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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Introduction

NORC at the University of Chicago (NORC) is pleased to submit the tenth 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 projects and activities being conducted within the CDSiC Innovation Center between October and December in year four.

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 PC 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 PC 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 October 2024 through December 2024. Over this period, the Innovation Center has focused on beginning four projects across both Cores and finalizing project work from year three of the CDSiC.

Innovation Center Cores

The Innovation Center Cores are tasked with developing and completing four projects that advance PC CDS research. Based on discussions with AHRQ and the Planning Committee, Innovation Center leadership identified projects aimed at developing new approaches for measuring PC CDS and building the evidence base for implementing and scaling PC CDS in real-world settings. The goals of these

projects are to conceptualize how artificial intelligence (AI) can be used in PC CDS, to develop a framework for patient engagement measurement concepts, and to conduct real-world pilots that test 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 I 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 II projects involve a medium amount of effort and one mode of research or real-world assessment.

- Level III projects are shorter-term and may be proof-of-concept ideas or pilots.

Core 1 is undertaking two Level III projects and Core 2 is undertaking two Level II projects.

Core 1: Measurement and Value of PC CDS

Significant gaps exist in the tools, techniques, and standards required to accurately measure and monitor the performance of PC CDS across the design, development, implementation, and use lifecycle.[1] To address these gaps, Core 1 has undertaken two projects: 1) identifying the key concepts across the PC CDS lifecycle to measure successful engagement with PC CDS technologies, and 2) detailing the current landscape of use cases for AI in PC CDS, to provide a foundation for future efforts in developing appropriate performance measures. In addition, Core 1 continued the prior year's project disseminating a measurement framework for PC CDS performance.

1. Identifying Patient Engagement Measures in PC CDS

In year three of the CDSiC, several Stakeholder and Innovation Center products found gaps in the measurement of patient engagement, including issues with the development, operationalization, and standardization of measures.[2,3,4,5] To address these gaps and better understand how patient engagement impacts PC CDS processes, it is necessary to develop more advanced, comprehensive, and standardized outcome-based measures of patient engagement.

This project aims to contribute to future patient engagement measure development by exploring patient engagement measurement concepts, measures, and strategies for measurement. The Core 1 team will map these concepts and measures to the PC CDS Lifecycle (Exhibit 1) developed by the Core 1 team to enable PC CDS developers, researchers, implementers, evaluators, and other stakeholders to assess successful engagement in different phases of the technology.[6] The PC CDS Lifecycle Framework defines the different phases, sequences and interactions of activities within the design, development, implementation, use, and evaluation of PC CDS. The lifecycle is separated into three separate phases: the clinical decision support phase (i.e., the transformation of evidence from research into computable logic for patients), the healthcare delivery phase (i.e., the clinical decision-making process among patients, caregivers, and clinicians), and the knowledge generation phase (i.e., the development of evidence-based guidelines from patient-centered outcomes research [PCOR]).

Exhibit 1. The Patient-centered Clinical Decision Support Lifecycle Framework

The Patient-centered Clinical Decision Support Lifecycle
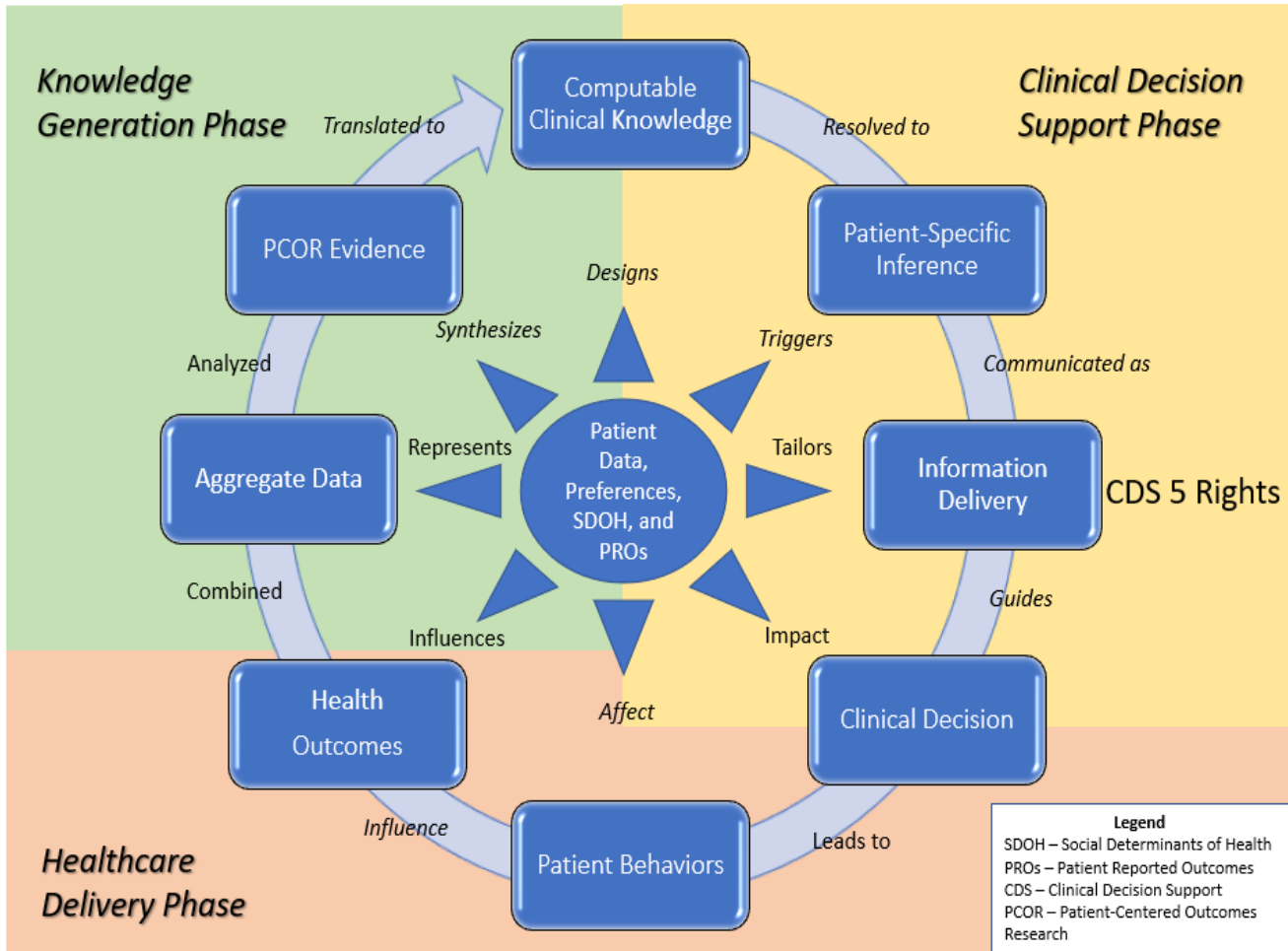
In Q4 2024, the Core 1 team abstracted and refined patient engagement measurement concepts from the following CDSiC products that explicitly discuss patient engagement: 1) Measurement and Outcomes Workgroup: Patient Prioritization of Measurement Areas for Patient-Centered Clinical Decision Support;[7] 2) Implementation, Adoption, and Scaling Workgroup: Exploring Challenges and Opportunities for Patient Engagement, Implementation, Adoption, and Scaling Through PC CDS Case Studies;[8] 3) Trust & Patient-Centeredness Workgroup: An Introductory Handbook for Patient Engagement Throughout the Patient-Centered Clinical Decision Support Lifecycle;[9] 4) Scaling, Measurement, and Dissemination of CDS Workgroup: PC CDS Performance Measurement Inventory; 5) Measurement and Outcomes Workgroup: Inventory of Patient Preference Measurement Tools for PC CDS Report;[10] 6) Outcomes and Objectives Workgroup: Patient-Focused Outcome Measures for Patient-Centered Clinical Decision Support;[11] 7) Measuring PC CDS Performance: A Unified Framework; and 8) Real-World Performance Measurement of Patient-Centered Clinical Decision Support Tools: AHRQ Project Assessment. The Core 1 team will use this information to inform key informant discussions on patient engagement measures in the next quarter.

Deliverables Submitted in Q4:

- A Project Outline & Timeline that describes the aims, scope, methods, deliverables, and timeline for the patient engagement literature review.

Dissemination Activities in Q4:

- Core 1 presented the project idea to Planning Committee members on October 9, 2024. The team provided minutes following the meeting.

2. Examining Use Cases of AI in PC CDS

The use of AI in PC CDS tools has potential implications for PC CDS technology, patients/caregivers, and clinicians. In particular, generative AI, which can create new content from textual and media input,[12] has strong capabilities to synthesize large amounts of data for PC CDS through various mediums (e.g., unstructured data in electronic health records [EHRs], clinical visit recordings, patient-generated health data [PGHD]).[13] Because of the rapid growth of AI and concerns with its transparency and regulatory oversight, there is need to clarify how it is being implemented in the PC CDS landscape.

The aim of this project is to create a consolidated resource that documents current use cases of AI in PC CDS and its implications and considerations for practice and research. The Core 1 team will emphasize the implications of AI in PC CDS for patients/caregivers, as the current literature focuses on implications for clinicians and healthcare leaders using traditional CDS.[14,15,16,17]

In Q4 2024, the Core 1 team conducted a targeted review of the following CDSiC resources that discuss AI, along with relevant literature from their reference lists: 1) Implementation, Adoption, and Scaling Workgroup: Landscape Assessment on the Use of Artificial Intelligence to Scale PC CDS;[18] 2) Trust and Patient-Centeredness Workgroup: Patient and Caregiver Perspectives on Generative Artificial Intelligence in Patient-Centered Clinical Decision Support;[19] 3) PAIGE Chatbot for Patient-Clinician Communication: Usability and Utility Assessment;[20] and 4) Quartz App to Support Medication Adherence: Usability and Feasibility Assessment.[21] The team also conducted targeted searches on use cases of AI within PC CDS in PubMed and Google Scholar. When abstracting data, the team focused on the type of AI used (focusing on generative AI), the PC CDS tool that was augmented, and the intended audience of the tool. The team will synthesize this information to create a brief and manuscript for this project.

Deliverables Submitted in Q4:

- A Project Outline & Timeline that describes the aims, scope, methods, deliverables, and timeline for the AI-based PC CDS review.

Dissemination Activities in Q4:

- Core 1 presented the project idea to Planning Committee members on October 9, 2024. The team provided minutes following the meeting.

3. PC CDS Performance Measurement Framework *[Continued from the Prior Year]*

In prior years, Core 1 developed a framework for measuring PC CDS performance that CDS developers, clinician informaticians, clinical leaders, and others could use to assess PC CDS across the lifecycle. The framework is informed by traditional CDS and health information technology literature as well as key informant interviews with experts in the field. It includes several domains and subdomains of measurement to ensure health care quality that are extensible to different health care settings, patient populations, and PC CDS developers.

In Q4 2024, the Core 1 team continued revising a manuscript that describes the framework's measurement areas for PC CDS. They submitted the manuscript to a peer-reviewed journal for publication and will make revisions based on reviewers' comments. The Core 1 team also presented findings from the validation of the framework at the *American Medical Informatics Association (AMIA) 2024 Annual Symposium*.

Dissemination Activities in Q4:

- Core 1 submitted a manuscript for publication to a peer-reviewed journal in November 2024.

- Core 1 presented a poster presentation on the PC CDS Performance Measurement Framework validation at the *AMIA 2024 Annual Symposium* in November 2024.

Core 2: Conducting and Coordinating PC CDS Projects

PC CDS tools have the potential to improve patient safety and quality of care by remotely monitoring patients' conditions and symptoms. Remote monitoring is particularly pertinent for chronic conditions such as hypertension that impact a large patient population and can contribute to more serious conditions like early onset cardiovascular disease and, if pregnant, complications during or after delivery. Mobile health technology, which utilizes mobile devices, smartphones, tablets, or personal computer in the management of chronic disease, has been shown to be effective for patients that must adhere to medication regimens or monitoring over extended periods of time.[22, 23]. Due to the burden of hypertension and the efficacy of mobile health, Core 2 has undertaken two projects: 1) implementation and evaluation of a PC CDS prototype to support hypertension medication adherence; and 2) implementation and evaluation of a PC CDS prototype for postpartum hypertension.

1. Implementation and Evaluation of a PC CDS Prototype to Support Hypertension Medication Adherence

In this project, the Core 2 team will expand on the prior year's project to implement and evaluate a text-messaging application (app) to help patients improve adherence to hypertension medications. The app leverages an AI-based tool to text patients who have uncontrolled blood pressure to ensure that a) patients continue taking their medications as prescribed, and b) the medications have the desired effect. The app uses natural language processing to understand variations in patients' responses but does not rely on AI to provide medical advice. The Core 2 team integrated the app with an EHR system at a pilot site using Substitutable Medical Applications and Reusable Technologies (SMART) on Fast

Healthcare Interoperability Resources (FHIR®)[24] to allow clinicians to monitor patients' medication use between visits and intervene if necessary. They then assessed the integration process to understand the feasibility and usability of the app in a lab simulation environment. This year, the Core 2 team will enhance the app to collect blood pressure data from patients and will implement the app with patients in a real-world primary care setting.

App Development and Deployment. In Q4 2024, the Core 2 team held weekly meetings with the technical team at the pilot site to discuss improvements to the app design and deployment to the production environment. They revised the text message content based on patients' feedback in the prior assessment to simplify and personalize the messages, such as by acknowledging the patient's prior responses during follow-up messages. They will also pause the text messages if patients report certain barriers that should be reviewed by the clinician. They successfully wrote back patient data (e.g., text messaging conversations) to the EHR using the vendor's proprietary application programming interface and began incorporating blood pressure data in the app and the clinician-facing monitoring dashboard. The text messages requesting patients' blood pressure readings will be programmed with adaptive frequency such that patients with more advanced stages of hypertension will receive more frequent text messages than patients with less severe hypertension. The team began testing components of the app in the health system's production environment, including the patient consent and enrollment and the adaptive frequency blood pressure scenarios.

Pilot Implementation. In Q4 2024, the Core 2 team worked closely with the pilot health system site to prepare for the app's rollout. They determined they would engage three to five primary care clinicians or residents to enroll a total of 40 patients in the pilot on a rolling basis. Clinicians will monitor patients' responses over a three-to-four-month period. Other discussions centered around patients' eligibility based on their stage of hypertension, patient recruitment and consent procedures, clinical workflows for patient enrollment, and data collection procedures. The health system site began preparing materials to train clinicians on the app, and the Core 2 team applied to NORC's Institutional Review Board (IRB).

Assessment. The Core 1 and Core 2 teams are collaborating to conduct another assessment, this time of the app's technical feasibility, performance, and usability in a real-world setting. In Q4, the team drafted an Assessment Plan that details the goals, research questions, data collection methods, and analysis methods for the assessment. The team aims to collect qualitative and quantitative data from: 1) the technical team on the feasibility of deploying the app in the EHR and performance in production; 2) the clinical team on the usability of the clinician dashboard and fit with clinical workflows; and 3) health system patients on the usability and acceptability of the app for self-management of hypertension medications. The team will develop a final report that summarizes key findings within each research aim by the end of year four.

Deliverables Submitted in Q4:

- A Project Outline & Timeline that describes the aims, scope, methods, deliverables, and timeline for the Medication Adherence PC CDS pilot.

Dissemination Activities in Q4:

- Core 2 presented in a panel at the *AMIA 2024 Annual Symposium* titled, "Leveraging Large Language Models and Other Artificial Intelligence Methods to Advance Patient-Centered Clinical Decision Support." The panel discussed considerations for using AI in PC CDS like the Medication Adherence app and how to foster patient trust in the process.

- Core 2 presented the project idea to Planning Committee members on October 9, 2024. The team provided minutes following the meeting.

2. Implementation and Evaluation of a PC CDS Prototype to Support Postpartum Hypertension

In this project, the Core 2 team will build on a prototype designed to monitor blood pressure for patients with postpartum hypertension. The prototype was developed under AHRQ's PCOR CDS project (2016-2023) to advance shareable, standards-based CDS. The app sends SMS text messages to patients with a web-based questionnaire that allows them to report their daily blood pressure readings and hypertensive symptom data post-delivery. It also leverages SMART on FHIR standards to safely store and write back data to the EHR for clinicians to monitor their patients' symptoms. Clinicians receive alerts for any abnormal readings, allowing for prompt intervention for patients. In 2023, the app was pilot tested at clinic site at Yale New Haven Health System and demonstrated preliminary effectiveness in promoting patient self-management of postpartum hypertension.[25] This year, the Core 2 team will conduct another pilot at a different site and enroll a larger sample of patients.

App Development. In Q4 2024, the Core 2 team drafted a Specifications and Requirements document that details the design, features, and technical and operational requirements of the app. The document provides an overview of the technical approach for key components: 1) the platform and device, which supports Google Chrome and Microsoft Edge browsers on desktop devices; 2) the system architecture, including the HL7 FHIR R4 standard; 3) data capture and decision support to support monitoring with alerts for out-of-range responses; and 4) data storage and management using a secure FHIR server.

Pilot Implementation. The Core 2 team met regularly with the pilot health system site to facilitate technical integration and plan for app rollout. These included discussions regarding the app's security review in the health system environment, decision trees for actions needed based on patients' responses, and clinical workflows at the new pilot site. Core 2 also applied to NORC's IRB to prepare for pilot implementation.

Deliverables Submitted in Q4:

- A Project Outline & Timeline that describes the aims, scope, methods, deliverables, and timeline for the Postpartum Hypertension PC CDS pilot.

- Specifications and Requirements document that details the app and technical infrastructure needed for the app.

Dissemination Activities in Q4:

- Core 2 presented the project idea to Planning Committee members on October 9, 2024. They provided minutes following the meeting.

Innovation Center Deliverables

In Exhibit 2, we outline each Core's completed deliverables to date.

Exhibit 2.   Summary Table of Deliverables

Project	Status
Innovation Center	
Project Outline and Timeline	Under AHRQ Review
Revised Charter	Complete
Revised Operational Framework	Complete
Core 1	
AI-Based PC CDS Brief	In Progress
Patient Engagement Measurement Framework Report	In Progress
Core 2	
Medication Adherence Prototype	
Medication Adherence Pilot Assessment Plan	In Progress
Medication Adherence Pilot Assessment Report	Not Started
Postpartum Hypertension Prototype	
Postpartum HTN Specifications and Requirements Documentation	Under AHRQ Review
Postpartum HTN Assessment Plan	Not Started
Postpartum HTN Assessment Report	Not Started

Planning Committee

The Planning Committee met once at the beginning of the Q4 reporting period on October 9, 2024. The meeting focused on sharing a recap of the projects, deliverables, and dissemination metrics for year three and presenting the new project ideas for year four. Core 1 presented three project ideas: 1) assessing approaches to measuring quality and performance of AI in PC CDS, 2) developing a framework to measure patient engagement in PC CDS, and 3) evaluating Core 2 projects using the PC CDS Performance Measurement Framework. Core 2 presented two project ideas: 1) implementing and evaluating the medication adherence app to assess the app's performance in a primary care clinical

setting, and 2) implementing and evaluating a postpartum hypertension app at a maternal-fetal clinic to assess the app's usability and feasibility.

- For the Core 1 project ideas, committee members thought the measurement of AI in PC CDS and the measurement of patient engagement were both viable project options.

  - Committee members suggested the Core 1 team examine current and future use cases of AI in PC CDS to better understand trends in its use and measurement methodologies.

  - Committee members agreed that current patient engagement measures in PC CDS were rudimentary, and creating a measurement framework would be beneficial. They shared resources from the CDSiC and Consumer Assessment of Healthcare Providers and Systems (CAHPS) to guide development of the product.

- Committee members approved of the Core 2 project ideas and provided logistical recommendations around design and deployment of the pilots.

  - For the Medication Adherence pilot, committee members suggested that the app administer interim assessments to assess process metrics and the app's usability.

  - For the Postpartum Hypertension pilot, committee members recommended that the team only send the hypertension data to clinicians, and to consider alternate ways to provide patient feedback to better engage patients in the PC CDS tool.

The next Planning Committee meeting is scheduled for February 3, 2025. The Committee will learn about the progress of the fourth year Innovation Center project ideas and help raise awareness of Core activities within the broader CDS community.

Next Steps

This quarterly report is the first to provide updates on the Innovation Center's project activities in the fourth year of the CDSiC. Over the next three months, Core 1 will finalize the AI-based PC CDS review and submit a Viewpoint manuscript to a peer-reviewed journal. Core 1 will also continue the review of patient engagement measures and conduct key informant interviews with guideline developers, PC CDS developers, and clinicians about their experiences measuring patient engagement in PC CDS. Core 2 will continue implementing the two PC CDS pilots. For the Medication Adherence pilot, they will complete the pilot Assessment Plan that outlines the aims, measures, data collection methods, and analysis. They will begin patient recruitment for the pilot in a clinic setting, as well as data collection for the assessment. For the Postpartum Hypertension pilot, they will continue developing and testing the app in the health system environment and begin drafting the Assessment Plan.

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