Standards and Regulatory Frameworks Workgroup:
Charter – Option Year 2

Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract No: 75Q80120D00018

Prepared by:
NORC at the University of Chicago

November 2024

FUNDING STATEMENT

This project was funded under contract number 75Q80120D00018 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services (HHS). The opinions expressed in this document are those of the authors and do not reflect the official position of AHRQ or HHS.

TASK & DELIVERABLE:

Deliverable 2.3.1: Revise and Submit Charters for Each of the Four Workgroups

PRESENTED BY

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

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CDSiC Vision and Mission

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 provider experience.

Purpose

The purpose of this charter is to formally initiate the CDS Standards and Regulatory Frameworks Workgroup under the CDSiC Stakeholder Community and Outreach Center (Stakeholder Center). The Affordable Care Act (Section 6301) established a mandate for the Agency for Healthcare Research and Quality (AHRQ) to engage diverse stakeholders in efforts to develop and advance the use of patient-centered outcomes research (PCOR).[1] Fulfilling this mandate, the CDS Standards and Regulatory Frameworks Workgroup will leverage the knowledge and experience of CDS experts and amplify the voice of patients to ensure CDS products and tools empower patients to make healthcare decisions that align with their values and preferences.

The CDSiC is comprised of three centers: the Operations Center, the Stakeholder Center, and the Innovation Center. Each will undertake a series of activities to identify, prioritize, and

[1] Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111–148, 124 Stat. 119 (2010), Codified as Amended 42 U.S.C. § 18001.

develop products that are broadly disseminated to relevant stakeholders and likely to contribute significantly to the field.

The Stakeholder Center and its Workgroups will provide crucial thought leadership for CDSiC activities and promote PC CDS within the U.S. healthcare system by (1) developing content-driven written products for the field, (2) partnering with the Steering Committee to guide the overall work of the CDSiC, and (3) providing input on projects undertaken by the Innovation Center.

Reasons for Establishing

Supporting healthcare delivery system and PCOR transformation through enhanced use of PC CDS will require recognized standards, regulations, and policies for interoperability between systems of healthcare data and knowledge. To that end, the CDS Standards and Regulatory Frameworks Workgroup will advise the CDSiC Steering Committee and the Innovation Center on the impact of standards, rules, regulations, or policies on the development and implementation of PC CDS. The Workgroup will monitor, track activities, and engage with external standards groups (e.g., HL7®) and regulatory groups (e.g., Food and Drug Administration, Office of the National Coordinator for Health Information Technology, Centers for Medicare & Medicaid Services, etc.) that have bearing on CDS progress; the group will also develop and vet recommendations to advance shareable, standards-based PC CDS. Ultimately, the efforts of the Workgroup will identify gaps in existing standards and regulatory frameworks, advocate for enhancements of standards and regulations to fill these gaps, and promote existing standards and regulatory frameworks that can be used to create CDS that supports patients and clinicians in making evidence-informed healthcare decisions, as well as improves healthcare delivery.

Composition and Relevant Stakeholders

The activities of the Workgroup will be informed by the Steering Committee and the Stakeholder Center Planning Committee. The Steering Committee will provide strategic input and the Planning Committee will ensure that the Workgroup activities are synergistic, informed by the Steering Committee vision, and in support of Innovation Center projects.

The Workgroup will be comprised of a multidisciplinary group of experts and stakeholders who reflect diversity across various dimensions, and who will draw on their respective experience and deep connections to support Workgroup objectives and outcomes. The Workgroup will include up to 15 expert members with backgrounds as clinicians, standards organizations, health IT developers (e.g., EHR vendors, app developers, CDS content developers), professionals who create or distribute content regarding or tools using CDS evidence, state and federal agency representatives, payers, and patients or patient representatives.

Workgroup activities and outputs will be designed to reach a broad set of stakeholders. The intended audience for products, such as CDS tools, resources, and evidence, developed by the Workgroup includes federal agencies/policymakers, clinicians, medical/academic institutions, patients/patient advocates, authors of CDS guidelines, CDS developers, informaticists, standards developers, PCOR researchers, EHR developers, and health systems.

Workgroup Leads. The Workgroup will be led by the Workgroup Co-Leads Aziz Boxwala and Rachel Richesson, with support from Desirae Leaphart. Drs. Boxwala and Richesson will co-lead Workgroup activities. Workgroup leadership will set the overall direction for the development of Workgroup products, facilitate meetings, lead product development, assign roles and responsibilities to members, work with the CDSiC leadership team to ensure that Workgroups have the right subject matter expertise to develop products, monitor progress, ensure products are developed consistent with proposed timelines, and communicate regularly with Stakeholder Center leadership.

Objectives

The objectives of the CDS Standards and Regulatory Frameworks Workgroup are outlined below:

- Identify current data representation and exchange standards and regulatory frameworks that influence and inform CDS development to assess gaps and identify existing standards that can be adopted to support PC CDS.
- Track external federal and non-federal efforts to promote and adopt standards to avoid duplication and promote synergies.
- Conduct literature reviews and interviews with external groups that develop health IT standards, regulations, and policies to better understand the standards development landscape and inform CDSiC projects and initiatives, including Workgroup products.
- Inform CDSiC Innovation Center projects focused on using CDS standards for development and implementation.

Outputs and Projected Outcomes

In pursuit of its objectives, the Workgroup will engage in a variety of activities to generate a set of specific outputs, or high-quality, written products. Outputs will aim to advance the use of standards for CDSiC and the CDS community. Examples of potential outputs include:

- Validation, refinement, and dissemination of the taxonomy of override reasons for PC CDS that was previously developed by the Workgroup, allowing for further added value of the taxonomy to inform improvements in PC CDS design, implementation, and acceptability.

- An updated diagram from the Workgroup's patient app interoperability report that details how digital health tools can be integrated into the PC CDS ecosystem, identifying additional examples (e.g., additional PC CDS tools) that illustrate standardized interoperability within the health IT ecosystem.
- Strategies to support adoption and implementation by health systems of a taxonomy of override reasons for PC CDS into existing standards or best practice (e.g., through incorporation into HL7 CDS Hooks).

If successful in operationalizing its objectives, the Workgroup, through its deliberations and outputs, will serve as a forum that:

- Ensures CDSiC projects and initiatives advance and benefit from the use of current CDS standards and regulatory frameworks.
- Advances coordination of standards-based CDS efforts between CDS stakeholders and implementers.
- Disseminates Workgroup products that facilitate translation of evidence on CDS standards into practice.
- Disseminates Workgroup products that facilitate the broader adoption of standards-based CDS.

Constraints and Potential Challenges

In conducting its activities, the Workgroup will adhere to the following constraints:

- All activities must be stakeholder-driven and fit within the scope and objectives of the Workgroup.
- All products developed by the Workgroup must fit within the AHRQ-provided guidelines.
- Activities must align with funding stipulations and be completed within allotted project timelines.

Throughout its tenure, the Workgroup may encounter one or more of the following potential challenges:

- Distilling the key priorities, given the large volume and breadth of federal and private CDS development currently underway.
- Determining specific areas within existing standards to focus efforts given the wide landscape of relevant technical standards (e.g., social determinants of health, patient generated health data).
- Being fully informed of external CDS standards and regulation activities, given the many ongoing parallel standards and regulatory initiatives.
- Sustaining engagement with diverse Workgroup members, in alignment with their communication and participation styles.

- Reconciling differing perspectives among Workgroup members to achieve consensus on decisions for Workgroup activities.
- Allowing for a diversity of perspectives within the Workgroup and creating an inclusive space where all members feel comfortable voicing their opinions.

To aid in mitigating these challenges, the group will establish bidirectional channels for communication and will cultivate an environment conducive to remaining strategic, adaptable, and responsive to the priorities of group members throughout the project duration.

Decision-Making Frameworks

Workgroup decision-making will prioritize consensus methods, particularly for operational decisions or determining recommendations for elevation to the CDSiC Steering Committee and/or Innovation Center. This approach involves Workgroup deliberation to achieve a final result based on agreement of a simple majority. To the extent possible, the Workgroup will explore the use of different decision-making frameworks when majority agreement cannot be achieved in cases involving complex decisions. 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.
- Risk-benefit analysis: comparison between the risks of a situation and its benefits to determine whether a course of action is worth taking or if risks are too high.
- 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.

Workgroup leadership will be responsible for selecting the appropriate decision-making framework. The rationale for selection will be documented in the Workgroup meeting notes. However, where appropriate and prudent, anonymous voting (facilitated by a virtual platform) can be used to resolve discrepancies and finalize decisions. Workgroup Leadership will be responsible for implementing the decisions in consultation with CDSiC leadership. The goals of the Workgroup will be to achieve majority agreement. However, in the event of irreconcilable differences within the group, AHRQ will be asked for their opinion or advice, to help break the stalemate.

Acknowledging Workgroup Product and Publication Contributions

The Workgroup may produce reports, frameworks, and other documents that are publicly posted on the CDSiC website (“products”). In addition, the CDSiC may develop manuscripts

based on Workgroup products for submission to peer-reviewed journals. Below, we describe guidelines for acknowledging contributions in Workgroup products and manuscript publications.

Acknowledging Workgroup Member Contributions in Products. For products posted on the AHRQ CDSiC website, the Workgroup as a whole will be included as a co-author. Workgroup members who provide input during Workgroup product development will be acknowledged for their contributions by being listed in a table of contributing Workgroup members. In order to be acknowledged in a final Workgroup product, Workgroup members must do at least one of the following:

1. Attend at least one Workgroup meeting to review and provide real-time feedback on product findings or product structure
2. Provide asynchronous feedback on Workgroup product drafts between Workgroup meetings (e.g., via email or on SharePoint)

Authorship Guidelines for Manuscripts. The CDSiC leadership (i.e., the CDSiC PI and Stakeholder Center lead), the Agency for Healthcare Research and Quality (AHRQ), and Workgroup support teams, and Workgroup leads will discuss expected contributions before manuscript 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, authors must be able to meet the following four criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or reviewing it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. 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.[2]

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 with the authors.

- 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

[2] https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

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.

Please note that authorship order of manuscripts may not reflect the authorship order of the corresponding Workgroup product.

Acknowledging Workgroup Member Contributions in Manuscripts. Each CDSiC Workgroup will generally be included as a co-author in the manuscript (e.g., manuscripts developed under the Measurement and Outcomes Workgroup will include "Measurement and Outcomes Workgroup" in the list of authors). Ahead of selecting a journal, NORC will reach out to target journals to confirm the Workgroup can be submitted as a co-author. In accordance with ICJME and journal guidelines, Workgroup members will be acknowledged for their valuable contributions to the work. Individual members will be named in the article's acknowledgments or contributors section. To be included in the list of Workgroup members noted in the manuscript, Workgroup members must have either:

- Contributed to the development of the original product(s) that undergird(s) the manuscript (i.e., the Workgroup member is listed as a contributor in the report), OR
- Contributed directly to manuscript development by participating in Workgroup meetings where manuscript-related activities (such as additional research activities to inform the manuscript) were discussed or providing asynchronous feedback on manuscript-focused activities.