Agency for Healthcare Research and Quality

Clinical Decision Support Innovation Collaborative

INNOVATION CENTER PROGRESS REPORT

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CDSiC Innovation Center Quarterly Report

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Table of Contents

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) Innovation Center. This quarterly report provides a summary of the status of all projects and activities being conducted within the CDSiC Innovation Center.

The CDSiC aims to advance the design, development, dissemination, implementation, use, measurement, and evaluation, of evidence-based, shareable, interoperable, and publicly available patient-centered clinical decision support (PC CDS) to improve health outcomes of all patients by creating a proving ground of innovation. Products put forth by the CDSiC will provide innovative solutions that promote the adoption of 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 Innovation Center's purpose and goals, then details developments and updates related to the work of the Innovation Center Cores and the Planning Committee.

Background

The U.S. healthcare ecosystem is in the midst of a transition in how it approaches care, payment, and research to support a learning health system that provides value-based, whole person care. This can lead to positive patient outcomes and confront systemic bias and disparities in healthcare and health outcomes.[i] Research shows that U.S. health care quality varies significantly by geographic region and condition; on average, only half of adults receive all recommended, evidence-based care.[ii] These substantial knowledge, dissemination, and performance gaps need to be filled.

The new focus on value-based, whole person care prioritizes positive patient outcomes as measured along multiple dimensions. These outcomes reflect HHS priorities,[iii] including the advancement of health information technology (IT), to promote personalized medicine, patient involvement in the clinical decision-making process, and treatment recommendations guided by evidence-based guidelines. To make this vision a reality, providers and patients must have access to evidence-based recommendations, which must be used to guide decisions about care.

To support healthcare decision-making that is patient centered and evidence-based, there is a need for the development of tools and techniques for dissemination of evidence-based information via methods such as clinical decision support (CDS). In addition, this future requires a constantly improving CDS infrastructure that becomes more shareable, scalable, standards-based, and consistent in translating guidelines into computable formats. It also requires a research agenda focused on better understanding the types of CDS needed, when and how they should be shown to patients and clinicians, and how we ensure interventions work as designed, are used as intended, and generate the patient outcomes we desire.[iv]

CDS is patient-centered when it incorporates findings from patient-centered outcomes research (PCOR), is based on patient-specific information, or facilitates the participation of patients and their caregivers in health-related decisions and actions.[v] [vi] PC CDS offers new ways to ensure that patient-specific, highly targeted, evidence-based clinical guidance is delivered to recipients where and when they want to receive it, in a manner that is easy for them to understand and act upon.[vii] PC CDS that incorporates patient-generated health data (PGHD) and other patient-centered data (e.g., patient preferences, patient-reported outcomes, and social determinants of health) has potential to improve patient and clinician shared decision-making to further support patient engagement, produce clinical recommendations, and reduce clinician burden.[viii]

Several challenges remain to address PC CDS implementation. A recent NORC study outlined these challenges, emphasizing standards for translating clinical guidelines into PC CDS, standards for managing data provenance, PGHD standards, standardized CDS insertion points, standards for non-clinical patient-centered data, integration of PGHD into EHRs, and integration of PGHD into EHRs.[ix] In addition, NORC also identified several salient challenges that must be addressed to further the development, implementation, and impact of PC CDS. These include an absence of patient voice in all phases of PC CDS development, lack of patient-centered terminology standards, limited application of research on patient decision-making, lack of alignment of PC CDS modalities with patients' daily lives, lack of PC CDS integration into clinical workflows, and lack of studies that measure clinical outcomes.[x] To address these challenges and advance PC CDS, there is a need for real-world implementation and assessments of PC CDS.

The following sections provide an overview of the CDSiC and Innovation Center updates.

CDSiC Overview

Through CDSiC, the NORC team, in partnership with AHRQ, will build upon the strong foundation of AHRQ's work in patient-centered CDS to help realize the promise of PC CDS. The CDSiC seeks to integrate diverse perspectives to produce resources and evidence to advance the field of patient-centered clinical decision support, making it more valuable and meaningful to patients, clinicians, and healthcare systems. Below we present the Vision and Mission Statement 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.

Innovation Center Overview

The Innovation Center will serve as the CDSiC research hub to facilitate real-world CDS measurement and testing, improve CDS usability and acceptability via improved design and implementation, and advance the translation of patient-centered outcomes research into clinical practice using CDS to improve individual’s and clinician’s decision-making.

The goals of the Innovation Center are to:

- Engage key clinicians, informaticians, researchers, payers and patients in the creation and implementation of comprehensive CDS measurement frameworks that assess the design, development, implementation, use, and outcomes of CDS. This may include:
  - Standardize measurement of CDS
  - Demonstrate CDS utility through implementation of effective CDS
  - Develop measurement framework(s) and standardized criteria for CDS usage and utility to providers and patients
  - Identify taxonomy and measurement concepts for assessing effectiveness and safety of PC CDS and unintended consequences
- Test various CDS design, development, monitoring, and evaluation strategies to identify best practices for widespread implementation and adoption of effective CDS. This may include:
  - Improve usability and acceptance of CDS through improved design and implementation
  - Advance practice of evidence-based CDS
  - Improve design of CDS tools and artifacts, including developing a robust evidence base for patient-centered design principles
  - Accelerate development and use of data interoperability standards that reduce last mile data integration and implementation challenges

The Innovation Center will facilitate real-world CDS testing and implementation via two Cores. The Cores will provide a unique mechanism to demonstrate, test, and advance novel PC CDS projects that advance key research priorities that support all phases of PC CDS development and align with the CDS Five Rights.$^{\text{Error! Bookmark not defined.}}$

- Core 1. Measurement and Value of CDS
    a. **Purpose:** The purpose of the Measurement and Value of CDS Core is to: 1) standardize the measurement of all aspects of PC CDS, and 2) demonstrate CDS utility through the implementation of safe and effective CDS.

    b. **Projected Outcomes:** Identifying measurement concepts for assessing the effectiveness and safety of PC CDS, and the development and implementation of frameworks to monitor progress of the field and inform continuous improvements.
- Core 2. Conducting and Coordinating CDS Projects
    a. **Purpose:** The purpose of the Conducting and Coordinating CDS Projects Core is to test CDS projects in real-world settings to ascertain best practices for implementation and monitoring to ease last mile implementation challenges.

    b. **Projected Outcomes:** Accelerating the development of best practices surrounding the use of data interoperability standards, measurement and monitoring tools and techniques, and feedback and evaluation strategies that can help advance the use of PC CDS in practice.

Innovation Center Leadership Structure

Principal Investigator (PI) Prashila Dullabh (NORC) provides strategic oversight for the Innovation Center, ensuring coordination of both Cores and that project selection is informed by input from the Stakeholder Center Work Groups, the CDSiC Steering Committee, and AHRQ.

Co-lead Dean Sittig (UT Health School of Biomedical Informatics, The University of Texas) is responsible for Core 1. Core 1 will explore PC CDS measurement and value concepts, including the creation and testing of PC CDS measurement concepts and frameworks to monitor CDS progress and inform continuous improvement.

Co-leads Aziz Boxwala (Elimu Informatics) and Adam Wright (Biomedical Informatics, Vanderbilt University Medical Center) are responsible for Core 2. Core 2 will conduct and coordinate real-world CDS demonstrations.

Status Report

The status report provides updates on progress of the activities of the Innovation Center from January to March 2022, including the establishment of a Planning Committee and development of project concepts for each Core. The status report also describes upcoming activities.

Planning Committee

The Innovation Center has established a Planning Committee comprised of seven thought leaders in the field of CDS. The Planning Committee is central to the operations of the Innovation Center and will provide strategic input for all Innovation Center Core activities. Planning Committee members are displayed in Exhibit 1.

Exhibit 1. Innovation Center Planning Committee Members

Committee Member and Organization Affiliation
Angela Dobes, MPH, Vice President IBD Plexus, Crohn's & Colitis Foundation
David Lobach, MD, PhD, Vice President, Health Informatics Research, Elimu Informatics
Marc Overhage, MD, PhD, Chief Medical Informatics Officer at Anthem, Inc.
Jonathan Teich, MD, PhD, Chief Medical Information Officer, InterSystems
Gil Kuperman, MD, PhD, Associate Chief Health Informatics Officer, Memorial Sloan Kettering Cancer Center
Ted Melnick, MD, MHS, Associate Professor & Director, Clinical Informatics Fellowship, Yale School of Medicine
Josh Mandel, MD, Chief Architect, Microsoft Healthcare

The Planning Committee officially kicks off on April 7, 2022, and will meet once every three months to provide input on the overall strategic direction of Core projects and ensure alignment across the objectives of the CDSiC Steering Committee, CDSiC Stakeholder Center Planning Committee and Workgroups, and AHRQ. The Committee will also review materials related to Core projects and help to raise awareness of Core activities within the broader CDS community.

Innovation Center Cores

The Innovation Center Cores are tasked with developing and completing three projects in the first two years of the CDSiC that advance PC CDS research. Based on discussions with AHRQ and the Planning Committee, Innovation Center leadership have identified three initial projects aimed at addressing gaps in measuring and monitoring PC CDS performance. The overarching goals of these projects are to develop a comprehensive performance measurement framework along with measurement and monitoring prototypes to help patients, clinicians, and CDS developers understand real-world implementation and measurement considerations for PC CDS and any unintended consequences.

The projects vary 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 and multiple modes of research or real-world assessments with the expectation of tangible results. Level 2 projects involve a medium amount of effort and one mode of research or real-world assessment. Level 3 projects are shorter-term and may be proof-of-concept ideas or pilots. The Cores will undertake one project at each level. The projects will be conducted concurrently and in an iterative manner, with findings from each project being incorporated as relevant into the others to enhance and refine outputs.

Core 1: Measurement and Value of CDS

Significant gaps exist in the tools, techniques, and standards required to accurately measure and monitor the performance of various forms of PC CDS across the design, development, implementation, and use spectrum.[viii] To begin with, Core 1 will undertake the development of a comprehensive PC CDS measurement framework.

To guide development of the framework, Innovation Center leadership merged and expanded upon the CDS five rights[xi], the analytic framework for action (AFA) developed by the PC CDS Learning network)[xii], and Donabedian's structure-process-outcome framework[xiii] to create a new, more comprehensive model that outlines a three-phase life cycle of patient-centered clinical decision support (see Exhibit 2). The goal of this new, expanded model is to highlight the myriad of steps in the PC CDS lifecycle that must be adequately negotiated by all participants in the healthcare delivery system, including patients and their caregivers, to achieve the desired changes in behavior and the resulting improvements in personal health and lifestyle, societal health and happiness, and economic outcomes.

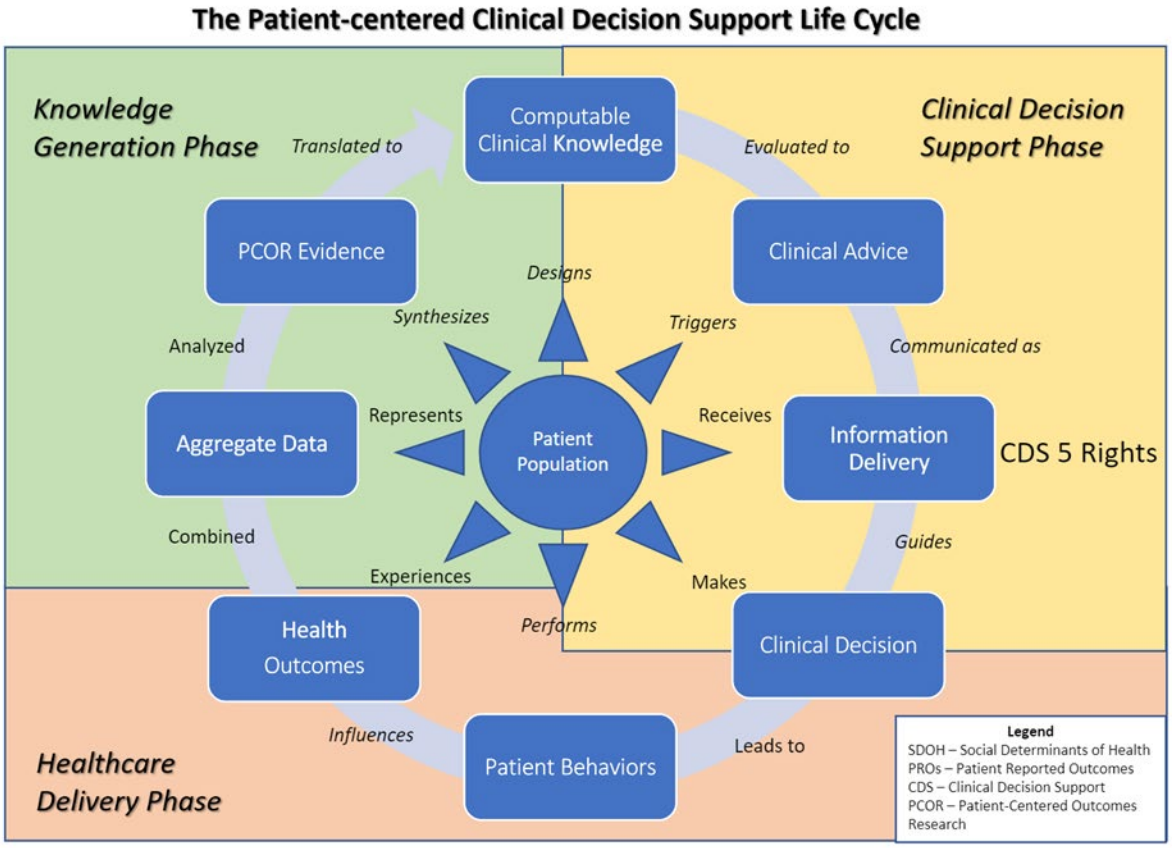
Briefly, the model begins with the "Clinical Decision Support Phase" that focuses on the translation of evidence-based, patient-centered outcomes research-based guidelines into CDS tools for both patients, caregivers, and their care teams. Further on in the clinical decision support phase, patient-provided information is fed into the CDS generation tools, which often reside in the EHR, or other patient-facing tools such as patient portal or apps to trigger the appropriate clinical advice which must be delivered to the patient or provider, leveraging the CDS "five rights." The use of CDS tools has the potential to impact clinical decisions (i.e., the final step in the CDS phase).

The second phase of the model involves "Healthcare Delivery." In this phase, patients make their decision whether to follow the advice recommended by the CDS or the advice they discussed with their healthcare provider. These decisions, such as deciding to fill and continue taking the recommended dose of the appropriate medication, for example, can lead to positive or negative (i.e., unintended outcomes or adverse events) clinical outcomes.

The final phase of the model, "Knowledge Generation," begins with the aggregation of clinical outcomes collected from many patients in some form of clinical data repository (e.g., data warehouse). This aggregate data is analyzed to inform patient-centered clinical outcomes (PCOR), or other observational studies using EHR data, which can be translated into evidence. This PCOR evidence then becomes the input into the clinical decision support phase of the model.

In short, the knowledge generated during the three phases of the PC CDS lifecycle, that is through development and implementation of clinical decision support, the provision of healthcare, and the aggregation and analysis of the resulting data will inform patient-centered outcomes research and refinement of evidence-based guidelines. Evaluation and measurement are necessary within all steps of each phase of the PC CDS lifecycle and will be used to inform continuous refinement and improvement of both the underlying knowledge driving CDS, its implementation, and use. Exhibit 2 depicts the PC CDS lifecycle.

Exhibit 2. The Patient-Centered Clinical Decision Support Life Cycle



The framework will provide a basis for consistent measurement and evaluation (e.g., identification of best practices; return on investment analyses; or assessment of the number of interventions needed to affect change) of CDS design, development, implementation, use, and evaluation across the structure, process, and outcome spectrum. The aim is for the framework to be extensible and adaptable to different health care settings, patient populations, and CDS developers. The ultimate goal is to develop methods to evaluate the effort involved in implementation, the performance and impact of CDS, and the factors affecting performance, which should encourage wider adoption of CDS.

Core 2: Conducting and Coordinating CDS Projects

Clinical dashboards provide real-time feedback to healthcare providers and leaders, as opposed to a retrospective summary of care activities. Data visualization techniques can lead to a more effective decision-making process by reducing cognitive load and improving comprehension of patient data. However, there are several considerations that can impact their performance, such as data sources and availability, the design of visualizations, level of user experience and expertise, individual cognitive factors, or device being used (i.e., PC or mobile device).[xiv]

Core 2 will develop dashboards intended to operationalize the fundamental PC CDS measurement framework being developed by Core 1. The dashboards will seek to create easy-to-use, succinct views of the key measures developed for each of the facets of the framework. The dashboards will contain utilization and performance data on PC CDS tools used by healthcare providers and patients. They will also contain additional measures related to utilization and availability of patient-centered data (for example, PGHD or PROMs) that are used in PC CDS. The dashboards will be developed in an iterative manner that will allow various stakeholders to provide feedback at numerous points in the development process.

The first dashboard will be a PC CDS clinical performance dashboard modeled on an existing prototype CDS dashboard that is under development at Vanderbilt University. Simultaneously using agile software development methods, the Core 2 team will create several iterations of the dashboard to help refine and better understand whether adequate data exists to make the various measures, how best to present the measures, and how the measures might be interpreted by CDS implementers, patients, and their caregivers. The team will conduct multiple rapid usability studies of both the measurement framework and the Performance Dashboard.

PC CDS clinical dashboards could support informed and shared decision-making processes with integration of PGHD. PGHD presents unique issues of integration into and presentation during clinical decision-making tasks due to limited availability and use of interoperability standards, the potential volume of data, and the variable circumstances in which the data is obtained and reported. On the other hand, use of PGHD to inform clinical decisions can improve engagement and connectedness with patients,[xv] which can lead to better health outcomes, increase patient satisfaction, and improve self-management.[xvi] PGHD can provide a holistic picture for continuous care.[xvii] Currently, there is a dearth of knowledge on optimal ways to integrate and visualize PGHD so that it informs care processes and integrates into provider workflows.

The second dashboard will be a prototype that implements best practices, gleaned through a scoping literature review, for presentation and analysis of selected types of patient-generated health data (e.g., medical device and social determinants of health data) during clinical decision-making. The prototype will build on existing PGHD presentation and analysis tools and best practices and test a variety of presentation techniques to ensure optimal usability. The team will also conduct discussions with CDS developers and PGHD experts to gain a better understanding of what data exists, what data is needed, and how these data could be aggregated, interpreted, or synthesized to create more patient-centered CDS interventions.

Next Steps

The Innovation Center will conduct the kickoff meeting for the Planning Committee on April 7, 2022. This meeting will focus on gaining member input on the design, methods, and outputs for the initial proposed projects. Over the next 3 months, the Innovation Center leadership will synthesize member input and refine the project ideas accordingly in collaboration with AHRQ. Once the project concepts have been finalized, the Cores will commence work on their respective projects, including building project teams, developing project schedules, identifying experts for interviews, and conducting preliminary research.

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