommendations to address trust attributes	▪ Group discussions ▪ Content analyses
6	Map recommendations to CDS functional use cases	▪ Group discussions ▪ Content analyses

Table 2: Four-Layer Framework for CDS Knowledge Representation [10]

	Narrative (L1)	Semi-structured (L2)	Structured (L3)	Executable (L4)
CDS Format	Narrative text	Organized text, logic flow diagram	Fully specified knowledge representation formalism (e.g., Clinical Quality Language)	Coded and implemented in an execution environment (e.g., Python)
Modality and Tool Independent	Yes	Yes	Yes	No
Site Independent	Yes	Yes	Yes	No

Between various stages of work, the TFWG members participated in internally-developed surveys to capture multiple perspectives and to arrive at consensus on the key results.

To identify and define actors and their roles, the TFWG used three scenarios provided by CDS Connect that exemplify the need for trust in the CDS ecosystem (see ***Table 3***).

Table 3: Scenarios

Scenario #1	Scenario #2	Scenario #3
A new CDS contributor would like to upload several hepatitis immunization artifacts. What responsibility does the CDS Connect team have to ensure the integrity of the metadata entries and coding?	Two different influenza vaccination artifacts are available on the repository. Both are L3 artifacts. One has been piloted and the other has not.	A quality improvement manager is considering implementation of an extubation checklist but is interested in knowing if others have downloaded and used the artifact.

The TFWG determined trust attributes by generating a 12x12 matrix of the actors to systematically evaluate the bidirectional trust relationships and what was required for different actors to trust one another in pairwise combinations. We conducted content analyses of the text in the matrix to derive key trust attributes in a CDS ecosystem. Further analyses of the matrix text and trust attributes led to recommendations for each trust attribute.

We then mapped recommendations to four "functional use cases" that had been provided by the Patient-Centered CDS Learning Network. The TFWG agreed that the functional use cases represent basic activities in a CDS ecosystem, including for CDS Connect (see ***Table 4***).

From these efforts we defined actors, generated recommendations, and applied to the functional use cases as described in the next sections.

The TFWG aimed to make recommendations for both CDS Connect and for the CDS field at large.

Table 4: Functional Use Cases

Functional Use Case	Description
Author and Upload	Create a CDS knowledge artifact and make it available to others via a repository.
Inspect and Compare	Review CDS knowledge artifacts in a repository and make assessments (e.g., fitness for use) based on available metadata.
Download and Use	Download and implement a knowledge artifact into a local environment and use that artifact.
Provide Feedback	Offer means for actors to share input about the effectiveness or experiences with a knowledge artifact.

Results

The TFWG identified and described the roles for 12 actors in a CDS ecosystem (see ***Table 5***) based on the scenarios described above. The actors spanned roles from the clinical enterprise (e.g., clinicians, patients), the private sector (e.g., health IT vendors), as well as those shaping policy and payers.

Based on the matrix described in the Methods section, TFWG members considered what would be needed for each pairwise set of actors to trust one another. Based on this effort, the TFWG identified and described nine attributes of trust (trust attributes) for actors in a CDS ecosystem. The trust attributes addressed more than one aspect of trustworthiness including: knowledge artifacts, actors who may develop or use knowledge artifacts, CDS repository systems, and CDS implementations. Further, the TFWG agreed on 33 recommendations across the nine trust attributes in a CDS ecosystem (see ***Table 6***).

The TFWG generated 33 recommendations for 9 trust attributes.

Table 5: Key Actors and Descriptions

Actors	Description
Clinicians	Medical professionals who care for patients (physicians, nurses, etc.).
Health IT Vendors	Commercial entities that provide health-related technology solutions (EHR vendors, CDS vendors, etc.).
Knowledge Authors	Professionals such as domain experts and professional societies who write guidelines or other materials that provide clinical evidence to users in unstructured format (narrative text, image files, etc.).*
Knowledge Curators	Professionals who maintain knowledge artifact libraries to insure evidence is trustworthy (accurate, reliable, timely, etc.).
Knowledge Distributors	Professional organizations that package, market, or sell knowledge artifacts as private organizations or in public-private partnerships.
Knowledge Engineers	Professionals who translate clinical guidelines into artifacts in semi-structured human readable form (L2), a computer interpretable form (L3), and machine-executable formats (L4).*
Organizational Governance Bodies	A governance body that reviews and approves CDS to be used in an organization or across networks.
Patients	Persons who are the ultimate decisionmakers in their healthcare and managing their health.
Payers	Organizations that pay clinicians or patients for health-related activities.
Policymakers	Persons who develop legal or policy guidance that guide care or payment.
Population Health End Users	Professionals who support clinicians and clinical teams by monitoring population health trends and recommending actions.
Quality Improvement Analysts	Professionals who measure the impact of implemented CDS within health IT.

*L1-L4 are Boxwala et al.'s [10] levels of interpretability from human readable (L1) to machine executable (L4)

Table 6: Trust Attributes, Descriptions, and Recommendations

Trust Attribute	Description	Recommendation
Competency	An actor is deemed to be competent in the role played in the CDS ecosystem. For example, an author of a knowledge artifact should be judged competent, qualified, and an appropriate authority to develop the artifact based on factors such as past performance, professional qualifications, or certifications.	1.1 Authors have descriptions with background information including affiliations, years participating, and frequency of participation. 1.2 Authors promote respect and dignity when providing feedback. 1.3 Authors are credentialed by an agreed-upon entity through education or training, experience, and dependability. 1.4 Knowledge professionals are certified that they are competent in the knowledge management lifecycle, competently interpret, encode, and execute knowledge, and are competent of issues in conflict of interest. 1.5 Competency should apply to both individuals and organizations.
Compliance	A knowledge artifact should conform to defined standards and criteria including copyright and intellectual property.	2.1 Knowledge artifacts provide human-readable and machine-readable forms (whenever applicable) as well as supporting references. 2.2 Knowledge artifacts are implemented in compliance with best practices for safe and effective implementation. 2.3 Knowledge artifacts are encoded using current standards for controlled medical terminologies, value sets, clinical data models, and knowledge representation formalisms.
Consistency	A knowledge artifact should repeatedly generate expected results over time when given requisite inputs (e.g., patient data or supporting CDS triggers).	3.1 Authors take on responsibility of ensuring accurate knowledge translation and specification of a knowledge artifact.
Discoverability & Accessibility	The evidence behind an executable knowledge artifact is documented (discoverable) from metadata associated with the artifact. Artifacts and their contents have clear and appropriate reasoning for recommendations available to the end users. Artifacts are accessible to potential users, including patients and policymakers.	4.1 Knowledge is made accessible through search technology in conjunction with effective and helpful key terms. 4.2 Knowledge can be reliably searched for and found over time, so that users can find the same knowledge across successive versions. 4.3 References to supporting evidence are clearly labeled and linked (preferably deep linked) to relevant supporting information. 4.4 Data that inform an artifact can be found and accessed.

Trust Attribute	Description	Recommendation
Evidence-based	The evidence instantiated within an artifact must apply to the clinical condition it is meant to support. Limitations are stated clearly, and the evidence supporting the clinical guideline/ predictive model, etc. in an artifact is substantiated and has clear clinical appropriateness.	5.1 Metadata indicate the date that evidence was originally published, and the date that evidence was last reviewed. 5.2 Metadata state any known limitations, restrictions, or exclusions to any given evidence. 5.3 Artifacts contain references to the evidence base on which they are based, including both narrative guidelines and the data supporting those guidelines. 5.4 Artifacts include metadata for all supporting citations. 5.5 Artifacts include evidence about its method (e.g., order set v. alert), usage history, and available outcomes.
Feedback and Updating	Stakeholders have the functional ability to provide timely feedback and suggest improvements to a knowledge artifact. Feedback may be directed to diverse actors in the ecosystem (knowledge engineers, knowledge authors, etc.).	6.1 Systems capture error logs and feedback about an artifact within the context of its use (e.g., EHR system, clinical setting, crash data etc.). 6.2 Systems provide feedback mechanisms including means for users to ask questions about an artifact's context of use. 6.3 Metadata capture the dates an artifact was first and last published, with update dates in between. 6.4 Artifacts contain a auditable records of updates and changes over time. 6.5 Artifacts are updated based in part on feedback from operational performance over time. 6.6 Authors provide bidirectional feedback to one another so to rate (and improve) each other's work.
Organizational Capacity	An organization that sponsors knowledge artifact development or implementation (or both) should have the necessary funding, staffing, and resources to maintain a knowledge artifact and measure its effect(s).	7.1 Develop skills and capacity of staff, systems, and resources that support implementation, ongoing evaluation, feedback, communications, and governance. Include implementation guidance with artifacts that conveys the necessary resources to implement that artifact. 7.2 Knowledge artifacts include implementation guidance that conveys the necessary resources to implement that artifact.
Patient-centeredness	When possible, a knowledge artifact should leverage patient-centered outcome research findings and/or patient-specific information (the patient's clinical data, patient-generated health data, patient-reported outcomes) to support decisions by individual patients, their approved caregivers, and/or their care teams.	8.1 Requirements for patient-level or patient-generated data input are clearly indicated. 8.2 Evidence that accounts for patient-level or patient-generated data is clearly indicated. 8.3 Consent for use of patient-level or patient-generated data is clearly indicated.

Trust Attribute	Description	Recommendation
Transparency	A knowledge artifact should be applied and used ethically to clearly convey all potential conflicts of interest and disclosures of interest related to its development or recommendation to detect bias or discrimination in its use.	9.1 Clearly indicated policies describe the procedures for implementing, updating, revising, and removing artifacts. 9.2 Clearly indicated policies address conflict of interest. 9.3 Knowledge artifacts are consistently implemented with licensing agreements and any secondary use rights are explicit. 9.4 Knowledge artifacts are consistently implemented in ways that support equity in health and healthcare.

Implications for CDS Connect and Other Emerging CDS Systems

We mapped the trust attributes and recommendations against four functional use cases for a CDS ecosystem that the Patient-Centered CDS Learning Network provided (see ***Table 7***).

In some cases, the work of the TFWG did not result in a recommendation for every functional use case—thus, some cells are empty. In other instances, the same recommendation(s) was applied to multiple functional use cases.

Table 7: Recommendations for Trust Attributes per the Four Functional Use Cases

Trust Attribute	Authoring and Uploading CDS Content to CDS Connect	Inspecting and Comparing CDS Content on CDS Connect	Downloading and Using CDS Content on CDS Connect	Providing Feedback on CDS Use in Practice
Competency	▪ Authors have descriptions with background information including affiliations, years participating, and frequency of participation. (1.1) ▪ Authors are credentialed by an agreed-upon entity through education or training, experience, and dependability. (1.3) ▪ Competency should apply to both individuals and organizations. (1.5)	A *	Knowledge professionals are certified that they are competent in the knowledge management lifecycle, competently interpret, encode, and execute knowledge, and are competent of issues in conflict of interest. (1.4)	▪ Authors promote respect and dignity when providing feedback. (1.2) ▪ Competency should apply to both individuals and organizations. (1.5)
Compliance	▪ Knowledge artifacts provide human-readable and machine-readable forms (whenever applicable) as well as supporting references. (2.1) ▪ Knowledge artifacts are encoded using current standards for controlled medical terminologies, value sets, clinical data models, and knowledge representation formalisms. (2.3)		Knowledge artifacts are implemented in compliance with best practices for safe and effective implementation. (2.2)	B *

Trust Attribute	Authoring and Uploading CDS Content to CDS Connect	Inspecting and Comparing CDS Content on CDS Connect	Downloading and Using CDS Content on CDS Connect	Providing Feedback on CDS Use in Practice
Consistency	Authors take on responsibility of ensuring accurate knowledge translation and specification of a knowledge artifact. (3.1)	C *	D *	E *
Discoverability and Accessibility	▪ Knowledge is made accessible through search technology in conjunction with effective and helpful key terms. (4.1) ▪ References to supporting evidence are clearly labeled and linked (preferably deep linked) to relevant supporting information. (4.3) ▪ Data that inform an artifact can be found and accessed. (4.4)	Knowledge can be reliably searched for and found over time, so that users can find the same knowledge across successive versions. (4.2)		
Evidence-based	▪ Metadata indicate the date that evidence was originally published, and the date that evidence was last reviewed. (5.1) ▪ Metadata state any known limitations, restrictions, or exclusions to any given evidence. (5.2) ▪ Artifacts contain references to the evidence base on which they are based, including both narrative guidelines and the data supporting those guidelines. (5.3) ▪ Artifacts include metadata for all supporting citations. (5.4) ▪ Artifacts include evidence about its method (e.g., order set v. alert), usage history, and available outcomes. (5.5)			
Feedback and Updating	▪ Systems capture error logs and feedback about an artifact within the context of its use (e.g., EHR system, clinical setting, crash data etc.). (6.1) ▪ Metadata capture the dates an artifact was first and last published, with update dates in between. (6.3) ▪ Artifacts contain a auditable records of updates and changes over time. (6.4) ▪ Artifacts are updated based in part on feedback from operational performance over time. (6.5)			▪ Systems provide feedback mechanisms including means for users to ask questions about an artifact's context of use. (6.2) ▪ Authors provide bidirectional feedback to one another to rate (and improve) one another's work. (6.6)
Organizational Capacity	▪ Develop skills and capacity of staff, systems, and resources that support implementation, ongoing evaluation, feedback, communications, and governance. Include implementation guidance with artifacts that conveys the necessary resources to implement that artifact. (7.1) ▪ Knowledge artifacts include implementation guidance that conveys the necessary resources to implement that artifact. (7.2)			

Trust Attribute	Authoring and Uploading CDS Content to CDS Connect	Inspecting and Comparing CDS Content on CDS Connect	Downloading and Using CDS Content on CDS Connect	Providing Feedback on CDS Use in Practice
Patient-centeredness	Evidence that accounts for patient-level or patient-generated data is clearly indicated. (8.2)	Requirements for patient-level or patient-generated data input are clearly indicated. (8.1)	F *	▪ Evidence that accounts for patient-level or patient-generated data is clearly indicated. (8.2) ▪ Consent for use of patient-level or patient-generated data is clearly indicated. (8.3)
Transparency	▪ Clearly indicated policies describe the procedures for implementing, updating, revising, and removing artifacts. (9.1) ▪ Clearly indicated policies address conflict of interest. (9.2) ▪ Knowledge artifacts are consistently implemented with licensing agreements and any secondary use rights are explicit. (9.3) ▪ Knowledge artifacts are consistently implemented in ways that support equity in health and healthcare. (9.4)			

*See the related letter on ***page 16*** for considerations of absent recommendations.

Considerations of Gaps in the Functional Use Case Table

The following items reference the letters A-F in the empty cells in Functional Use Case Table (***Table 7***):

- **Competency (A)** in inspecting and comparing CDS content on CDS Connect—the functional use case of comparing CDS content in a knowledge repository—was not directly addressed by the TFWG. This competency is clearly a requirement for most if not all of the actors described in the CDS ecosystem. It may be missing because of the relative novelty of such repositories and, thus, people do not have a mental model for comparing knowledge artifacts. A post-hoc recommendation for this functional use case would be to show users of the knowledge repository a wide variety of information associated with each knowledge artifact such as number of downloads, user ratings, user feedback, artifact provenance, target clinical conditions or processes, implementation scenarios (workflow details, L4 screenshots), etc.
- **Compliance (B)** in providing feedback on CDS use in practice was not discussed directly by the TFWG. In this case, post-hoc recommendations could include the automatic submission of EHR performance data about the implemented CDS (firing rates, override rates, impact assessments) to the various stakeholders involved in authoring, implementing, and governing the use of knowledge artifacts in CDS.

- **Consistency (C, D, E)** in comparing CDS content, downloading artifacts, and providing feedback are use cases that also were not directly addressed by the TFWG. Post-hoc recommendations for these use cases might include establishing validated methods for comparing knowledge artifacts by impact and type: that is, standard methods to assess impact of CDS interventions such as measures for changes to intermediate process changes (override rates, number needed to remind, etc.), as well as using standard set of clinical outcomes measures of impact on patient safety, quality, or costs of care as a baseline measure set across all knowledge artifacts for CDS implementations.

- **Patient-centeredness (F)** in the functional use cases of comparing and downloading knowledge artifacts was not directly assessed by the TFWG. For the comparing knowledge artifacts use case, the patient-centeredness trust attribute is a subtle concept: how does one determine one artifact is more patient-centered than another? The post-hoc recommendation in this case is that measures or assessments of patient-centeredness for comparing knowledge artifacts warrant further research. We suggest that patient-centeredness is not a requirement for the use case of downloading knowledge artifacts.

Gaps in the functional use case table highlight areas for future work.

Discussion

In this study, a work group of the Patient-Centered CDS Learning Network was formed to examine the issue of trust in the creation, dissemination, and use of knowledge artifacts for CDS. These findings are to our knowledge the first time the essential ingredient of trust has been identified, and we have used them to further define 33 recommendations for building and maintaining trust in the CDS ecosystem across the nine trust attributes. These recommendations represent a set of principles that must be considered throughout the knowledge management lifecycle.

In the Results section we demonstrate how the trust attributes and recommendations can be mapped to the key functions of CDS ecosystems. Mapping reveals potential gaps in system design. For example, we did not initially articulate the need for competency in inspecting and comparing CDS content, though this is clearly an issue. Gaps also point to areas where future capabilities might be developed. Providing automatic submission of EHR performance data about the implemented CDS to specific people would be a major step toward supporting compliance but remains aspirational for available systems. We also note that patient-centeredness in downloading capabilities needs further attention such as providing robust means for patients to compare and contrast artifacts for personal use or

using metadata that inform potential users in the ways that evidence is patient-centered. Mapping attributes and recommendations also reveals efficiencies where specific actions might address a trust attribute for multiple functions. Recommendations for robust evidence, for example, would address the needs for trustworthiness across all functional use cases.

Notably, the TFWG did not generate a trust attribute relating to security or privacy. We expect that future work will focus on these concepts given the importance that both have for building (or losing) trust among actors of all types.

As a final consideration of the utility of the attributes and recommendations, we discuss here their applicability to the Leaning Network's Analytic Framework for Action [11] that defines the principal components of a Learning Health System: evidence, authoring, implementing, and measuring the use of patient-centered CDS in healthcare delivery. We discuss each attribute and associated recommendations in this context (see ***Table 8***):

Table 8: Analytic Framework for Action and Trust Attributes

Analytic Framework for Action	Related Trust Attributes
Evidence	Evidence-based, Patient-centeredness
Authoring	Competency, Consistency, Discovery and accessibility
Implementing	Organizational capacity, Compliance, Transparency
Measuring	Feedback and updating

Evidence: Trust in these recommendations has to do with how solidly each recommendation is evidence-based first and foremost. This may mean that there is a formal evidence-rating system used to assess and weigh the quality of the evidence being used to create a clinical guideline, or ultimately a knowledge artifact for CDS. The evidence should be interpreted and applied in a patient-centered manner for the decision context at hand: it should be applicable to the unique patient data and context, and incorporate either patient preferences, patient-reported outcomes, or other patient-generated data where appropriate. The implications for maintaining and building trust in clinical systems are significant in that they may imply a common metadata schema across public and private knowledge repositories, a direct linkage to primary source documentation (evidence), and an ability to determine that the evidence applies to the patient context at hand.

Mapping the 9 trust attributes to the AFA's core elements informs how to promote trust in CDS.

Authoring: The essential trust attributes surrounding authoring have to do with the qualifications and performance of artifact authors, as well how they reliably implement knowledge artifacts that lead to consistency in use as CDS. The implemented knowledge artifact must be true to the evidence from which it is derived—any assumptions made, localizations, or deviations from the guideline logic (expected data inputs, triggers, outputs, or workflows, etc.) must be clearly noted in the artifact. Competency may be assessed by a governing body such as a professional society certification, federal agency, vendor certifications, state clinical licensure boards, as well as by experience and track record (measured artifact performance) for an author. Consistency relates to the

reliable and consistent performance of an implemented knowledge artifact as CDS across disparate implementations of health IT as well as across different systems. Finally, the evidence trail, or the provenance of a knowledge artifact, should be traceable to the sources whether they be a clinical guideline, or other source documentation.

Implementing: As a knowledge artifact moves from authoring to implementing, the health system (inclusive of care delivery system, as well as the contracted IT vendors, knowledge vendors, implementers, etc.) must have the capacity to safely and effectively implement CDS, monitor its use, and keep the implemented CDS up to date. This is essential to build and maintain the capacity underlying a Learning Health System. Further, the implemented knowledge artifact must be implemented in a manner both compliant with the current best practices for knowledge representation standards (terminology, ontologies, value sets, etc.), as well as best practices for CDS implementation [9] of the right information, to the right people, via the right intervention formats, the right channels, and at the right workflow). As with authoring, full transparency must exist in the implementation to capture any assumptions made, deviations from guideline evidence logic, or other changes in data structures used in the CDS. Implementation details must be fully transparent and should be captured and made accessible to users or governance bodies for inspection. Transparency may also include the ability to test a knowledge artifact on a standard clinical data set, or even a potential implementation site's clinical data, to evaluate potential performance before clinical implementation.

Measuring: Finally, the most critical component of a Learning Health System is the capacity to provide feedback on the implemented knowledge artifact or CDS from the vantage point of any user: whether that be physician, nurse, or other member of the care team, as well as the patient him or herself. This process of measuring CDS impact on both intermediate processes as well as near-, and long-term clinical, and other, outcomes, is not typically done yet in health IT. Feedback may occur at multiple levels: from a user to the system implementers, to the CDS author, IT system designers, and potentially even to the creators of the primary evidence. Feedback may occur both at the individual patient level, as well as the population level. In this way, refinement can occur to the implemented CDS to perform better in the clinical workflow, the underlying logic to better fit the decision context, and in the aggregate be monitored for untoward effects much like a drug may be monitored in post-marketing surveillance or population health agencies may monitor health disparities

Factoring trust is critical to successful CDS implementations and sustainability.

Future Work

We anticipate future work in trust for CDS knowledge artifacts will refine the trust attributes themselves, and the recommendations, based on real-world experience. We anticipate that further work will explore potential trust

attributes related to privacy and security. Finally, we hope to develop methods (assessment instruments or rating scales) that may be based upon these attributes to develop a trust metric for knowledge artifacts.

Limitations

The TFWG process took advantage of an opportunistic sample of stakeholders in the broad field of health IT. Thus, it may not be a representative sample and opinions of voluntary stakeholders may be biased. Similarly, the 9 attributes across three domains we considered have not been validated with an independent assessment nor have they been used prospectively in practice to assess their impact on the use, or sharing, of knowledge artifacts.

Conclusion

The idea of sharing knowledge for CDS has been a pursuit for decades [12, 13]. With the broad adoption of EHR technologies, it imperative—and technologically possible—that knowledge be readily shared in computable forms to enable CDS to help derive the value proposition predicted with EHR adoption. We describe a CDS ecosystem, the actors in it, and roles they play in generating, translating and specifying, and implementing knowledge for CDS. In this ecosystem, increasing the trust between actors would reduce some of the barriers and facilitate the realization of sharing computable CDS to improve health. Through the work of the TFWG, we define trust attributes that can help facilitate building and maintain trust among the actors in the CDS ecosystem, and in knowledge artifacts and their use. The attributes and recommendations can inform the development and sustainability plans of CDS sharing platforms. We recognize that some recommendations will be straightforward to implement, while others are more aspirational. As systems mature, however, we hope that the CDS ecosystem continues to grow as a trusted and trustworthy movement toward better health for all.

Acknowledgements

We would like to acknowledge the funding from Agency for Healthcare Research and Quality Cooperative Agreement (U18 HS024849) that made the TFWG's work possible.

The opinions expressed in this document are those of the authors and do not reflect the official position of AHRQ or the U.S. Department of Health and Human Services.

References

1. Cabitza F, Simone C, Sarini M. Knowledge Artifacts as bridges between theory and practice: The Clinical Pathway case. Knowledge Management in Action 2008; 270:37-+.
2. Wright A, Goldberg H, Hongsermeier T, Middleton B. A description and functional taxonomy of rule-based decision support content at a large integrated delivery network. J Am Med Inform Assoc 2007; 14(4):489-96.
3. Patient-Centered Outcomes Research Institute (PCORI). Establishing the definition of patient-centered outcomes research Washington, DC: Patient-Centered Outcomes Research Institute; 2012 [updated July 15, 2014; cited 2018 September 12]; Available at: https://www.pcori.org/establishing-definition-patient-centered-outcomes-research.
4. Luhmann N. Trust and Power: John Wiley & Sons, 2018.
5. Bresnick J. Success of AI in healthcare relies on user trust in data, algorithms. Health IT Analytics 2018.
6. Couzin-Frankel J. Trust me, I'm a medical researcher. Science 2015; 347(6221):501-3.
7. Harris B. 4 ways health IT can build trust. Healthcare IT News 2013.
8. Hall MA, Dugan E, Zheng B, Mishra AK. Trust in physicians and medical institutions: what is it, can it be measured, and does it matter? The Milbank Quarterly 2001; 79(4):613-39.
9. Osheroff JA, Teich JM, Levick D, *et al.* Improving outcomes with clinical decision support: An implementer's guide. Chicago, IL: HIMSS Press, 2012.
10. Boxwala AA, Rocha BH, Maviglia S, *et al.* A multi-layered framework for disseminating knowledge for computer-based decision support. J Am Med Inform Assoc 2011; 18 Suppl 1:i132-9.
11. Marcial LH, Richardson JE, Lasater B, *et al.* The Imperative for Patient-Centered Clinical Decision Support. EGEMS (Wash DC) 2018; 6(1):12.
12. Middleton B, Sittig DF, Wright A. Clinical decision support: A 25 year retrospective and a 25 year vision. Yearb Med Inform 2016; Suppl 1(Suppl 1):S103-16.
13. Sonnenberg FA, Hagerty GG. Computer-interpretable clinical practice guidelines. Where are we and where are we going? Yearbook of Medical Informatics 2006:145-58.