Recommendations for Trust in Clinical Decision Support Knowledge Artifacts

Trust Framework Work Group
Acknowledgements
Thank you to the TFWG members

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

Thanks to the Agency for Healthcare Research and Quality for its support via a Cooperative Agreement (U18 HS024849).
Why Trust Matters
To Build Trust In Artificial Intelligence
IBM Wants Developers To Prove Their Algorithms Are Fair

You know how you can trust your car’s brakes to work? Researchers want you to trust AI like that.

U.S. Preventive Services Task Force
STANDARDS FOR GUIDELINE DEVELOPMENT

GUIDES CHECKLIST

SUCCESSFUL IMPLEMENTATION OF GUIDELINES WITH CDS REQUIRES:

- Enabling CDS context
- Appropriate CDS content
- Effective CDS system
- Effective CDS implementation

CLINICAL PRACTICE GUIDELINES WE CAN TRUST

INSTITUTE OF MEDICINE

THE PRECISION MEDICINE INITIATIVE

2018
Trust matters
Trust for CDS

• Trust is inherently relational
  • Needed in contexts of vulnerability or uncertainty (Hall et al, 2002)
• Legal frameworks are new and governance is unclear (Hongsermeier et al 2010)
• Ethics of care focuses on relationships (Pols, 2014)
• CDS ecosystem involves people with diverse roles
  • Technical development of PCCDS artifacts and platforms
  • Clinical care
  • Patient experience
Developing Trust Recommendations for CDS Knowledge Artifacts
The TFWG was chartered to make recommendations

**Goal**
Address the AFA’s external factors regarding trust barriers and facilitators for the exchange of clinical knowledge and use of CDS

**Key Deliverables**
- One or more use cases identifying the barriers and facilitators to operationalizing a trust framework
- A white paper with recommendations for achieving fair, equitable, transparent, and trustworthy operations for contributing to and managing CDS repositories, including CDS Connect.
The work was carried out in six stages

<table>
<thead>
<tr>
<th></th>
<th>Research</th>
<th>Develop a shared understanding in trust and CDS</th>
<th>Presented background webinar (Dr. Platt)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td></td>
<td>Developed an online bibliography</td>
</tr>
<tr>
<td></td>
<td>Roles</td>
<td>Define Actors within a CDS ecosystem</td>
<td>Conducted group discussions</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td>Surveyed TFWG members</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Presented to CDS Connect WG</td>
</tr>
<tr>
<td></td>
<td>Relationships</td>
<td>Describe relationships between actors</td>
<td>Conducted group discussions</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td></td>
<td>Completed matrix exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Define trust attributes among actors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recommend</td>
<td>Develop recommendations to address trust attributes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Map recommendations to CDS functions (not covered)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Recommendations for trust were applied to four “Functional Use Cases”

- Authoring and uploading CDS content
- Inspecting and comparing CDS content
- Downloading and using CDS content
- Providing feedback on CDS use

CDS Connect
Recommendations for Trust
We identified 12 actors in a CDS ecosystem
We identified 9 “trust attributes” in a CDS ecosystem

<table>
<thead>
<tr>
<th>Competency</th>
<th>Compliance</th>
<th>Consistency</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Graduation Cap" /></td>
<td><img src="image" alt="Checklist" /></td>
<td><img src="image" alt="Clock" /></td>
</tr>
<tr>
<td>Discoverability and Accessibility</td>
<td>Evidence-based</td>
<td>Feedback and Updating</td>
</tr>
<tr>
<td><img src="image" alt="Magnifying Glass" /></td>
<td><img src="image" alt="Balance" /></td>
<td><img src="image" alt="Sound" /></td>
</tr>
<tr>
<td>Organizational Capacity</td>
<td>Patient-centeredness</td>
<td>Transparency</td>
</tr>
<tr>
<td><img src="image" alt="Carriage Wheels" /></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. Competency

An actor is deemed to be competent in the role they play 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 lifecycle, competently interpret and execute knowledge, and are competent of issues in conflict of interest.

1.5 - Competency should apply to both individuals and organizations.
2. 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.
3. 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.
4. Discoverability and 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 policy makers.
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.
5. Evidence-based

The evidence instantiated within an artifact must apply to the clinical condition that 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.
6. 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 Implementers, Knowledge Engineers, Knowledge Authors, etc.).
Recommendations

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 bi-directional feedback to one another so to rate (and improve) each other’s work.
7. 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.
8. Patient-centeredness

A knowledge artifact should whenever possible leverage patient-centered outcome research findings and/or patient-specific information (e.g. 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.
9. Transparency

A knowledge artifact should be applied and used ethically clearly convey all potential conflicts of interest and disclosures of interest related to its development or recommendation so to detect bias or discrimination in its use.
Recommendations

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.
We applied recommendations to the four use cases

Full Results Available at pccds-ln.org/tfwg

<table>
<thead>
<tr>
<th>Trust Attribute</th>
<th>Authoring and Uploading CDS Content to CDS Connect</th>
<th>Inspecting and Comparing CDS Content on CDS Connect</th>
<th>Downloading and Using CDS Content on CDS Connect</th>
<th>Providing Feedback on CDS Use in Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence-based</td>
<td>▪ Metadata indicate the date that evidence was originally published, and the date that evidence was last reviewed. (5.1)</td>
<td>▪ Metadata state any known limitations, restrictions, or exclusions to any given evidence. (5.2)</td>
<td>▪ Artifacts contain references to the evidence base on which they are based, including both narrative guidelines and the data supporting those guidelines. (5.3)</td>
<td>▪ Artifacts include metadata for all supporting citations. (5.4)</td>
</tr>
</tbody>
</table>
Discussion
Explicitly addressing trust in knowledge artifacts is a novel effort

Trust matters for promoting knowledge sharing

Trust attributes and recommendations provide stakeholders with discussion points, and can be the foundation for future work

- Checklists, ‘Trust’ measures
- Establishing governance for trust
Future Efforts

▪ Applying in practice
  – Develop a “Product Information Label” for knowledge artifacts
  – Experiments in crowdsourcing, e.g. Cochrane Crowd

▪ Engaging stakeholders
  – AHRQ CDS Connect and other Repositories
  – FDA on Certification of Software as a Medical Device
  – MCBK
  – PCCDS Learning Network stakeholders
  – Vendors

▪ Develop and disseminate the work for academic consideration
Limitations

- Opportunistic sample of stakeholders, potential bias
- Trust Attributes not validated beyond development
- Nor prospectively assessed in practice to assess impact prospectively on sharing
- Future work to further define methods to support trust
Conclusions

- Trust is essential for the sustainability of shareable CDS within a CDS ecosystem
- Considering actors and their relationships inform matters of trust within the CDS ecosystem
- TFWG recommendations provide “trust attributes” that actors can use to engage in discussions for sharing CDS artifacts (and knowledge)
Questions

TFWG Contact Information:

▪ Blackford Middleton, MD, MPH, MSc - Chair -
  blackford.middleton@apervita.com

▪ Jodyn Platt, PhD, MPH - Co-chair - jeplatt@umich.edu

▪ Joshua E. Richardson, PhD, MS, MLIS - Co-chair – jrichardson@rti.org

www.pcorcds-ln.org/tfwg