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Clinical Decision Support Innovation Collaborative

INNOVATION CENTER PROGRESS REPORT

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CDSiC Innovation Center Quarterly Report

Presented by:
Prashila Dullabh, Dean Sittig, Aziz Boxwala, Adam Wright, Edna Shenvi, Elise Russo, Laura Zahn, and Courtney Zott
NORC at the University of Chicago
4350 East-West Highway
Suite 800
Bethesda, MD 20814

Presented to:
Ed Lomotan and James Swiger
Agency for Healthcare Research and Quality
5600 Fishers Lane, Room 06B03
Rockville, MD 20857

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Introduction

NORC at the University of Chicago (NORC) is pleased to submit the fourth 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 CDSiC Innovation Center is the real-world test bed of the CDSiC, leading the development and application of CDSiC tools, learnings, and insights. The Innovation Center consists of a Planning Committee and two Cores:

- **Core 1. Measurement and Value of CDS**: This purpose of this Core is to standardize the measurement of all aspects of PC CDS and demonstrate PC CDS utility through the implementation of safe and effective PC CDS.
- **Core 2. Conducting and Coordinating CDS Projects**: The purpose of this Core is to test PC CDS projects in real-world settings to ascertain best practices for implementation and monitoring to ease last mile implementation challenges.

Status Report

This status report provides updates on Innovation Center activities from October to December 2022[i], including the facilitation of a Planning Committee and the development of reports, manuscripts, and dashboard prototypes. The report also describes upcoming activities.

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 identified three 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

[i] More detailed background on the CDSiC, the Innovation Center, and Innovation Center activities from January through September 2022 can be found in the first, second, and third quarterly reports.

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.

Core 1 is undertaking one Level 1 project and Core 2 is undertaking one Level 2 and one Level 3 project. The projects are being 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

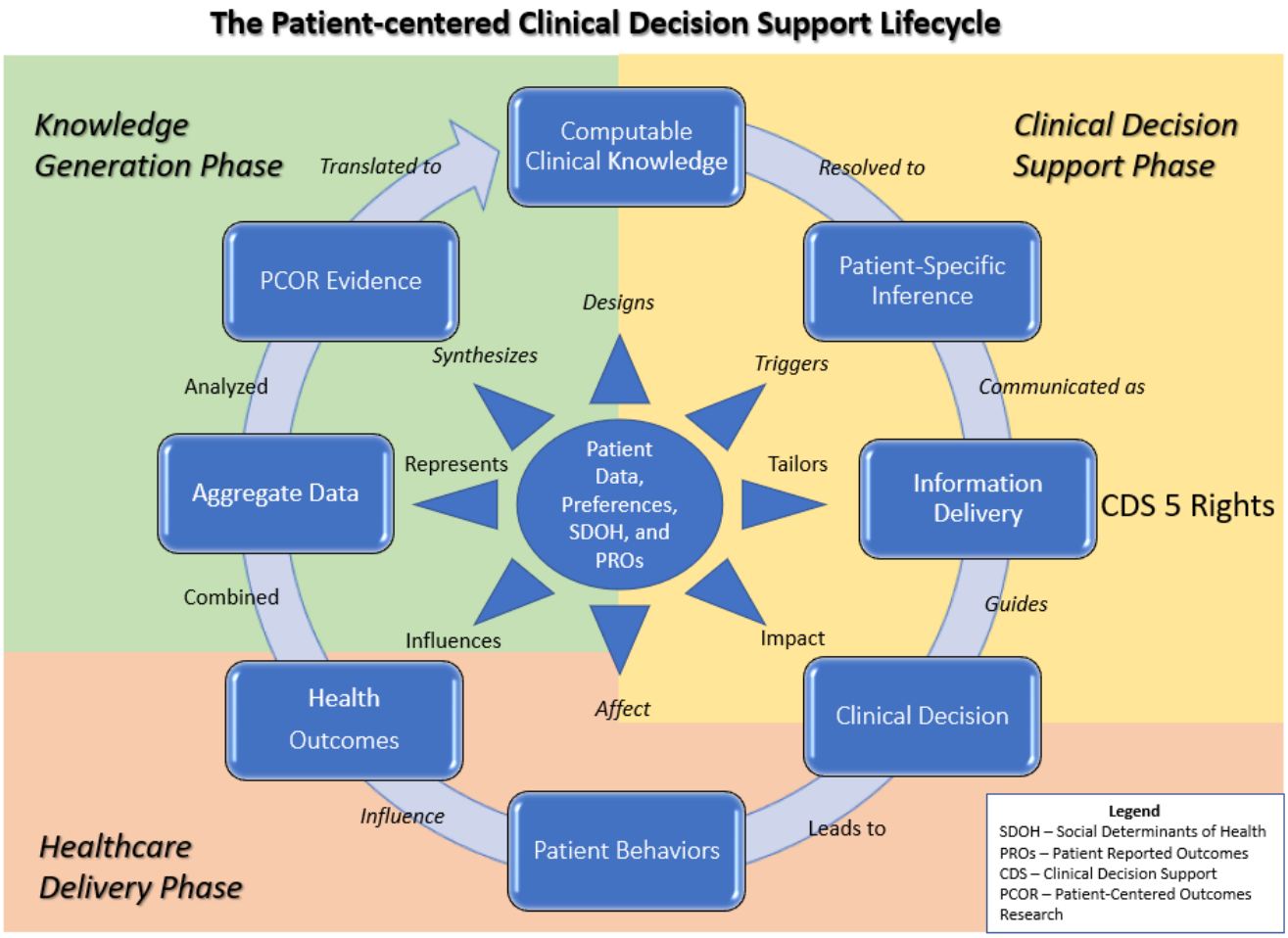
Significant gaps exist in the tools, techniques, and standards required to accurately measure and monitor the performance of various forms of PC CDS across the design, development, implementation, and use spectrum. To address these gaps, Core 1 is undertaking three activities: 1) the development of a PC CDS lifecycle diagram; 2) a PC CDS workflow execution model; and 3) a performance measurement framework.

1. PC CDS Lifecycle Diagram

To guide development of the framework, Innovation Center leadership merged and expanded upon the CDS five rights[1], Multilayer Knowledge Representation Framework,[2] Learning Health System,[3] and the Analytic Framework for Action (AFA) developed by the PC CDS Learning network)[4] to create a new, more comprehensive model (see Exhibit 1) that outlines a three-phase lifecycle of PC CDS.[ii] The goal of this new, expanded model is to highlight the myriad of stages 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. During Q4, Innovation Center leadership finalized a manuscript on the PC CDS lifecycle. The manuscript was reviewed by AHRQ and the Planning Committee and submitted as a viewpoint paper to the Journal of the Medical Informatics Association (JAMIA) in December 2022. The paper is currently under review at JAMIA.

[ii] A detailed description of the model can be found in the Q1 report.

Exhibit 1. The Patient-centered Clinical Decision Support Lifecycle



2. PC CDS Workflow Execution Model

PC CDS interventions are typically composed of complex, multi-step processes that are predicated on medical knowledge, clinician experience, and patient data. The processes for defining, managing, and executing system-level tasks required to generate and deliver PC CDS interventions can be described by various PC CDS workflow execution models. The processes within these models can be carried out by humans, computer applications, or a combination of the two. In Q4, Core 1 developed initial versions of PC CDS workflow models that describe the following three generic types of PC CDS workflows:

1. *Collection and use of patient-reported outcomes (PRO) data*
2. *Collection and use of patient-generated health data (PGHD)*
3. *Encouragement or facilitation of a shared decision-making session*

The workflow models will provide PC CDS designers and developers with an overview of the workflow components (i.e., both those performed by humans and computers) necessary to create and use PC CDS interventions. They also provide a basis for describing the types of measures that are relevant to both developers and users of these interventions, such as whether the interventions are working as designed, being used as expected, and generating the expected results.

3. Performance Measurement Framework

In Q4, Core 1 developed an initial version of the performance measurement framework. The initial version of the framework is based on literature review findings and inputs from the Innovation Center Planning Committee and provides domains and subdomains of measurement that CDS developers, clinical informaticians, clinical leaders, and others should use to assess PC CDS performance across the PC CDS lifecycle. As a next step, the Core 1 team will conduct a framework validation process involving 8-9 key informant interviews with PC CDS developers, clinician informaticians, and patients between January–February 2023.

Ultimately, the framework will provide a basis for consistent measurement and evaluation of PC CDS design, development, implementation, use, and evaluation. The aim is for the framework to be extensible and adaptable to different health care settings, patient populations, and PC CDS developers.

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 summarization 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).[5]

Core 2 is developing two types of dashboards intended to operationalize the PC CDS measurement framework being developed by Core 1. The dashboards will seek to create easy-to-use, succinct views of metrics related to the measure domains and subdomains outlined in the framework. One set of dashboards is focused on presenting aggregate data to a clinical leader or informatician to facilitate a better understanding of PC CDS performance and use. The other set of dashboards is focused on presenting individual patient data to support patient and clinician shared decision-making.

Project 1: PRO Performance Measurement Dashboards. While the use of patient-reported outcomes (PROs) is well-established and validated within the research setting, their incorporation into routine clinical care for the purpose of informing healthcare decisions is relatively new.[6,7] For PROs to be useful for clinical decision-making, research in this area suggests there must be full integration and real-time synergy with clinician workflows so the data is easily retrievable at the point of care.[8,9] Even still, knowing how to interpret the PRO data and incorporate the results into care plans can be a barrier for clinicians, further limiting the usefulness of PROs.[9] Developing PC CDS driven by PROs creates a valuable opportunity to utilize this rich patient-centered data while providing clinicians an automated

interpretation and potentially actionable, evidence-based care responses that are timely and appropriate to patient needs.

The team will develop 2 dashboards focused on different types of PRO data. Specifically, one dashboard will visualize PC CDS metrics involving use of the Patient Health Questionnaire (PHQ-9), a screening tool for depression in Vanderbilt University Medical Center's pediatric rheumatology department. The second dashboard will visualize PROs for Vanderbilt University Medical Center's Inflammatory Bowel Disease (IBD) Clinic. The dashboards are intended to present aggregate-level data only to support clinical director-level personnel and informaticians/developers. The intent is for the dashboards to improve quality and patient safety of PC CDS interventions associated with the PROs collected.

In Q4, Core 2 finalized their dashboard design considerations document, which describes at a high level the information, use cases, and capabilities of the dashboards, and developed initial prototypes of the dashboards. The team then conducted a first round of heuristic usability testing according to Nielson's 10 usability heuristics: 1) Visibility of system status; 2) Match between system and the real world; 3) User control and freedom; 4) Consistency and standards; 5) Error prevention; 6) Recognition rather than recall; 7) Flexibility and efficiency of use; 8) Aesthetic and minimalist design; 9) Help users recognize, diagnose, and recover from errors; and 10) Help and documentation.[10,11] Experts assessed multiple factors relevant to dashboard design within each heuristic. For example, with Flexibility and efficiency of use, experts assessed problematic navigation between components and item selection in menu lists. Identified problems were assigned severity ratings from 1-4, with 1 as "need not be fixed unless extra time is available on project" and 4 as "imperative to fix this before product can be released." Experts also provided recommendations to fix identified usability problems. All problems identified with the highest severity ratings will be resolved prior to the next phase of the usability evaluation: think-aloud tests.

Think-aloud tests will be conducted with a representative sample of users. Users will be given goals, based on their role or use case, to achieve with the dashboard. Stakeholders will be encouraged to verbalize their thoughts and actions as they navigate the dashboard. Following 2-3 think-aloud tests, study moderators and developers will discuss whether the dashboard needs to be modified prior to a second round of think-aloud tests. Overall, the dashboard will be iteratively modified to improve usability after the heuristic evaluation and each round of think-aloud tests.

Project 2: PGHD Software Toolkit. PC CDS clinical dashboards that integrate PGHD could support informed and shared decision-making processes. PGHD, including continuously measured physiologic parameters such as blood pressure or glucose, presents unique issues for 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, the use of PGHD to inform clinical decisions can improve engagement and connectedness with patients,[12] which can lead to better health outcomes, increase patient satisfaction, and improve self-management.[13] PGHD can provide a holistic picture for continuous care.[14] 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 other set of dashboards being developed in Core 2 will be for patient and clinician use and implement best practices for presentation and analysis of selected types of PGHD (e.g., patient-collected, physiologic measurements like blood pressure readings). It will include a patient dashboard app, a clinician dashboard app, and a software library that will allow others to adapt or create new visualizations for their needs. The clinician app will include prepackaged visualizations for hypertension (e.g., blood pressure) and diabetes (e.g., blood glucose), timeline views and tabular metric displays, and the ability for the app user or support staff to add new visualizations through point-and-click configuration (e.g., for asthma, for sleep). The patient app will present self-reported blood pressure information visually to patients. Finally, the software will involve modules for visualization of Fast Healthcare Interoperability Resources (FHIR) data.

As a first step in developing the toolkit, the Core 2 team completed a scoping literature review of existing patient-collected, physiological measurements and visualization techniques and drafted a manuscript summarizing best practices and challenges for presentation of this data. In Q4, the team finalized the manuscript with AHRQ in preparation for submission to a peer-reviewed journal. The team also finalized a design considerations document based on the literature review to inform the development of the dashboard. The document describes at a high level the information, use cases, and capabilities of the dashboard.

The team then began creating prototype versions of the clinician- and patient-facing dashboard apps to refine ideas, understand the limitations of existing data and analysis methods, and gather feedback on presentation methods. The team plans to use synthetic data designed to mimic real-world data to test the PGHD dashboard. The team began preparing to conduct a usability evaluation of the prototype, similar to the one conducted for the PRO dashboards described above.

Planning Committee

The Planning Committee met once during this quarterly reporting period.

The third Planning Committee meeting occurred on October 18, 2022. During the meeting, members were asked for input on three of the deliverables being developed by the two Cores. First, members discussed initial concepts for the dashboard that will visualize PC CDS metrics involving use of the PHQ-9.

Members then discussed initial concepts for the PGHD dashboard apps. Members discussed the emerging nature of PGHD and how it may be too soon to create alerts based on this data. Members also discussed differences in the level and/or frequency with which PGHD data should be monitored in outpatient settings versus inpatient settings. In addition, members provided suggestions and resources on data visualization techniques for PGHD.

Finally, members discussed initial concepts for the workflow execution models developed by Core 1. Members provided suggestions and helpful resources for categorizing the PC CDS tasks and use cases used in the models.

The fourth Planning Committee meeting is scheduled for February 16, 2023. The Committee will review materials related to Core projects and help to raise awareness of Core activities within the broader CDS community, such as by sharing the CDSiC newsletter and final deliverables (e.g., manuscripts and reports) with members of their networks.

Next steps

The Innovation Center will conduct the fourth meeting for the Planning Committee on February 16, 2023. Over the next three months, Core 1 will finalize the PC CDS workflow execution models and the performance measurement framework, and Core 2 will finalize the PRO PC CDS dashboards and develop a PGHD software toolkit. The PRO PC CDS dashboard team will develop a demonstration video, and both the PRO PC CDS and PGHD dashboard teams will draft evaluation reports.

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