INNOVATION CENTER PROGRESS REPORT

JULY 2023

CDSiC Innovation Center: Quarterly Report

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PURPOSE

The CDS Innovation Collaborative (CDSiC) Innovation Center prepares a publicly available quarterly progress report to provide a summary of the status of all projects and activities being conducted within the CDSiC Innovation Center's two Cores and Planning Committee during the reporting period.

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Introduction

NORC at the University of Chicago (NORC) is pleased to submit the second 2023 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:** The 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 quarterly report provides a summary of the status of all projects and activities being conducted within the CDSiC Innovation Center from April 2023 through July 2023. Over this period, the Innovation Center has focused on finalizing deliverables for three projects.

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 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

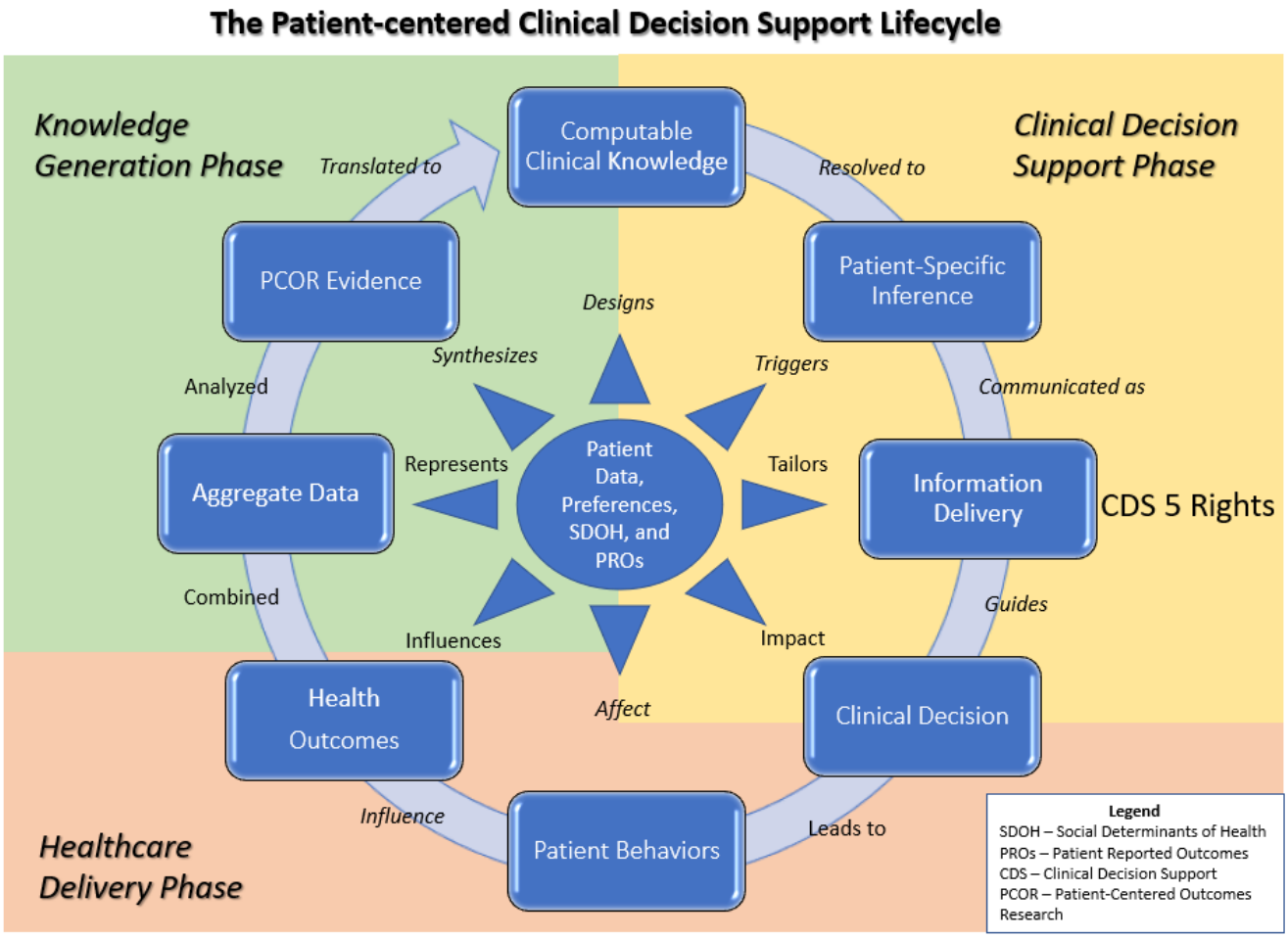
Significant gaps exist in the tools, techniques, and standards required to accurately measure and monitor the performance of various forms of PC CDS across the design, development, implementation, and use spectrum. To address these gaps, Core 1 is undertaking three activities: the development of 1) a 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[a]. 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.

[a] A detailed description of the model can be found in the Q1 2022 report.

Exhibit 1. The Patient-centered Clinical Decision Support Lifecycle



Deliverables Submitted in Q2:

- The team developed a manuscript describing the lifecycle and submitted it as a viewpoint paper to the Journal of the Medical Informatics Association (JAMIA) in December 2022. During Q2 of 2023, the Innovation Center received feedback from JAMIA reviewers, made relevant revisions with AHRQ approval, and resubmitted the manuscript in June. The manuscript was accepted by JAMIA at the end of June.

Dissemination Activities:

- The viewpoint was published by JAMIA in July 2023. [5] The AHRQ and NORC teams are in the process of planning dissemination activities to promote the manuscript.

2. PC CDS Workflow Execution Models

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. The Core 1 team developed initial versions of PC CDS workflow models in 2022 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*

In Q2 of 2023, Core 1 continued to refine the models based on six key informant interviews with representatives at connected device and remote patient monitoring companies and individuals with experience implementing PC CDS in health systems. The interviews focused on understanding workflows, policies, and procedures developed by companies and health systems as well as the resulting challenges and facilitators to capturing and using patient provided information in PC CDS tools.

The 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. They also provide an overview of the new policies and procedures that healthcare systems and technology companies are going to need to develop and manage to support these new workflows and tools.

Deliverables Submitted in Q2:

- Core 1 submitted the PC CDS Workflow Execution Model report in May 2023, and AHRQ approved it as final in June 2023.

Dissemination Activities:

- Core 1 submitted an abstract to AMIA's Annual Symposium on the lessons learned from the development of the workflow models, and it was accepted as a poster presentation.

3. PC CDS Performance Measurement Framework

The Core 1 team developed an initial version of a framework for measuring PC CDS performance in 2022 that outlines 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. The initial version of the framework is based on literature review findings and inputs from the Innovation Center Planning Committee. In Q2 of 2023, the Core 1 team continued refining the framework based on six key informant interviews with CDS measurement experts and individuals with experience implementing and measuring PC CDS in health systems. The interviews focused on soliciting feedback on proposed measurement subdomains in the framework. Core 1 revised the framework based on findings from key informant interviews and AHRQ's feedback on the first draft.

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.

Deliverables Submitted in Q2:

- Core 1 first submitted the PC CDS Measurement Framework report to AHRQ in December 2022. Following the key informant interviews in the Spring of 2023, Core 1 revised the report to highlight key informant feedback and resubmitted the report to AHRQ in April 2023. AHRQ approved the report in June 2023.

Dissemination Activities:

- The Core 1 team presented the PC CDS Measurement Framework at the CDSiC Annual Meeting in May 2023. The presentation outlined the six domains of the framework and described the importance of measurement for the advancement of PC 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 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).[6]

Core 2 developed two types of data visualizations intended to operationalize the PC CDS measurement framework developed by Core 1. The visualizations—one a set of dashboards and the other a software toolkit with demonstration apps—seek to create easy-to-use, succinct views of metrics related to the measure domains and subdomains outlined in the framework. The dashboards are focused on presenting aggregate data to a clinical leader or informatician to facilitate a better understanding of PC CDS performance and use. The demonstration apps are 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.[7,8] 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.[9,10] 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.[10] 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 developed two dashboards focused on different types of PRO data. Specifically, one dashboard visualizes 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 visualizes 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 Q2 of 2023, the Core 2 team completed final think-aloud tests with a representative sample of five users. Users were assigned a role or use case and were given goals to achieve with the dashboard based on the use case. Users were encouraged to verbalize their thoughts and actions as they navigated the dashboard. The dashboards were iteratively modified to improve usability after each round of think-aloud tests. In April, the team developed a report describing the findings from the Q2 think-aloud testing and a heuristic evaluation conducted in Q1. The team also began developing demonstration videos describing the dashboards and how to use them, which will eventually be posted on the public-facing CDSiC website.

Deliverables Submitted in Q2:

- Core 2 submitted the PRO Dashboard Usability Evaluation report to AHRQ in April 2023, and it was approved by AHRQ in May 2023.

Dissemination Activities:

- A member of the Core 2 team demonstrated the PRO dashboards at the CDSiC Annual Meeting in May 2023. The demonstration presented the key features of the PHQ-9 and IBD dashboards and discussed the importance of incorporating patient data into patient-centered care.
- Another member of the Core 2 team presented on the PRO dashboard usability evaluation assessments at the CDSiC Annual Meeting in May 2023. The presentation described the process and key lessons learned from the heuristic and think-aloud assessments.
- Core 2 submitted an abstract to the AMIA 2023 Annual Symposium for a panel on the lessons learned in developing and conducting the usability assessment of the PRO performance dashboards. It was accepted as a poster presentation in July 2023.

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,[11] which can lead to better health outcomes, increase patient satisfaction, and improve self-management.[12] PGHD can provide a holistic picture for continuous care.[13] 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.

Dissemination Activities:

- Core 2 published the software toolkit on Elimu Informatics's GitHub page[14] in November 2022 and has been continuously maintaining the page for contributions. The toolkit will also eventually be available on AHRQ's Github.

PGHD Data Visualization Apps. The demonstration apps developed by Core 2 are 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). They include a patient app, a clinician dashboard app, and a software library that allows others to adapt or create new visualizations for their needs. The clinician app includes 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 presents self-reported blood pressure information visually to patients. Finally, the software involves modules for visualization of Fast Healthcare Interoperability Resources (FHIR) data.

In Q2 of 2023, the team completed the usability testing of the clinician and patient app prototypes. They completed a heuristic evaluation for both apps similar to the one conducted for the PC CDS performance dashboard described above as well as think-aloud assessments for the clinician dashboard app with three representative potential end users. The team developed a report describing findings from the usability assessment.

Deliverables Submitted in Q2:

- The team submitted the PGHD Data Visualization App Usability Evaluation report to AHRQ in May 2023. They received feedback from AHRQ in June and resubmitted the report in July 2023.

Dissemination Activities:

- Core 2 presented the PGHD Data Visualization Apps at the CDSiC Annual Meeting in May 2023. The demonstration highlighted the key features incorporated in the team's clinician- and patient-facing apps for cardiovascular health.
- Core 2 submitted an abstract for a poster presentation at AMIA's Annual Symposium on the design, development, and lessons learned from the usability evaluation of the clinician-facing app. It was accepted as a poster presentation in July 2023.

PGHD Data Visualization Manuscript. 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 Q2 of 2023, the team continued working with AHRQ on revisions to the manuscript.

Deliverables Submitted in Q2:

- The team submitted a revised version of the PGHD Data Visualization manuscript to AHRQ in March 2023 and received feedback in April 2023. The team revised and finalized the manuscript

and submitted the manuscript to the Journal of Applied Clinical Informatics (ACI) in May 2023. The team received feedback from reviewers in July and began drafting a resubmission.

Dissemination Activities:

- The team will conduct dissemination activities if the manuscript is accepted after resubmission.

In Exhibit 2, we outline each Core's project deliverables to date, as well as the future deliverables in progress.

Exhibit 2. Summary Table of Deliverables

Project	Status
Core 1	
PC CDS Lifecyle Manuscript	Complete
PC CDS Workflow Execution Models Report	Complete
PC CDS Performance Measurement Framework	Complete
PC CDS Workflow Execution Model Manuscript	In Progress
PC CDS Performance Measurement Manuscript	In Progress
Core 2	
PRO Dashboard	
Dashboard Design Considerations Document	Complete
Dashboard Usability Evaluation Report	Complete
Dashboard Demonstration Video	In Progress
PGHD Dashboard	
PGHD Visualization Literature Review Manuscript	Under Journal Review
Design Considerations Document	Complete
Dashboard Usability Evaluation Report	Complete
Dashboard Software	In Progress

Planning Committee

The Planning Committee did not meet in Q2 2023 due to members attending the CDSiC Annual Meeting on May 16-17. The next Planning Committee meeting is scheduled for October 12, 2023.

Next Steps

Over the next three months, Core 1 will draft manuscripts for the Workflow Execution Model and Performance Measurement Framework and seek feedback from AHRQ before submission to peer-reviewed journals. Core 2 will finalize the PRO PC CDS dashboard demonstration videos. Both Core 1 and 2 will prepare materials for the AMIA Annual Symposium in November and begin planning for projects and deliverables for the next contract year that begins in October 2023.

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