

STAKEHOLDER CENTER PROGRESS REPORT

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CDSiC Stakeholder Community and Outreach Center: Quarterly Report

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Introduction

NORC at the University of Chicago (NORC) is pleased to submit the first quarterly report to the Agency for Healthcare Research and Quality (AHRQ) on the Clinical Decision Support Innovation Collaborative (CDSiC) Stakeholder Community and Outreach Center (Stakeholder Center). This quarterly report provides a summary of the status of all Center-level and Workgroup activities conducted within the CDSiC Stakeholder Center from January 2022 to June 2022.

The CDSiC seeks to integrate diverse perspectives to make clinical decision support (CDS) more valuable and meaningful to patients, clinicians, and healthcare systems. Products put forth by the CDSiC will provide resources that promote the adoption of patient-centered CDS (PC CDS) to facilitate whole-person, evidence-based care and improve patients' health and care experience. Ultimately, the CDSiC aims to create a world where patients, caregivers, and clinicians have the information needed to make decisions that improve health and well-being for all individuals.

The report begins with background on the Stakeholder Center's purpose and goals, then details developments and updates related to the work of the Stakeholder Center Planning Committee and Workgroups.

Background

CDS effectively and efficiently delivers evidenced-based recommendations at the point of care to support informed health-related decision-making.ⁱ Despite advances in clinical and medical informatics and the CDS ecosystem, the ability of CDS to support clinicians in developing care plans that align with patient preferences as well as patients in becoming active participants in health care decisions is limited. By disseminating patient-centered outcomes research (PCOR) evidence, PC CDS promises to shift clinical guidelines and practice to enable patient empowerment and direct involvement of patients in their own health care decisions, and to ultimately improve outcomes.ⁱⁱ

While still a relatively new term, the definition of PC CDS has evolved over recent years as stakeholders have sought to describe and refine the concept. The AHRQ Patient-Centered CDS Learning Network (PCCDS Learning Network) laid the foundation for PC CDS, defining PC CDS as "CDS that supports individual patients and their approved caregivers and/or care teams in health-related decisions and actions by leveraging information from patient-centered outcomes research (PCOR) findings and/or patient-specific information."ⁱⁱⁱ Since then, AHRQ has expanded the definition of PC CDS to include clinical decision support that supports care for individual patients (or specific patient populations) and satisfies any of the four patient-centered criteria:

- **Knowledge.** PC CDS fosters evidence-based research findings for comparative effectiveness research (CER) and PCOR.

- **Data.** PC CDS uses patient-generated health data, patient-reported outcomes and preferences, patient-specific data (i.e., labs, medications); and/or social determinants of health (SDOH) data that affect individual patient health.
- **Delivery.** PC CDS directly engages patients or caregivers via apps or patient portals in different settings (e.g., at home, in the community, or in a doctor's office).
- **Use.** PC CDS includes patient and/or caregiver involvement in understanding and applying the decision support provided.

While PC CDS is a promising tool to advance patient-centered care and improve health outcomes, the field is relatively new and several challenges hinder its broad adoption. These challenges include technical barriers to standardization of PC CDS data elements, workflows, and measures; data collection and standardization discrepancies in patient-generated health data; limited involvement of patients in related research; limited understanding of patient decision-making processes; and lack of clinical effectiveness data on PC CDS interventions.^{iv,v}

To help address these barriers, the CDSiC aims to advance the current state of evidence for PC CDS through engagement of diverse stakeholders. The following sections provide an overview of the CDSiC and Stakeholder Center updates.

CDSiC Overview

Through the CDSiC, the NORC team, in partnership with AHRQ, will build upon the strong foundation in PC CDS set by AHRQ to advance the translation of PCOR findings into practice. Below we present the Vision and Mission Statements for the CDSiC.

Vision Statement: A world where patients, caregivers, and care teams have the right information at the right time to make evidence-informed decisions that improve health and well-being for all individuals.

Mission Statement: CDSiC aims to advance the design, development, dissemination, implementation, use, measurement, and evaluation of evidence-based, shareable, interoperable, and publicly available PC CDS to improve health outcomes of all patients by creating a proving ground of innovation. To achieve this, CDSiC will:

- Create a learning community to share and advance the knowledge, tools, standards, frameworks, and techniques for designing, developing, implementing, using, measuring, and evaluating high-quality, PC CDS.
- Promote the practice and adoption of PC CDS that facilitates whole-person care and considers the patient, caregivers, and clinician workflows, preferences, and values around shared decision-making.
- Advance standards-based PC CDS that can be shared with patients, caregivers, clinicians, healthcare organizations, and health IT developers across the U.S. and result in measurable improvements in healthcare, patient health, patient care experience, and provider experience.

Stakeholder Center Overview

The Stakeholder Center and its four Workgroups provide CDSiC's thought leadership—developing products that advance CDS for the broader community, guiding the overall work of the CDSiC (in partnership with the CDSiC Operations Center Steering Committee), and offering input on projects the CDSiC Innovation Center develops. Critically, the Stakeholder Center includes various stakeholders in CDSiC activities, consistent with the mandate established by Section 6301 of the Affordable Care Act for AHRQ to engage and obtain feedback from diverse stakeholders.^{vi}

The Stakeholder Center's activities primarily focus on the four Workgroups and the development of products. The objectives of the Stakeholder Center are outlined below:

- Establish four stakeholder-led Workgroups focused on key topic areas: 1) CDS Outcomes and Objectives, 2) Scaling, Measurement and Dissemination of CDS, 3) Trust and Patient-Centeredness, and 4) CDS Standards and Regulatory Frameworks.
- Develop 12 high-quality, written products across the four Workgroups that will inform the activities of the CDSiC Innovation Center and support the external community in advancing the development, implementation, and measurement of CDS to reach short- and long-term CDS goals.
- Provide thought leadership across CDSiC in conjunction with the CDSiC Steering Committee to inform the direction of the collaborative and its work products.

Through its Workgroups, the Stakeholder Center will create a forum where members representing varied perspectives within the CDS ecosystem can tackle persistent CDS challenges, foster innovation, and accelerate uptake of CDS within the U.S. healthcare system. Workgroups will develop products to advance CDS and, in collaboration with the CDSiC Innovation Center, will help review and recommend CDS concepts for demonstration in real-world applications.

Stakeholder Center Leadership Structure

The Stakeholder Center consists of two leadership components: 1) Center leadership, including a Stakeholder Center Planning Committee, which will provide oversight, and 2) four topic-focused Workgroups that will be dedicated forums for stakeholder engagement and product development.

Stakeholder Center Leadership. Priyanka Desai from NORC and Elizabeth Cope from AcademyHealth co-lead the Stakeholder Center. They work collaboratively with Workgroup leadership to ensure that each Workgroup provides meaningful input to CDSiC activities and creates products to help advance CDS development and implementation. Additionally, they provide operational leadership and establish logistics, expectations, and staffing for each Workgroup. Desai and Cope, along with CDSiC Principal Investigator (PI) Prashila Dullabh, Co-Investigators Dean Sittig and David Lobach, Workgroup Chairs and Associate Leads (see below), and AHRQ project leadership form the Stakeholder Center Planning Committee.

Workgroup Leadership. Each Workgroup is led by a dedicated Chair and Associate Lead (see Exhibit 1). Workgroup leads set the overall direction for the development of Workgroup products, facilitate meetings, manage product development, and communicate regularly with Stakeholder Center leadership.

Exhibit 1. Workgroup Leadership

Workgroup	Leadership
CDS Outcomes and Objectives	Chair: Gilad Kuperman, MD, PhD (Memorial Sloan Kettering Cancer Center) Associate Lead: Karen Nanji, MD, MPH (Massachusetts General Hospital, Harvard Medical School)
CDS Standards and Regulatory Frameworks	Chair: Aziz Boxwala, MD, PhD, FACMI (Elimu Informatics) Associate Lead: Rachel Richesson, PhD, MPH, MS (University of Michigan)
Scaling, Measurement, & Dissemination of CDS	Chair: Jerome Osheroff, MD, FACP, FACMI (TMIT Consulting) Associate Lead: Adam Wright, PhD, FACMI, FAMIA, FIAHSI (Vanderbilt University)
Trust and Patient-Centeredness	Chair: Tonya Hongsermeier, MD, MBA (Elimu Informatics) Associate Lead: Angela Dobes, MPH (Crohn's & Colitis Foundation)

Status Report

The status report provides updates on progress of the activities of the Stakeholder Center from January through June 2022, including the establishment of a Stakeholder Center Planning Committee and four Workgroups as well as development of three product ideas for each Workgroup. The status report also describes upcoming activities.

Stakeholder Center Planning Committee

The Stakeholder Center established a Planning Committee comprised of Stakeholder Center Leads, AHRQ project officers, the CDSiC PI and Co-Investigators, and Workgroup Chairs and Associate Leads. The Planning Committee first convened in January 2022 with additional meetings in March and May 2022. The Committee meets once every other month to provide input on the overall strategic direction and coordination of the Stakeholder Center as well as the collaborative as a whole.

This input involves:

- Meeting regularly to provide strategic guidance and direction on key decisions that relate to the Workgroups, the CDSiC Innovation Center, or the collaborative.
- Facilitating cross-Workgroup synergy and coordination through regular communication.
- Providing strategic input into Operations Center and Innovation Center activities based on Workgroup activities.

Thus far, the Planning Committee has focused on defining parameters of each Workgroup's scope, establishing selection criteria for Workgroup products, and ensuring that Workgroup products are synergistic without overlapping in their proposed activities.

Stakeholder Center Workgroups

The four Stakeholder Center Workgroups are tasked with developing three written products each—for a total of 12 products—that advance the CDS field in the first two years of the CDSiC. The target audience for Workgroup products may vary by resource, but broadly include patients/caregivers and their care team, clinicians, CDS researchers, CDS content developers, CDS vendors, policymakers, and payers.

To ensure that the Workgroup products reflect diverse perspectives and needs and are of utility to the CDS field as well as patients and their care teams, the CDSiC project team recruited 44 Workgroup members who bring a range of experience and expertise. Workgroup members include patient representatives and advocates, clinicians, informatics researchers, payors, CDS developers, and federal regulatory agency representatives.

Workgroup activities officially began in March 2022, with the Stakeholder Center Kickoff Meeting. Individual Workgroup meetings began in April 2022.

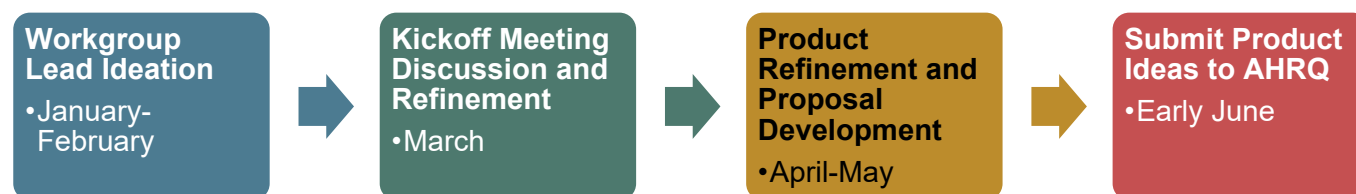
Stakeholder Center Kickoff

On March 22 and 23, 2022, the CDSiC project team held the virtual Stakeholder Center Kickoff Meeting to officially welcome and orient Workgroup members to the CDSiC. All eight Workgroup leads and 37 Workgroup members attended the meeting. The meeting's purpose was to provide an overview of the CDSiC project and to generate discussion and collaboration between Workgroup members on their Workgroup's scope and objectives, potential product ideas, and dissemination activities.

Product Development Process

CDSiC Workgroups participated in a multi-step process to brainstorm ideas for potential products (Exhibit 2).

Exhibit 2. Workgroup Product Development Process



Starting in January 2022, Workgroup leads generated up to five initial product ideas based on the scope of their respective Workgroups in collaboration with Stakeholder Center and CDSiC leadership. These product ideas were used to guide discussions during the March Stakeholder Center Kickoff

Meeting. All four Workgroups brainstormed and refined initial product ideas during the meeting. Following the meeting, Workgroup leads worked the Stakeholder Center support team to further refine product ideas in preparation for Workgroup meetings in April. In May, Workgroups leads worked collaboratively with Workgroup members to further refine product ideas and develop product proposals for 12 products (three per Workgroup). The products varied in terms of expected length of time to complete based on scope, falling into one of three Levels. Level 1 projects are the largest in scope, involving significant effort. Level 2 projects involve a medium amount of effort. Level 3 projects are shorter-term activities. The product proposals were submitted to AHRQ in June 2022. Summaries of Workgroup scope and potential products are provided below.

1. CDS Outcomes and Objectives

An important aspect of PC CDS research is to understand if and how PC CDS interventions have impacted healthcare decision-making, the patient experience, and patient outcomes.^{vii} However, there is limited research on PC CDS that measures these substantive targeted outcomes.^{viii} Conducting this type of research requires a clear understanding of what measures are appropriate to examine the safety and effectiveness of patient-centered decision support tools.

The CDS Outcomes and Objectives Workgroup is tasked with addressing this gap by exploring what PC CDS is ultimately meant to accomplish. In particular, the CDS Outcomes and Objectives Workgroup is identifying and examining measurement criteria that will allow us to understand the impact of PC CDS on outcomes important to patients, caregivers, and care teams. The reports, resources, and tools created by this Workgroup will support the CDSiC and the broader CDS community in advancing the translation of PCOR-based evidence through PC CDS. Exhibit 3 summarizes the proposed products for this Workgroup.

Exhibit 3. CDS Outcomes and Objectives Workgroup Proposed Products

Product Title	Description
Analysis of Most Appropriate Outcome Measures for PC CDS (Level 1)	Although a broad set of outcome measures exist for clinician-centered CDS, it is not clear which of those measures may be appropriate for PC CDS. Furthermore, there is not a comprehensive catalog of the tools that might be used to measure appropriate outcome measures for PC CDS nor a research agenda to make recommendations where improvements are needed. This analysis will review all the current clinician-centered CDS measures to determine which are appropriate for PC CDS. This product will also attempt to identify new sets of PC CDS outcome measurement categories – not yet identified in medical or public health scenarios – that take into consideration the participation of the patient in the clinical decision-making process.

Product Title	Description
Taxonomy for Patient Preferences That Are Relevant to PC CDS (Level 3)	Taking patient preferences into account is critical to the acceptance of PC CDS and assuring that the outcomes of PC CDS are realized; however, there is no common understanding of what constitutes preferences. The goal of this product is to identify and categorize the preferences that may be relevant to PC CDS, with an emphasis on context-independent preferences. The organized and categorized scheme of preferences will be presented as a taxonomy to support developers in incorporating patient preferences into PC CDS interventions.
Framework for Understanding the Role of PC CDS in Supporting Shared Decision-Making (Level 3)	Shared decision-making (SDM) is a key outcome of PC CDS. This product will describe the complexities and considerations around advancing SDM with the use of PC CDS. Currently, it is unclear to what extent PC CDS could support some or all aspects of a SDM process (i.e., available options, the provider's knowledge and experience, and the patient's values and preferences). This product will include a review of SDM models, a framework that crosswalks PC CDS and SDM components highlighting how PC CDS can support each element of SDM, and a research agenda for further study.

2. CDS Standards and Regulatory Frameworks

CDS standards set ways of defining data elements, which allow CDS artifacts to be shared, integrated, and implemented in various systems. Without them, consistency and interoperability would be impossible as many of the healthcare systems work in siloed health IT systems. While many standards are available, new innovations in PC CDS, such as the use of data directly from patients and the use of artificial intelligence, may require additional standards development and regulatory considerations.

The Standards and Regulatory Frameworks Workgroup is identifying, monitoring, and promoting standards for the development of PC CDS. The Workgroup will also recommend ways to enhance existing standards and identify areas where new standards and regulatory frameworks are needed. The reports, resources, and tools developed by the Workgroup will support the creation of standards-based PC CDS that can be scaled across systems to support patients and clinicians in making evidence-informed healthcare decisions. Exhibit 4 summarizes the proposed products for this Workgroup.

Exhibit 4. CDS Standards and Regulatory Frameworks Workgroup Proposed Products

Product Title	Description
Standards and Regulatory Frameworks Environmental Scan (Level 1)	Infrastructure that supports shareable, scalable, and standards-based CDS is a necessary step in the broader movement to transition towards value-based, person-centered care. This environmental scan of standards and regulatory frameworks for PC CDS will examine the current state of standards, regulatory frameworks, and technical barriers and will identify salient gaps, opportunities, and challenges to support development of interoperable PC CDS. The report will culminate in recommendations and an action plan for addressing identified barriers.

Product Title	Description
Improving Interoperability of Patient Apps with the Health Information Technology (Health IT) Ecosystem (Level 2)	Clinicians are increasingly recommending and prescribing apps to patients to help manage clinical conditions; however, apps' limited integration with electronic health records (EHRs) and other technologies in the health IT ecosystem (e.g., Health Information Exchanges [HIEs], analytic platforms, personal health data platforms, population health management tools, care management tools) can cause many issues with the quality of care and the burden on providers and patients. The proposed product is a written report that describes the needs and potential approaches to addressing the lack of interoperability between the EHR and other health IT systems used by healthcare providers and patient apps. The report will describe the current state of integration and the existing standards and regulations; the impact of inadequate integration; common scenarios in which integration is needed, with accompanying data flow diagrams; and a call for creating standards or regulations to fill the needs of PC CDS, including an action plan and recommendations for improving interoperability.
Advancing Standardized Representations for Patient Preferences and Values to Support Scalable and Patient-Centered CDS Report (Level 3)	Both clinician and patient-directed CDS apps will require data that is relevant to patients' specific situations, needs, values, and preferences; however, there is no standard for representing or integrating this information into CDS applications. This product will be a report on the current state of content adoption and use of data standards for collecting and using patient preference data to guide PC CDS, accompanied by a set of recommendations to address any gaps or implementation barriers for these standards. It will summarize currently available data standards that can represent patient preferences and other types of patient-contributed health data and clarify their consistent implementation and optimal use. It will also summarize approaches and best practices for soliciting, documenting, and storing data related to patient preferences, both disease-specific and regarding general health and wellness.

3. *Scaling, Measurement, and Dissemination of CDS*

While CDS tools support clinicians with decision-making, broad uptake of CDS has been modest and largely limited to clinicians. Advancing CDS within our healthcare systems requires measures to determine that CDS tools not only work as intended, but also aid patients.

The Scaling, Measurement, and Dissemination of CDS Workgroup is addressing this need by assessing and recommending measures of CDS adoption, implementation, and use, with a particular focus on CDS that supports patients in healthcare decisions. In developing such guidance, this Workgroup encourage scaling safe and effective CDS tools beyond one-off settings. The reports, resources, and tools created by this Workgroup will consider factors such as how PC CDS affects the patients' navigation of decision-making processes and how well it captures and responds to patient preferences. Ultimately, the Workgroup will help demonstrate the value of CDS in delivering patient-centered and value-based healthcare. Exhibit 5 summarizes the proposed products for this Workgroup.

Exhibit 5. Scaling, Measurement, and Dissemination of CDS Workgroup Proposed Products

Product Title	Description
PC CDS Implementation Description Framework (Level 2)	Although there is a substantial and growing literature describing CDS implementations, inconsistent reporting on CDS interventions makes it difficult to synthesize and leverage implementation information to provide evidence-based guidance on applying CDS to improve care processes and outcomes. The product will provide a standard approach for describing how patient-centered CDS interventions are designed, developed, deployed, used, maintained, and evaluated. This product extends and complements earlier CDS frameworks and checklists through its explicit focus on patient-centered CDS.
Catalog of Approaches Used to Measure Workflow Impact of PC CDS Interventions (Level 3)	Clinician burnout is a growing problem associated with many CDS interventions. Relatively little is known across studies about how CDS interventions affect clinical workflows, and even less is known across studies about the impact on patient activities or “life flows”. This product will identify how organizations are measuring PC CDS effects on workflows/life flows, with a focus on workflow impacts for care team members involved in PC CDS interventions, patients and care teams engaged in shared decision-making, and patients and caregivers utilizing patient-facing PC CDS. This broad survey of how PC CDS workflow effects are being assessed will lay the foundation for subsequent efforts to more robustly analyze and improve PC CDS effects on specific workflows of interest.
PC CDS Performance and Value Measurement Guide (Level 1)	Evaluating PC CDS intervention development, implementation, and performance is key to supporting understanding and maximizing the intervention’s impact. However, measures used to analyze CDS performance and implementation are not well-standardized. The product will provide recommendations on strategies and measures for evaluating the performance and value of PC CDS interventions, with a particular focus on patient interactions. This guide will include recommended measurement and evaluation frameworks, approaches, and measures for evaluating each step of the PC CDS development and implementation process, as well as patient-oriented process outcomes and the care process effects these interventions produce.

4. Trust and Patient-Centeredness

To ensure optimal use of PC CDS tools and products, tools must support the values and preferences of patients. Without transparent development processes, patients and their caregivers may not trust the accuracy and safety of PC CDS tools, hindering the ability of PC CDS to support patients and their care teams. Use of clear and understandable evidence to inform CDS tools may address patient and provider concerns.

The Trust and Patient-Centeredness Workgroup is working to increase transparency in the processes of CDS design, development, testing, implementation, and use. To do this, the Workgroup focuses on the development and dissemination of trust-building CDS products with an emphasis on CDS that reflects the needs of patients and clinicians and supports shared decision-making between patients and

their care teams. The reports, resources, and tools developed by the Workgroup will support the design and uptake of trustworthy PC CDS. Exhibit 6 summarizes the proposed products for this Workgroup.

Exhibit 6. Trust & Patient-Centeredness Workgroup Proposed Products

Product Title	Description
Handbook for Incorporation of Patient-Centered Inputs into CDS Artifact Development (Level 3)	CDS development has traditionally not included patient-centered inputs, such as patient preferences, values, goals, health literacy, and social determinants of health. This product will be a handbook for developers on best practices for incorporating patient-centered inputs into CDS development. The handbook will be informed by a landscape analysis focused on identification of the types and characteristics of CDS artifacts and interventions that would benefit most from patient-centered input, with a particular focus on artifact and CDS intervention development.
Best Practices and Methodology for Patient-Centered Co-design and Co-deployment of PC CDS Artifacts and Interventions (Level 1)	Co-design strategies are a potential model for ensuring patient-centered approaches that could be applied to CDS design and deployment. This product will outline recommended best practices to promote patient partnerships in co-design and co-deployment of PC CDS. This recommendations report will document how best to engage patients across the PC CDS continuum from planning and designing, to building and testing, and through deployment and adoption phases of work. The product will also highlight specific practices that have proven effective in past and will detail any information relevant to adapting the practices for us in new contexts.
Root Cause Analysis and Recommendations for Mitigation of Mistrust in CDS Artifacts due to Source Credibility (Level 2)	Ensuring that patients and their caregivers trust the source of information or guidance (“source credibility”) is crucial to the success of PC CDS. This product will consist of a three-part report that includes (1) a framework for defining the factors that enhance or detract from source credibility; (2) a proposed revision, expanding Middleton and colleagues’ 2018 <i>Trust Framework</i> ^{ix} to include source credibility as a new and distinct trust attribute; and (3) a series of recommended approaches for increasing source credibility of PC CDS artifacts among providers and patients. These efforts will ultimately result in producing a novel conceptual framework for source credibility that includes an operational definition, key drivers, and impacts on PC CDS uptake.

Next Steps

Workgroups will continue to meet on a monthly basis throughout the project period. Upon completion of AHRQ’s review of product proposals, Workgroups will refine product proposals based on AHRQ feedback, as needed. While each product development process will slightly differ between Workgroups, immediate next steps entail commencing activities on developing Workgroup products, including finalizing product parameters, developing detailed product timelines, and briefing Workgroup members on potential tasks. As products are developed, Workgroup leads will solicit and incorporate input from Workgroup members to ensure that products align with diverse needs and will ultimately benefit patients and the CDS field. Throughout, the Stakeholder Center Planning Committee and CDSiC project leadership will ensure that products are synergistic without being duplicative of each other or CDSiC Innovation Center activities.

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