

Innovation Center: Operational Framework – Option Year 2

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Prepared by:
NORC at the University of Chicago

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TASK & DELIVERABLE:

Task 3.1: Final Revised Innovation Center Operational Framework



PRESENTED BY

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

Table of Contents

- Purpose of Operational Framework 1

- Innovation Center Structure 1
 - Innovation Center Leadership 1
 - Team Support Staff 2

- Innovation Center Planning Committee 2
 - Planning Committee Primary Function 2
 - Planning Committee Meetings and Communications 2
 - Planning Committee Reporting 3

- Innovation Center Cores 3
 - Innovation Center Cores' Primary Function 3

- Roles and Responsibilities 4
 - Facilitating Communication Across CDSiC Centers 4

- Synergies, Challenges, and Mitigation Strategies 4

- Product Authorship 5

Purpose of Operational Framework

The purpose of this Operational Framework is to provide direction for the Innovation Center of the Clinical Decision Support Innovation Collaborative (CDSiC) regarding process and day-to-day matters. The Innovation Center's activities will primarily focus on the two Cores and the development of projects. The Innovation Center will function to:

- Operate two Innovation Cores focused on key topic areas with distinct research priorities designed to understand how and what patient-centered clinical decision support (PC CDS) works best and under what conditions: 1) Core 1 – Measurement and Value of PC CDS, and 2) Core 2 – Conducting and Coordinating PC CDS Projects.
- Develop a minimum of three projects (two Level II projects and one Level III project).

This document describes the Innovation Center's structure and processes, specifically the composition of the Innovation Center Planning Committee, the processes for coordinating across the Cores, as well as the mechanisms for scheduling, tracking Core activities and progress, and reporting.

The primary audiences of this framework are the Agency for Healthcare Research and Quality (AHRQ), the Innovation Center Leadership, and the Innovation Center Planning Committee. The Framework will be ratified by the Project Directorate and the Innovation Center Planning Committee. The Framework will be publicly available on the CDSiC website.

Innovation Center Structure

The Innovation Center will consist of two components: 1) Center Leadership, including an Innovation Center Planning Committee that will provide oversight, and 2) two topic-focused Cores that will serve as the research hub for the CDSiC.

Innovation Center Leadership

Principal Investigator Prashila Dullabh from NORC at the University of Chicago (NORC) will lead the Innovation Center. She will work in partnership with Core 1 Lead Dean Sittig (University of Texas Health) and Core 2 Lead Aziz Boxwala (Elimu Informatics, Inc.) in leading each Innovation Center Core and ensuring that each Core conducts projects that help advance PC CDS research by addressing information gaps and mitigating real-world implementation challenges.

The Innovation Center Leadership and AHRQ project leadership will engage with external thought leaders to maintain the Innovation Center Planning Committee (Exhibit 1).

Exhibit 1. Innovation Center Planning Committee Members

| Committee Member and Organization Affiliation |
|---|
| Angela Dobes, MPH , Vice President IBD Plexus, Crohn's & Colitis Foundation |
| Gil Kuperman, MD, PhD , Associate Chief Health Informatics Officer, Memorial Sloan Kettering Cancer Center |
| David Lobach, MD, PhD , Vice President, Health Informatics Research, Elimu Informatics |
| Marc Overhage, MD, PhD , Chief Health Informatics Lead, Elevance Health |
| Lipika Samal, MD , Clinician Investigator in Internal Medicine, Brigham and Women's Hospital |
| Jonathan Teich, MD, PhD , Chief Medical Information Officer, InterSystems |
| Mark Zhang, DO, MMSc, FAMIA , Chief Innovation Officer, Veterans Health Affairs Office of Healthcare Innovation and Learning |

Team Support Staff

Additional support staff will work with Innovation Core Leadership and the Planning Committee to help with meeting planning and logistics as well as potential operational challenges or concerns. Specifically, Core 1 will be supported by NORC staff and Core 2 will be supported by Elimu Informatics staff.

Innovation Center Planning Committee

Planning Committee Primary Function

The Planning Committee will provide input on the overall strategic direction and coordination of the Innovation Center Cores and will liaise with the CDSiC as a whole, integrating input from the Stakeholder Center workgroups, Steering Committee, and AHRQ. This will involve the following actions:

- Meet regularly to provide strategic guidance and input on key decisions that relate to the Cores.
- Facilitate cross-Core synergies through regular communication.
- Provide critical review of Core results and products that will be broadly disseminated.
- Help to raise awareness of the Core activities and project products within the broader CDS community.
- Ensure that work of the Innovation Center builds on CDSiC Workgroups' plans and is informed by the strategic vision and ideas shared by the Steering Committee.

Planning Committee Meetings and Communications

The Planning Committee will convene virtually every four months to facilitate regular communication and will schedule ad hoc meetings when needed. Dullabh or one of the Planning Committee members will chair the meeting. Core Leads will circulate a draft agenda and materials (e.g., background

documents) at least one day before meetings. Detailed meeting notes and any materials used during the meeting will be sent to the AHRQ TOO within 14 days of each meeting.

In between meetings, the Planning Committee will use the CDSiC SharePoint Website to facilitate asynchronous work. As needed, Dullabh will provide a bulleted list of updates via email to the Planning Committee to highlight future meeting agenda items.

Planning Committee Reporting

Dullabh will submit quarterly reports summarizing the activities of each Core. These reports will coincide with the periodic Stakeholder Center reports submitted to AHRQ. The reports will include the following, at a minimum.

- A summary of activities taken by each Core since the last report
- Individual project updates
- A description of challenges encountered

Following submission of the draft report, NORC will address AHRQ’s comments, and prepare a 508-compliant version within two weeks of receipt of AHRQ’s feedback. The final Planning Committee quarterly report will be shared with the Stakeholder Centers and posted to the CDSiC website.

Innovation Center Cores

Innovation Center Cores’ Primary Function

Through the two Cores, the Innovation Center will establish a forum to conduct PC CDS projects that advance key research priorities that align with the CDS Five Rights. Core 1 will focus on assessing PC CDS and its alignment with the Five Rights. Core 2 will focus on developing and testing projects that mitigate implementation challenges to achieving the CDS Five Rights. The Cores will be guided by the following research priorities (Exhibit 2).

Exhibit 2. Innovation Center Research Priorities for Each Core

| Core 1: Measurement and Value of PC CDS | Core 2: Conducting and Coordinating PC CDS Projects |
|---|---|
| <ul style="list-style-type: none"> ■ Standardize measurement of PC CDS ■ Evaluate PC CDS utility through review of its implementations ■ Develop and validate measurement frameworks and standardized criteria for PC CDS usage and utility to providers and patients ■ Identify taxonomy and measurement concepts for assessing PC CDS performance and unintended consequences | <ul style="list-style-type: none"> ■ Improve usability and acceptance of PC CDS through better design and implementation ■ Advance practice of PC CDS ■ Improve design of PC 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 |

Roles and Responsibilities

Each component of the Innovation Center will have a distinct role and responsibilities, which are summarized in Exhibit 3.

Exhibit 3. Innovation Center Roles and Responsibilities

| Role | Responsibility |
|-------------------------------------|--|
| Innovation Center Leadership | <ul style="list-style-type: none"> • Contribute to overall strategic direction and coordination of the Innovation Center and provide strategic input in the Core activities. • Provide technical expertise and guidance for Core activities ensuring execution of all Core projects • Ensure adequate staffing and support for Planning Committee and Core activities • Establish review and quality assurance processes • Facilitate Planning Committee Meetings • Communicate with Planning Committee about operational concerns |
| Planning Committee | <ul style="list-style-type: none"> • Facilitate cross-Core synergies through regular communications • Establish consistent expectations and processes for each Core as well as expectations for timeline and projects • Inform Steering Committee, Stakeholder Center Planning Committee, and AHRQ of Center and Core activities |
| Team Support Staff | <ul style="list-style-type: none"> • Work with Core Leads to support project activities • Work with Innovation Center Leadership to provide Planning Committee meeting support |

Facilitating Communication Across CDSiC Centers

Dullabh will be responsible for communicating and coordinating with Priyanka Desai (NORC) to provide updates from the Innovation Center. As needed, Innovation Center Leadership will join Workgroup meetings to obtain direct feedback on products and engage Workgroup Leads to help prioritize issues that need to be addressed.

Synergies, Challenges, and Mitigation Strategies

To ensure synergy and proactively address potential challenges, the Innovation Center Leadership will ensure mitigation strategies are in place for all Center activities. These include:

- Regular review and discussion of challenges encountered by Cores, using decision-making frameworks to solve problems as noted in the Innovation Center Charter.
- Regular agenda items for Planning Committee meetings to review and discuss Core activities, challenges encountered, and mitigation strategies.
- Engage dedicated, experienced CDSiC Core support staff to ensure the smooth operation of all meetings and timely development of products.

- Engage experienced technical experts to provide guidance on resolving implementation challenges.
- Cross-Core and cross-CDSiC discussions to ensure alignment in activities and overall strategic approach.

Product Authorship

Authorship for Innovation Center products posted publicly on the CDSiC website as well as any resulting manuscript publications will be determined following the CDSiC's Authorship Guidelines. All participants will discuss expected contributions before product development, including authorship and the anticipated order of authors. The anticipated authorship order will be determined and agreed upon before product drafting begins.

Following International Committee of Medical Journal Editors (ICJME) guidelines,¹ authors must be able to meet the following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or reviewing it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All authors are responsible for fairly evaluating their role to ensure that authorship is attributed according to these standards. Authorship order will be discussed collectively as a group.

- The lead author is generally the individual responsible for writing the first draft of the manuscript.
- The co-authors will be listed in order of contribution to the conception, drafting, and review of the manuscript.
- The CDSiC Principal Investigator will be listed as the final author, reflecting their involvement throughout the manuscript development process, oversight, and overall strategic direction of manuscripts. Workgroup leads may be listed as co-senior authors to reflect their contribution to the conceptualization of a product, when appropriate.
- The CDSiC PI or Stakeholder Center lead will serve as the corresponding author. The corresponding author will be responsible for manuscript submission and coordination with the journal during the peer-review and publication process.
- Each manuscript will have AHRQ co-authors.

Non-author Innovation Center members will be credited as contributors in publicly posted products and included in the acknowledgements of publications.

¹ International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors. Available from: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>