INNOVATION CENTER PROGRESS REPORT

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CDSiC Innovation Center: Quarterly Report

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Prepared by:
NORC at the University of Chicago
4350 East - West Highway Suite 800
Bethesda, MD 20814

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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PUBLIC DOMAIN NOTICE

Table of Contents

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 quarterly report provides a summary of the status of all projects and activities being conducted within the CDSiC Innovation Center from January 2023 through March 2023. Over this period, the Innovation Center has focused on advancing 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

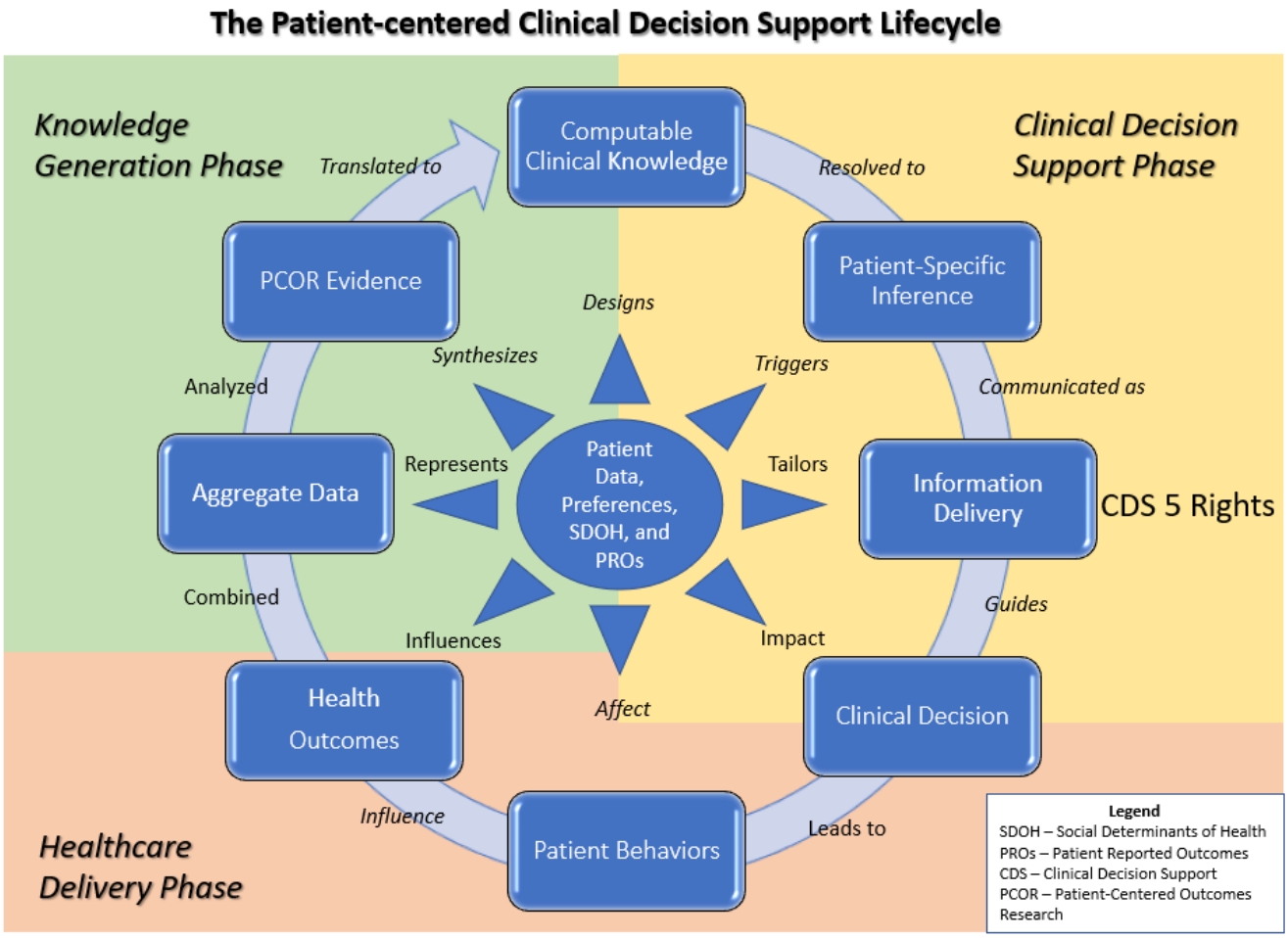
Significant gaps exist in the tools, techniques, and standards required to accurately measure and monitor the performance of various forms of PC CDS across the design, development, implementation, and use spectrum. To address these gaps, Core 1 is undertaking three activities: 1) the development of a 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[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. 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 Q1 of 2023, the Innovation Center received feedback from JAMIA reviewers, made relevant revisions, and resubmitted the manuscript in February. JAMIA reviewers provided additional feedback in March and the team revised and resubmitted the manuscript again. The manuscript is currently under review at JAMIA.

[a] 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 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 Q1 of 2023, Core 1 refined 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, and the resulting challenges and facilitators to capturing and using patient provided information in PC CDS tools. Core 1 also submitted an abstract for a podium presentation at AMIA's Annual Symposium on the lessons learned from the development of the workflow models.

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 and 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.

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 Q1 of 2023, the Core 1 team refined 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.

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 Q1 of 2023, Core 2 refined prototypes of the dashboards based on findings from heuristic usability testing. This testing was done 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 were resolved.

After completing heuristic testing, the team presented a demonstration of the prototypes to AHRQ and the Innovation Center Planning Committee in February to provide an update on progress and solicit feedback.

The team then began conducting think-aloud tests with a representative sample of users. Users were given goals, based on their role or use case, to achieve with the dashboard and encouraged to verbalize their thoughts and actions as they navigate the dashboard. Following two initial think-aloud tests, the team began discussing modifications prior to continuing further think-aloud testing. Overall, the dashboard will be iteratively modified to improve usability after each round of think-aloud tests. The team will ultimately develop a report describing the findings from the testing.

Finally, the team submitted an abstract for AMIA's Annual Symposium for a panel poster on the lessons learned in developing and conducting the usability assessment of the PRO performance dashboards.

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.

PGHD Data Visualization Dashboards. 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.

The team also finalized a prototype version of the clinician-facing dashboard app and engaged in several activities to solicit feedback on the design, including a demonstration to AHRQ and the Planning Committee as well as interviews with patient stakeholder members of the CDSiC. Feedback from these activities was used to adjust the design of the app prior to usability testing.

The team commenced usability testing in Q1 of 2023 and completed a heuristic evaluation similar to the one conducted for the PC CDS performance dashboard described above. All identified problems were resolved as feasible in preparation for the next stage: think-aloud assessments. The team will ultimately develop a report describing findings from the usability assessment.

Finally, the team 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.

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 Q1 of 2023, the team continued working with AHRQ on revisions to the manuscript in preparation for submission to the journal of Applied Clinical Informatics.

Planning Committee

The Planning Committee met once during this quarterly reporting period.

The fourth Planning Committee meeting occurred on February 16, 2023. During the meeting, members received a demonstration of the dashboards being developed by Core 2 and were asked for input on the workflow execution models being developed by Core 1.

Members generally expressed enthusiasm about the dashboards and felt they were heading in the right direction. They also provided several ideas for improving the usability and actionability related to the types and methods of information display.

For the workflow execution models, members suggested new ways of conceptualizing patient preferences and CDS, and the connection between the two. They noted that patient preferences inform how actions should be taken (e.g., what method to use or time to contact a patient) and CDS informs what actions should be taken (e.g., collecting more data from a patient).

The fifth Planning Committee meeting is scheduled for June 6, 2023.

Next Steps

The Innovation Center will conduct the fifth meeting for the Planning Committee on June 6, 2023. Over the next three months, Core 1 will deliver the final PC CDS workflow execution models and performance measurement framework to AHRQ. Core 2 will finalize the PRO PC CDS dashboards and the PGHD software toolkit and deliver usability evaluation reports for both to AHRQ. Core 2 will also develop and submit a demonstration video of the PRO PC CDS dashboards to AHRQ.

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