Innovation Center:
Charter – Option Year 2

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TASK & DELIVERABLE:

Deliverable 3.1: Final Revised Innovation Center Charter

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CDSiC Mission and Vision

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 patient-centered clinical decision support (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 clinician experience.

Reasons for Establishing

The purpose of this project charter is to formally operate the CDSiC Innovation Center. The literature underscores that the greatest challenges to widespread "plug-and-play" CDS use are integration issues, rather than availability of CDS artifacts or evidenced-based clinical guidelines.[1,2,3] These challenges require CDS implementation improvements to satisfy the CDS Five Rights (right information, to right people, in right CDS intervention formats, through right channels, and at right workflow points). We propose the Innovation Center Cores use these principles to guide their objectives and research priorities. The Innovation Center will serve as the CDSiC research hub to advance PC CDS, which encompasses a spectrum of decision-making tools that significantly incorporate patient-centered factors related to knowledge, data, delivery, and use[4] Knowledge refers to the use of comparative effectiveness research or patient-centered outcomes research (PCOR) findings. Data focuses on the incorporation of patient-generated health data, patient preferences, social determinants of health, and other patient-specific information. Delivery refers to directly engaging patients and/or caregivers across different settings. Finally, use focuses on facilitating bi-directional information exchange in support of patient-centered care, including shared decision-making. The Innovation Center aims to facilitate real-world PC CDS measurement and testing; improve PC CDS usability and acceptability via improved design and implementation; and advance the translation of PCOR into clinical practice using PC CDS to improve individual's and clinician's decision-making. The Innovation Center will also draw upon the PC CDS Lifecycle Framework developed by Innovation Center Leadership.[5]

The primary audiences of this charter are the Agency for Healthcare Quality and Research (AHRQ), the CDSiC Innovation Center Planning Committee, the CDSiC Stakeholder Community and Outreach

Center Planning Committee and Workgroups, and the CDSiC Steering Committee. The charter will be ratified by the Project Directorate and the Innovation Center Planning Committee. The Charter will be publicly available on the CDSiC website.

Purpose

The Innovation Center will operate two Cores:1) Measurement and Value of PC CDS; and 2) Conducting and Coordinating PC CDS Projects. The Cores will provide a unique mechanism to demonstrate, test, and advance novel PC CDS projects that advance key research priorities that align with the Five Rights. The purpose of Core 1: Measurement and Value of PC CDS is to conduct projects to standardize the measurement of all aspects of CDS and evaluate CDS utility through the review of CDS implementations. The purpose of Core 2: Conducting and Coordinating PC CDS Projects is to implement PC CDS projects in real-world settings for the purpose of learning best practices for implementation and monitoring to ease last mile implementation challenges.

The Innovation Center will 1) regularly convene a Planning Committee to guide Center and Core activities and 2) execute PC CDS projects across the two Cores.

Objectives

The Innovation Center's activities will primarily focus on the two Cores and the development of projects. The objectives of the Innovation Center are outlined below:

- Engage key clinicians, informaticians, researchers, payers and patients in the creation and implementation of comprehensive PC CDS measurement frameworks that assess the design, development, implementation, use, and outcomes of PC CDS. This may include the following actions:
  - Standardize the measurement of PC CDS
  - Demonstrate PC CDS utility through implementation of effective PC CDS
  - Develop measurement framework(s) and standardized criteria for PC CDS usage and utility to clinicians and patients
  - Identify taxonomy and measurement concepts for assessing effectiveness and safety of PC CDS and unintended consequences
- Test various PC CDS design, development, monitoring, and evaluation strategies to identify best practices for widespread implementation and adoption of effective PC CDS. This may include the following actions:
  - Improve usability and acceptance of PC CDS through better design and implementation
  - Advance the practice of evidence-based PC CDS
  - Improve the 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

Outputs and Projected Outcomes

The Innovation Center will achieve the objectives through a variety of activities as well as through continued communication and collaboration with the CDSiC Steering Committee and Stakeholder Planning Committee. The outputs of the Innovation Center are outlined below:

- Produce a Revised Operational Framework to describe the Innovation Center's structure and activities in this project year.
- Maintain processes to ensure that the activities of the Innovation Center Planning Committee are properly sequenced and information flows across Cores to inform each other.
- Convene regular meetings of the Planning Committee to discuss, make decisions on, and provide input for Core activities and facilitate coordination with the Stakeholder Center Workgroups.
- Operationalize Core 1 and Core 2 to advance PC CDS measurement research and to serve as a test bed for improving the uptake of evidence-based practices, respectively.

The projected outcomes of the Innovation Center are as follows:

- Identify and test measurement concepts for assessing the performance of PC CDS across all phases of the lifecycle.
- Examine representative examples of PC CDS interventions and inform continuous improvements to measurement, adoption, and use.
- Accelerate the development of best practices surrounding the use of data interoperability standards, measurement and monitoring tools and techniques, newer technologies, and feedback and evaluation strategies that can help advance the use of PC CDS in practice.
- Identify challenges to implementing and using PC CDS and recommend areas for further research (e.g., gaps in data interoperability standards).

Constraints and Potential Challenges

Potential constraints to achieving the objectives of the Innovation Center are described below:

- Existing electronic health records (EHRs) and healthcare organizations do not routinely collect much of the data needed to measure PC CDS implementation, use, and outcomes. Compounding this is the lack of consensus definitions for key PC CDS measurements.
- The field of CDS interventions that incorporate patient-centered factors to support whole-person care is emerging (e.g., patient-facing apps, shared decision-making, patient preferences).
- Certain PC CDS projects and tools must be prioritized over others due to time constraints with production.

- Implementation of PC CDS projects will require engagement and participation of health systems. Garnering health system participation within the specified timelines of this project may be a constraint.

The potential challenges to the Innovation Center achieving desired outcomes are outlined below:

- There is a lack of existing standards and measures to assess PC CDS performance, particularly for patient engagement and AI-driven PC CDS.
- PC CDS standards, tools, and artifacts are maturing and are not consistently implemented across EHR vendors and healthcare sites.
- There is a need for sustained patient engagement and participation of health systems stakeholders in pilot studies.
- There is a learning curve for healthcare organizations and EHR developers to use novel data interoperability standards.
- The technical capabilities and available resources to participate in novel pilots may vary by implementation site partner and should be considered during pilot site selection as well as when establishing project timelines. These resources may not be available outside of the leading healthcare organizations selected as implementation partners.
- PC CDS projects are often complex and multidimensional, of which the PC CDS may only be a small component of the overall goals, making implementation and impact difficult to measure.
- AI-driven PC CDS is an emerging field that should be navigated with careful consideration of patient and stakeholder perspectives.

Relevant Stakeholders

The Innovation Center Planning Committee will be central to the operations of the Innovation Center and provide oversight for all Core activities. The Center's two Cores will be led by thought leaders within the CDS community. Each Core will have co-leads and dedicated support staff. The Steering Committee, Stakeholder Center Planning Committee and Workgroups, and AHRQ will serve in an advisory capacity to the Planning Committee, sharing input on project selection. The Stakeholder Center Workgroups outputs may provide critical contributions that directly inform project development.

A broader set of the CDS community will be impacted by the Innovation Center's activities including federal agencies/policymakers, clinicians, healthcare organizations, patients and caregivers, CDS content developers, informaticists, standards developers, PCOR/informatics researchers, and EHR developers.

Decision-Making Frameworks

The Innovation Center will come to decisions regarding recommendations for the Cores using applicable decision-making frameworks depending on the needs of the Center and the type of decision to be made. The Innovation Center will utilize the RACI (Responsible, Accountable, Consulted, and Informed) matrix framework as a starting framework to determine the role different parties will play in

making decisions, including defining when and how the Planning Committee will be involved. Definitions for the RACI matrix are outlined below:

RACI Definitions[6]:

- R – Responsible ("The Doer")
  - The "doer" is the individual(s) who actually complete the task. The "doer" is responsible for action/implementation. Responsibility can be shared. The degree of responsibility is determined by the individual with the "A".
- A – Accountable/sign off ("The Buck Stops Here")
  - The accountable person is the individual who is ultimately answerable for the activity or decision. This includes "yes" or "no" authority and veto power. Only one "A" per row.
- C – Consult/two way ("In the Loop")
  - The consult role is individual(s) (typically subject matter experts) to be consulted prior to a final decision or action. This is a predetermined need for two-way communication. Input from the designated position is required.
- I – Inform/one way ("Keep in the Picture")
  - This is the individual(s) who needs to be informed after a decision or action.

Exhibit 1 organizes the high-level roles and responsibilities of the Innovation Center using the RACI matrix framework. A fuller description of the roles and responsibilities of the Innovation Center follows the exhibit.

Exhibit 1.   Roles and Responsibilities of the Innovation Center (High-Level)

	Project Directorate	Task 3 Leadership	Innovation Center Core 1 and 2 Co-Leads	Planning Committee	AHRQ Project Officer
Governance	A	R	R	I	C
Strategy	A	R	R	C	C
Project Management	A/R	A/R	R	I	C
Develop Work Products	A	A	R	C	C
Dissemination	C	A	A/R	C	C
Communicate Challenges and Need for Support	A	R	R	I	C

The Planning Committee's role in decision-making according to the RACI definitions will align with the "Consult" and "Inform" dimensions of the RACI framework. The Planning Committee will provide high-level direction and input regarding what projects the Cores should undertake as well as inform the Innovation Center about related PC CDS activities occurring outside the CDSiC. These inputs will then be considered by the Project Directorate and AHRQ throughout the decision-making process.

The Planning Committee may make a variety of decisions as part of operating the Cores, providing guidance and strategic input about potential projects. Different types of decisions may benefit from the use of more robust decision-making frameworks (see **Exhibit 2**). Such frameworks may include but are not limited to:

- Decision matrix: evaluates and prioritizes a list of options against an established list of weighted criteria and then evaluates each option against those criteria.
- Feasibility-impact analysis: comparison of the factors of a project/activity that determine the probability of its successful completion relative to the significance in change that would occur as a result of the project/activity.
- SWOT analysis: evaluates internal factors (strengths, weaknesses) and external factors (opportunities, threats) to broadly assess strategies related to a project/activity.

Exhibit 2. Utilization of Decision-Making Frameworks by the Innovation Center

Decision-Making Framework	Examples
SWOT Analyses	• Prioritizing marketing and outreach strategies to maximize outreach to different stakeholder groups • Decisions on which types of CDSiC products to move forward to the Innovation Center • Assessing activities to pursue during the Option Year
Logic Trees, Decision Matrices	• Determining content to be included on the CDSiC website • Determining which audience(s) to prioritize when disseminating CDSiC products • Determining the order in which to develop/roll-out certain PC CDS products to the public • Determining scope and format of CDSiC innovation and dissemination activities
Risk/Benefit Analyses & Feasibility/Impact Analyses	• Weighing positive/negative impacts of PC CDS products on stakeholder groups • Prioritizing CDSiC Workgroup products to explore, develop, or implement

The goals of the Committee will be to achieve consensus. However, in the event of irreconcilable differences within the group, AHRQ will be asked for their opinion or advice, to help break the stalemate.

In the execution of the two Cores, the Core co-leads will be responsible for identifying potential Core projects through discussion and deliberation and determine a final list of projects for consideration and approval from AHRQ. Workgroup members will also provide input into Innovation Center activities. After the projects are determined the Core co-leads, support staff, and implementation partners (as applicable) will fulfill the "Responsible" dimension for a particular project. Innovation Center Leadership and the CDSiC Project Directorate will ultimately be responsible and accountable for the timely completion of high-quality project outputs.

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