Agency for Healthcare Research and Quality

Clinical Decision Support Innovation Collaborative

STAKEHOLDER CENTER PROGRESS REPORT

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CDSiC Stakeholder Community and Outreach Center:

Quarterly Report

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Introduction

NORC at the University of Chicago (NORC) is pleased to submit the second quarterly report to the Agency for Healthcare Research and Quality (AHRQ) on the Clinical Decision Support Innovation Collaborative (CDSiC) Stakeholder Community and Outreach Center (Stakeholder Center). This quarterly report provides a summary of the status of all projects and activities being conducted within the CDSiC Stakeholder Center from July 2022 to September 2022.

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. 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.

Through its Workgroups, the CDSiC Stakeholder Center provides the project's thought leadership—developing products that advance CDS for the broader community, informing the overall work of the CDSiC (in partnership with the CDSiC Operations Center Steering Committee), and offering input on projects the CDSiC Innovation Center develops. Critically, the Stakeholder Center will engage diverse stakeholders in CDSiC activities, consistent with the mandate established by Section 6301 of the Affordable Care Act for AHRQ to engage and obtain feedback from diverse stakeholders.[1] The Stakeholder Center consists of a Planning Committee and four Workgroups, 1) CDS Outcomes and Objectives, 2) CDS Standards and Regulatory Frameworks, 3) Scaling, Measurement, and Dissemination of CDS, and 4) Trust and Patient-Centeredness.

Status Report

This status report provides updates on progress of the activities of the Stakeholder Center from July to September 2022[1], including finalizing Workgroup product proposals, commencing product development work, and facilitating a Planning Committee.

Planning Committee

The Stakeholder Center established a Planning Committee comprised of Stakeholder Center Leads, AHRQ project officers, the CDSiC PI and Co-Investigators, and Workgroup Co-leads. The Committee

[1] More detailed background on the CDSiC, the Stakeholder Center, and Stakeholder Center activities from January to June 2022 can be found in the first quarterly report.

meets once every other month to provide input on the overall strategic direction and coordination of the Stakeholder Center, as well as discuss product development activities across Workgroups.

The Planning Committee convened in July 2022. During the meeting, the Committee debriefed about Workgroup meetings and product development and discussed challenges and successes. The Committee also reviewed the three phases of the PC CDS lifecycle—knowledge generation, decision support, and healthcare delivery—and discussed where Workgroup products align with the lifecycle. Products from the Outcomes and Objectives, Trust and Patient-Centeredness, and Scaling, Measurement, and Dissemination Workgroups align with steps in the decision support and healthcare delivery phases. The products of the Standards and Regulatory Frameworks Workgroup are foundational and support the entire lifecycle. The Committee will reconvene in October 2022.

Stakeholder Center Workgroups

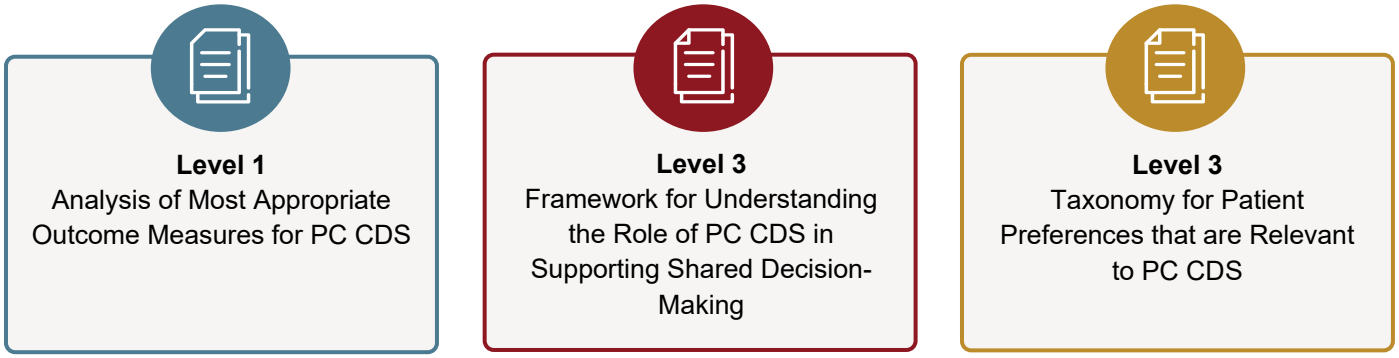
The four Stakeholder Center Workgroups are tasked with developing three written products each—for a total of 12 products—that advance the CDS field in the first two years of the CDSiC. The products vary in terms of expected length of time to complete based on scope, falling into one of three Levels. Level 1 projects are the largest in scope, involving significant effort. Level 2 projects involve a medium amount of effort. Level 3 projects are shorter-term activities. The target audience for Workgroup products may vary by resource, but broadly include patients/caregivers and their care team, clinicians, CDS researchers, CDS content developers, CDS vendors, policymakers, and payers.

Workgroups continued to meet on a monthly basis through the reporting period, using meetings to update Workgroup members on product progress and solicit their input on product scope and activities. Below, we provide a detailed update on the progress of each of the four Workgroups.

CDS Outcomes and Objectives Workgroup

The Outcomes and Objectives Workgroup is identifying stakeholder-driven short- and long-term PC CDS goals that will advance the translation of patient-centered outcome research (PCOR)-based evidence into clinical practice through safe and effective PC CDS. The Workgroup is also developing measurement and effectiveness criteria for assessing the impact of PC CDS on health-related outcomes and informing the CDSiC's objectives for advancing PC CDS and the desired impact of the collaborative based on stakeholder input**.** A brief description of the Workgroup products' (Exhibit 1) scope and activities to date is provided below.

Exhibit 1. CDS Outcomes and Objectives Workgroup Products



Analysis of the Most Appropriate Outcomes Measures for PC CDS (Level 1)

This product will be a report of the most appropriate outcome measures for PC CDS. The analyses will include the identification of publicly available instruments, where known, that could be used to measure specific outcomes, including instrument evaluation criteria such as accuracy, validity, and ease of measurement. Furthermore, the analysis will identify instances of outcomes for which instruments need to be developed or improved. The product will also include a research agenda that will denote specific gaps and questions for further study uncovered during analysis. The final report will summarize the information gathered and the identification of areas of available knowledge, as well as gaps.

The product development process includes conducting a scoping review to identify categories of outcome measures, followed by the identification of additional outcome measures and tools through key informant interviews (KIIs). In September 2022, the Workgroup began developing research questions and the literature review search string and strategy. To date, the work has centered around refining scope and aims of the product and initial literature searches to vet the search string and strategy, and to identify outcome measurement domains relevant to PC CDS.

Framework for Understanding the Role of PC CDS in Supporting Shared Decision-Making (Level 3)

This product will be a framework for advancing shared decision-making using PC CDS. The product will describe the complexities and considerations around advancing shared decision-making with the use of PC CDS and identify how PC CDS can help enable shared decision-making within clinical workflows. The product will also discuss how the impact of PC CDS on shared decision-making can be evaluated. The final product will be a report that includes the framework, a summary of SDM models, and key points from expert interviews.

Development of this product will begin in November 2022**.** To develop this product, the Workgroup will conduct a literature review, develop the framework, validate the framework, and write the final report for submission to AHRQ.

Taxonomy for Patient Preferences that are Relevant to PC CDS (Level 3)

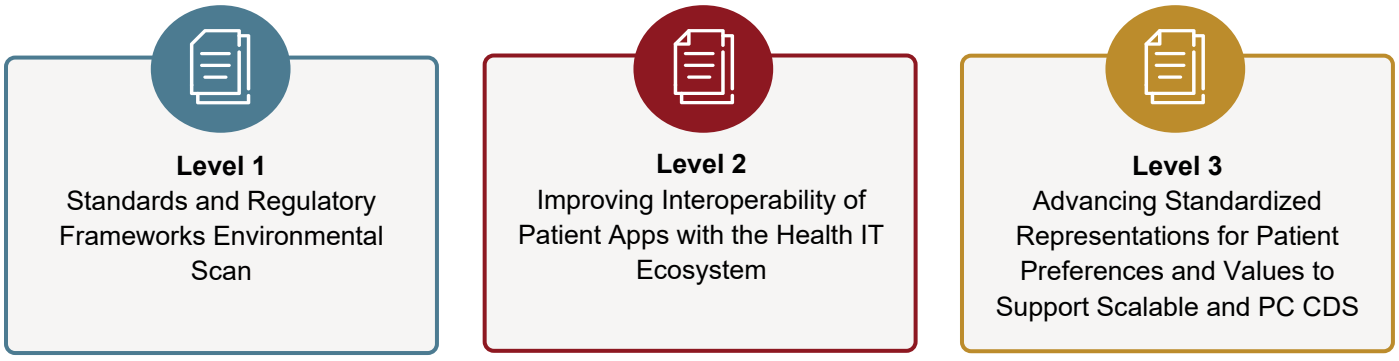
This product will be a taxonomy that describes and categorizes patient preferences relevant to PC CDS. The product will also provide examples of where these preferences might be captured in the workflow, along with examples of how those preferences could be incorporated into PC CDS. Additionally, this product will document challenges related to the capture or use of preference data as potential items for a research agenda. The final product will be the taxonomy converted into a tabular form, accompanied by a high-level summary report to describe the methods and overarching findings.

To support the development of this product, the Workgroup is performing a scoping literature review of grey literature and PubMed to assess the current usage of patient preferences in CDS and other clinical information systems (e.g., electronic health records [EHRs], patient apps). Between July and August 2022, the Workgroup developed research questions and a literature review search strategy. To date, the team has conducted several targeted literature searches, initiated data extraction, and compiled preliminary findings. The team will continue screening and coding articles, adding supplemental material as needed to address identified gaps. Additionally, the Workgroup is conducting KIIs with experts from consumer technology organizations as well as experts on clinical information systems. The Workgroup will also convene a focus group consisting of leaders in patient-centered care and patient advocates, to be held in late September or early October. The Workgroup began outreach for KIIs and focus group participants in August 2022 and finalized recruitment/scheduling in September 2022. The Workgroup will synthesize literature review and KII findings to identify relevant preferences for PC CDS and develop the taxonomy.

CDS Standards and Regulatory Frameworks Workgroup

The CDS Standards and Regulatory Frameworks Workgroup is identifying, monitoring, and promoting standards for the development of PC CDS, recommending ways to enhance existing standards, and identifying areas where new standards and regulatory frameworks are needed. This work will support the creation of standards-based PC CDS that can be scaled across health systems to support patients, caregivers, and care teams in making evidence-informed healthcare decisions. A brief description of the Workgroup products' (Exhibit 2) scope and activities to date is provided below.

Exhibit 2. Standards and Regulatory Frameworks Workgroup Products



Standards and Regulatory Frameworks Environmental Scan (Level 1)

The environmental scan will examine the current state of standards, regulatory frameworks, and technical barriers, and identify salient gaps, opportunities, and challenges to support the development of interoperable PC CDS. The report will also provide recommendations and an action plan for addressing identified barriers and furthering advancing PC CDS.

The development process for this product includes a targeted literature review of peer-reviewed and gray literature on PC CDS standards and regulatory frameworks and KIIs with members of the PC CDS community, including standards developers, app developers, informaticians, and members of patient advocacy organizations. To date, the Workgroup has completed its literature review and data abstraction and has conducted interviews with nine key informants. The team has also applied an organizing framework to qualitatively summarize findings across the literature and key informant interviews; identified four illustrative use cases; and created an action plan for the PC CDS standards community. The draft report for this product will be submitted to AHRQ in September 2022.

Improving Interoperability of Patient Apps with the Health IT Ecosystem (Level 2)

This product will describe the needs and potential approaches to addressing the lack of interoperability between patient apps and health IT systems used by clinicians. The report will describe the current state of integration and the existing standards and regulations; the impact of inadequate integration; and common scenarios in which integration is needed, with accompanying data flow diagrams.

To develop this product, the Workgroup will conduct a scoping review of peer-reviewed and gray literature, interview key informants, identify outstanding interoperability issues for use cases, and develop an action plan based on its synthesis of findings. The action plan may include recommendations to develop new resources, implementation guides, or to enhance existing resources. The Workgroup began product development in September 2022. To date, work has focused on developing a conceptual model of the workflow between patient apps and health IT systems to inform the product's research questions.

Advancing Standardized Representations for Patient Preferences and Values to Support Scalable and PC CDS (Level 3)

This product will be a report on the current state of content adoption and use of data standards for collecting and using patient preference data to guide PC CDS, accompanied by a set of recommendations to address any gaps or implementation barriers for these standards. It will summarize currently available data standards that can represent patient preferences and other types of patient-contributed health data and clarify their consistent implementation and optimal use. It will identify gap areas where standards for patient preference data are lacking. It will also summarize approaches and best practices for soliciting, documenting, and storing data related to patient preferences, both disease-specific and regarding general health and wellness.

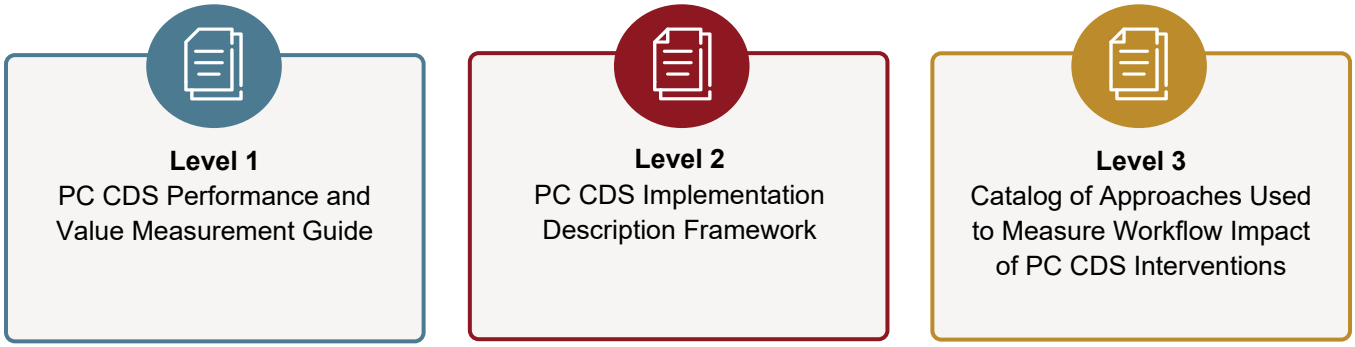
Development of this product will begin in January 2023. To produce this report, the Workgroup will conduct a targeted literature review, interview key informants, evaluate existing standards, and

synthesize recommendations and priorities for representing and exchanging patient preferences and values to inform PC CDS.

Scaling, Measurement, and Dissemination of CDS Workgroup

The Scaling, Measurement, and Dissemination of CDS Workgroup will address PC CDS implementation needs by demonstrating the value of PC CDS, considering how to advance shareable PC CDS that can be integrated into clinician and patient workflows, and identifying adoption, implementation, and use measures —in order to promote the adoption and use of safe and effective PC CDS. A brief description of the Workgroup products' (Exhibit 3) scope and activities to date is provided below.

Exhibit 3. Scaling, Measurement, and Dissemination Workgroup Products



PC CDS Performance and Value Measurement Guide (Level 1)

This product will provide recommendations on strategies and measures for evaluating the performance and value of PC CDS interventions, with a particular focus on patient interactions. This guide will include recommended measurement and evaluation frameworks, approaches, and measures for evaluating each step of the PC CDS development and implementation process, as well as patient-oriented process outcomes and the care process effects these interventions produce. The final product will be a written document that captures and structures these recommendations to both provide measurement guidance.

This product will be produced through a scoping review of peer-reviewed literature on existing measurement efforts and measurement frameworks, key informant interviews, and consensus development with subject matter experts through a technical expert panel (TEP) that the Workgroup will convene specifically for the Guide. The TEP will consist of approximately 12-15 invited stakeholders, including patients. The TEP will meet three times throughout the product development process, with the first meeting planned for early Winter 2023. Since June, the team has developed research questions and a search strategy to guide literature review activities. The literature review will occur iteratively in a multi-stage approach. The Workgroup completed the first stage, having screened and abstracted systematic reviews focused on CDS intervention measurement. Like the approach being used for the PC CDS Implementation Description Framework, the team developed a product strawman that outlines

potential measurement domains and example measures, as well as the potential guide structure. The Workgroup will continue to refine the strawman based on findings from the literature review, key informant interviews, and TEP to develop a draft measurement guide. The Workgroup finalized a list of proposed key informants and TEP members. The Workgroup will engage CDS and EHR developers, health system leaders, and patient advocates as key informants and TEP members.

PC CDS Implementation Description Framework (Level 2)

The Framework will provide a standard approach for describing how PC CDS interventions are designed, developed, deployed, used, maintained, and evaluated. This product extends and complements earlier CDS frameworks and checklists (e.g., the GUIDES framework) through its explicit focus on PC CDS.[2] The final product will be a written document that outlines key PC CDS implementation domains, associated measures of success (as applicable), and considerations that CDS researchers, evaluators, patient advocates, and health system leaders can consult to describe and assess the process impacts of a given PC CDS intervention.

The product development process includes a scoping review and key informant interviews. Between July and September 2022, the Workgroup developed research questions and a literature review search strategy. The literature search will be carried out in multiple stages to capture the breadth of topics addressed by the research questions, as well as to search peer-reviewed literature, grey literature, and clinical trial reporting. To date, the Workgroup has completed the first literature review stage and has screened and abstracted literature on CDS implementation frameworks or descriptions of CDS intervention implementation. To inform what information to gather through the literature review data abstraction process, the team developed a product strawman that outlines potential content and structure details for the product, including potential implementation domains, patient-centered implementation factors, and example measures. The strawman will help ensure that the right information is sought and gathered in a way that will enable it to be applied efficiently and effectively to build out the product. The Workgroup will continue to refine the strawman based on findings from the scoping review and key informant interviews to develop a draft Implementation Framework.

Catalog of Approaches Used to Measure Workflow Impact of PC CDS Interventions (Level 3)

The Catalog will identify how organizations are measuring PC CDS effects on workflows/life flows, with a focus on workflow impacts for care team members involved in PC CDS interventions, patients and care teams engaged in shared decision-making, and patients and caregivers utilizing patient-facing PC CDS. This broad survey of how PC CDS workflow effects are being assessed will lay the foundation for subsequent efforts to analyze and improve the effects of PC CDS on specific workflows of interest. The final product will be a written document.

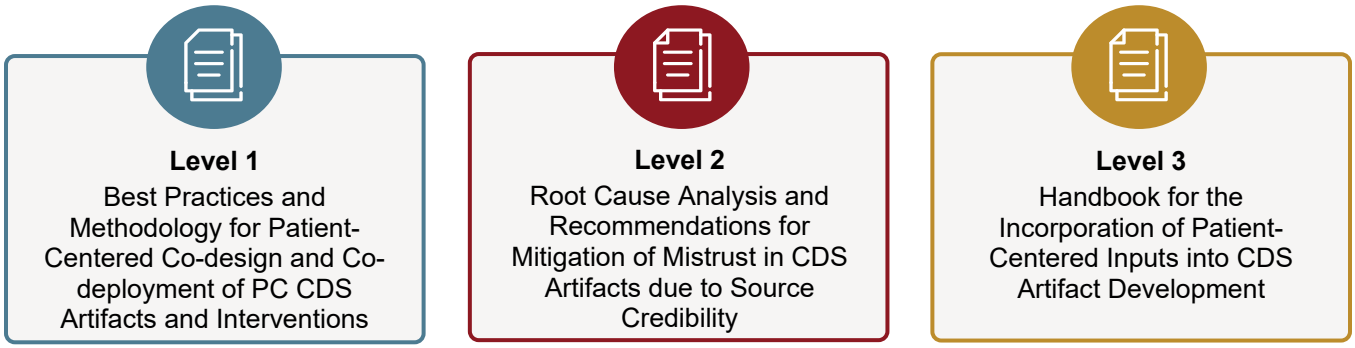
[2] Van de Velde S, Kunnamo I, Roshanov P, Kortteisto T, Aertgeerts B, Vandvik PO, Flottorp S; GUIDES expert panel. The GUIDES checklist: development of a tool to improve the successful use of guideline-based computerised clinical decision support. Implement Sci. 2018 Jun 25;13(1):86.

To develop this product, the Workgroup will conduct a literature review and key informant interviews. Product development activities for the Catalog began in September 2022. In September, the Workgroup developed research questions and the search strategy for peer-reviewed and grey literature. Additionally, the team designed a data abstraction tool and draft product strawman during this period.

Trust and Patient-Centeredness Workgroup

The Trust and Patient-Centeredness Workgroup is developing products that support the engagement of patients and clinicians as partners throughout the CDS design and development process and ensure that these processes are transparent to foster trust in PC CDS. This work will ensure that PC CDS products are designed with their end-users—patient, caregivers, and care teams—in mind. A brief description of the Workgroup products' (Exhibit 4) scope and activities to date is provided below.

Exhibit 4. Trust and Patient-Centeredness Workgroup Products



Best Practices and Methodology for Patient-Centered Co-design and Co-deployment of PC CDS Artifact and Interventions (Level 1)

This product will be a resource guide outlining recommended best practices to promote patient partnerships in the co-design and co-deployment of PC CDS artifacts. The resource guide will document how best to engage patients across the PC CDS continuum from planning and designing, to building and testing, and through deployment and adoption phases of work. The final product will be a summary highlighting specific practices that have proven effective in the past, and detailing any information relevant to adapting the practices for use in new contexts.

To develop this product, the Workgroup is conducting a scoping review of the literature to identify best practices for PC CDS co-design and examine how other fields are pushing forward best practices in co-production and co-design. The team began developing a search string and strategy, coding matrix, and data extraction tool in August 2022 and is currently reviewing and abstracting literature to inform preliminary findings. These preliminary findings will inform future targeted searches, as needed. Based on the literature review, the Workgroup will begin drafting the resource guide in November 2022, to be reviewed and refined through end-user feedback interviews.

Root Cause Analysis and Recommendations for Mitigation of Mistrust in CDS Artifacts due to Source Credibility (Level 2)

This product will support the uptake of PC CDS by enhancing patients' and providers' trust in PC CDS artifacts and the suggestions they generate, as well as patients' trust in providers using PC CDS artifacts. The product will consist of a three-part report that includes a framework for defining the factors that enhance or detract from source credibility, a proposed revision to the Middleton et al. (2018) *Trust Framework,*[3] to include source credibility as a new and distinct trust attribute, and lastly, a series of recommended approaches for increasing source credibility of PC CDS artifacts among providers and patients.

To support the development of this product, the Workgroup is conducting a literature review on literature related to source credibility in health care and other contexts to inform understanding of the models, drivers, and techniques used to confer credibility on published information and guidance. To date, the Workgroup has developed and iteratively refined a search string and strategy, coding matrix, and data extraction. In August 2022, the team began drafting a preliminary source credibility model. The model is currently being refined by the Workgroup and will be reviewed during KIIs.

Handbook for the Incorporation of Patient-Centered Inputs into CDS Artifact Development (Level 3)

This product will be a handbook that can guide CDS artifact developers in using patient-centered approaches. The handbook will help to ensure patients' top priorities are consistently and appropriately incorporated into CDS artifact and intervention development and will additionally promote inclusivity (especially for historically excluded groups) by incorporating data inputs—such as those related to social determinants of health and/or health literacy. The final product will act as a guide for CDS developers to facilitate inclusion of comprehensive and representative patient-centric input into CDS as the mechanisms for delivering CDS recommendations evolve.

Development of this product will begin in December 2022. To develop this product, the Workgroup will conduct a landscape analysis and key informant interviews, finalize the handbook scope, and then review and refine the prototypical handbook before the final submission to AHRQ.

Next Steps

Product development and refinement will continue until September 2023. Workgroups will continue to meet on a monthly basis throughout the project period to scope and develop their products. They will also work asynchronously to provide feedback and comments on research questions, search

[3] Middleton B, Platt JE, Richardson JE, Blumenfeld BH. Recommendations for Building and Maintaining Trust in Clinical Decision Support Knowledge Artifacts. Research Triangle Park, NC: Patient-Centered Clinical Decision Support Learning Network; 2018.

strategies, KII guides, detailed outlines, and product drafts. As product development continues, Workgroup leads will solicit and incorporate input from Workgroup members and other experts to ensure that products align with diverse needs and benefit end-users. The Stakeholder Center Planning Committee and CDSiC project leadership will ensure that products are synergistic without being duplicative.