Measurement and Outcomes Workgroup: Patient-Centered Clinical Decision Support Planning and Reporting Tool User Guide

Prepared by:
Polina Kukhareva, PhD, MPH and Rachel T. Kurtzman, PhD
Ruth Nwefo, MPH
Frances Jiménez, MPH
Mustafa Ozkaynak, PhD, MS
Priyanka J. Desai, PhD, MSPH
Prashila M. Dullabh, MD, FAMIA
CDSiC Measurement and Outcomes Workgroup

PURPOSE

The Clinical Decision Support Innovation Collaborative (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.

The Measurement and Outcomes Workgroup supports the measurement of PC CDS implementation and effectiveness to ensure that PC CDS works as intended. The Workgroup is comprised of 8 experts representing diverse perspectives related to CDS. All qualitative research activities conducted by the CDSiC are reviewed by the NORC at the University of Chicago Institutional Review Board (FWA00000142).

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Contributors: CDSiC Measurement and Outcomes Workgroup

Members of the Measurement and Outcomes Workgroup who contributed to this report are listed below.

Name	Affiliation
Jonathan Einbinder, MD, MPH	Harvard University School of Public Health
Ben Hamlin, DrPH	Liaison to Federal Agencies and HL7 Communities
Wayne Liang, MD, MS	Emory University, Children's Healthcare of Atlanta
Scott MacDonald, MD, FACP, FAMIA	University of California Davis Health
Kistein Monkhouse, MPA	Patient Orator
Richard Schreiber, MD, FACP, FAMIA, ABPM-CI	Pennsylvania State University
Karen Sepucha, PhD	Harvard Medical School, Mass General Research Institute
Dean Sittig, PhD	University of Texas

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A. About This User Guide

This user guide provides information about how to complete the Patient-Centered Clinical Decision Support (PC CDS) Planning & Reporting Tool. PC CDS can accelerate whole-person approaches to care delivery and transformation. PC CDS includes digital tools that have the potential to support patient-centered care by helping clinicians and patients make the best decisions given each individual's circumstances and preferences.[1]

What Does the User Guide Cover?

The PC CDS Planning & Reporting Tool User Guide is intended to support PC CDS researchers in consistently and comprehensively describing how PC CDS was designed, developed, deployed, used, maintained, and evaluated along four key sections: 1) planning and needs assessment; 2) design and development; 3) implementation and adoption; and 4) evaluation, maintenance, and sustainability.

> **What is Patient-Centered Clinical Decision Support?**
>
> Patient-centered clinical decision support encompasses a spectrum of decision-making tools that significantly incorporate patient-centered factors related to knowledge, data, delivery, and use.
>
> ► **Knowledge:** Refers to the use of comparative effectiveness research (CER) 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:** Directly engaging patients and/or caregivers across different settings.
> ► **Use:** Focuses on facilitating bi-directional information exchange in support of patient-centered care, including shared decision making.

This user guide accompanies a fillable tool (the PC CDS Planning & Reporting Tool) that enables users to describe details of how each section was addressed within their PC CDS approach. In doing so, the tool:

► Allows users to document (or address) the 'why, what, and how' details for their PC CDS implementation.
► Ensures that the key dimensions that drive PC CDS success are described in a complete and consistent way. This will provide a more consistent and transparent context for related process and outcome measurement within and across PC CDS evaluation efforts.
► Promotes patient-centeredness within the lifecycle of clinical decision support (CDS) to help shift the field from CDS to PC CDS.

What Gap Does This Resource Fill?

The tool and user guide aggregate guidance from a range of existing CDS implementation guidance and implementation science and evaluation frameworks to provide a unified resource for reporting PC CDS research.

Details relevant to the patient-centered activities that are critical components of PC CDS, such as patient needs elicitation, patient co-design, incorporation of patient generated health data (PGHD), and

involvement of patients as key implementation stakeholders, are currently missing from existing CDS implementation guides and frameworks. While incorporation of these activities in CDS implementation is still emerging, this user guide provides preliminary guidance on reporting them. Through documenting these components, users are able to produce a comprehensive report that fosters best practice syntheses across efforts and facilitates replication of implementation successes by others. This guidance can be further refined by subsequent initiatives that evaluate and enhance results from applying this initial tool.

Who Should Use the User Guide and Planning & Reporting Tool?

The intended users of the user guide and tool include researchers, electronic health record (EHR) and app developers, users and evaluators of PC CDS aimed at improving particular care processes or outcomes, patients and caregivers, and others who are interested in participating in the documentation of PC CDS. In this guide, we use the term "users" to encompass the team responsible for reporting on PC CDS implementations. This can include, but is not limited to, researchers, project managers, members of the organization's IT department, informaticians, clinical champions, clinicians, and patient partners who are part of research teams.

How Can You Use the User Guide and Planning & Reporting Tool?

Research teams can use this user guide and tool during and after implementation of PC CDS to produce a comprehensive report describing their work. Detailed, comprehensive PC CDS implementation reports can help others replicate implementation successes and contribute richly to efforts to synthesize best practices across implementation efforts. It might not be feasible for organizations to describe every item listed in the user guide and tool. These materials are intended to help surface important items that might otherwise be missed.

In Section B we describe how to use the PC CDS Planning & Reporting Tool. Using the fillable tool, users can describe how they addressed each task and the associated patient-centered activities for their specific PC CDS implementation. The tool also allows users to describe which performance measures they considered, challenges encountered, and factors that led to implementation success. *The tool is provided as a separate document that accompanies this user guide.*

In Section C, we describe the PC CDS areas included within the tool. For each section, we outline specific tasks to consider when reporting on PC CDS implementations. Additionally, in this section we synthesize guidance from the literature on what to consider—including example elements —as well as patient-centered activities to prioritize for each task.

B. About the PC CDS Planning & Reporting Tool

Through the process of completing the tool, users will be able to describe details of how each PC CDS implementation dimension, including associated patient-centered activities, were addressed by their PC CDS approach. This can help organizations report activities and results in a manner that supports a robust and consistent evidence base for comparing and improving PC CDS implementation across organizations.

Under each task, a user's team can use the checkbox to indicate whether the task was addressed. It might not be feasible for all organizations to complete all tasks, given that implementation context varies across PC CDS in terms of setting, target end users, software requirements, available resources, and other factors.

The PC CDS Planning & Reporting Tool is organized by the sections, areas, and tasks described in Section 3 of this user guide. The tool contains four fillable sections for users to populate relevant to their PC CDS research. It provides a brief description of tasks and patient-centered activities, as well as fillable sections to describe approaches for completing the task and addressing the patient-centered activities.

> **Reporting Considerations for Planning & Reporting Tool Users**
>
> ► The amount of detail provided by teams for each fillable section of the tool will vary depending on the PC CDS tool and available resources. This user guide and planning & reporting tool are versatile and intended to support a spectrum of planning & reporting uses and audiences, ranging from published manuscripts to documents solely for internal use.

The reporting tool features language asking how users addressed the task and patient-centered activities is included across all tasks. For this item, users can specify their approach to addressing the task and describe how they prioritized patient-specific needs, preferences, and values for each applicable task. The approaches can be unique or guided by the examples provided in Section 3 of the user guide. Given the nascency of PC CDS literature, users may identify patient-centered activities that were not initially included when this tool was developed and should describe them when possible.

C. PC CDS Implementation Sections

Below we describe the information users will need to know to use the tool and apply it effectively. There are four key sections relevant to PC CDS (Exhibit 1).

Exhibit 1. PC CDS Implementation Sections

Each of these sections can be further stratified into areas that are organized into discrete tasks. Within each area, there are patient-centered activities users should consider when reporting on a PC CDS implementation. Below, we describe each section and area, and provide example approaches to address the tasks.

1. Planning & Needs Assessment
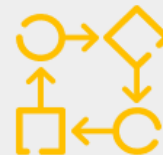
Implementation planning and needs assessment is the process of identifying the needs of the organization (e.g., to improve care quality and/or safety) and intended end users (e.g., clinicians, patients, and caregivers), and describing how the proposed PC CDS will meet these needs. Within the planning and needs

> **Patient-Centered Activities to Address**
>
> Throughout Section 3, this patient icon indicates patient-centered activities to consider for each task.

assessment section, we identified tasks in four areas: 1) business case assessment, 2) user requirements gathering, 3) technical requirements gathering, and 4) planning for knowledge maintenance.

1.1 Business Case Assessment

The first step in a PC CDS implementation is conducting a business case assessment, which is the process of justifying the need for a new PC CDS tool.[2]

Task: Describe Identified Clinical Quality/Safety Goals and Opportunities for the PC CDS to Achieve the Goals. Users may have conducted a local needs assessment to identify issues that could be addressed by PC CDS, which may have included questionnaires, interviews with target end users, and expert panel discussions with PC CDS users.[3,4] Users should describe the performance or quality measures used to inform the decision to implement the PC CDS, which may be derived from findings from a literature review, best practices gleaned from CDS case studies in similar settings, and input from stakeholders to set performance goals.[5] Users should also document any processes that were used to obtain buy-in from leadership or established governance committees to implement the PC CDS in order to fill the identified gaps.

> Users should note performance measures related to patient/caregiver daily activities and how the proposed PC CDS can reduce health disparities among these groups.[6] Users should also note if patients and caregivers were involved throughout the needs elicitation and goal identification process, either formally (e.g., involvement in interviews or brainstorming sessions) or informally (e.g., conversations with clinicians that are passed on to implementation teams).[7]

Task: Summarize the Evidence Base for the PC CDS. Users should synthesize the knowledge base that informed the PC CDS decision logic.[8] This knowledge base may have included meta-regression analyses, case studies of CDS implementations in similar settings, clinical guidelines or

recommendations, or systematic reviews of existing CDS tools or CDS success factors.[4,9,10] When pertinent, users should identify the framework, theory, clinical guidelines, or model they used to guide PC CDS development and justify that decision.[10] This can include disease-specific conceptual models or behavior change theories that guide design features of the PC CDS.

> Users should report if they incorporated patient-centered implementation frameworks, such as the Analytic Framework for Action [11] or the PC CDS lifecycle 8-stage framework,[70] patient-centered clinical guidelines such as the U.S. Preventive Services Task Force (USPSTF) recommendations,[12] or patient-focused behavior change models into the PC CDS design.

Task: Assess the Anticipated Costs, Risks, and Benefits of the PC CDS. Users should note if they assessed the anticipated monetary costs, risks, benefits, and/or return on investment (e.g., costs, financial benefits, and health outcomes) of developing and implementing the PC CDS when determining if the project was financially feasible in a given setting.[7] While assessments may have focused on monetary indicators of cost, (e.g., dollar amounts), other qualitative and quantitative indicators may be relevant, such as time, staffing requirements, or perceived end-user satisfaction.[2]

> Users should report if they considered anticipated costs, risks, and benefits, financial or otherwise, that patients may incur through the PC CDS.

Task: Describe the Process for Leveraging or Establishing Governance Mechanisms Specific to the PC CDS. Users should report the process undertaken to establish, inform, and maintain formal CDS governance bodies specific to the proposed PC CDS.[5,14,15,16] This reporting step may not be necessary if CDS governance structures already exist.

> **Examples of Established Governance in CDS work may include, but are not limited to:**
> ► Institutional Review Boards (IRB)
> ► Office of the National Coordinator for Health IT (ONC)[5] certification
> ► Food and Drug Administration (FDA) guidance for EHR support[13]
> ► Literature on CDS governance such as Kawamoto and colleagues' guide to establishing CDS governance bodies when describing their approach to establishing their own governance mechanisms[16]

> When applicable, users should report how they involved patients in PC CDS governance structures.

1.2 User Requirements Gathering

User requirements gathering involves compiling information on user needs, opportunities to improve existing workflow and communication tasks, and system readiness to choose the right PC CDS to address end-user needs.

Task: Describe Process for User Requirements Gathering. Users should report if they identified requirements from end users, such as information on user needs and decision and communication tasks, and the current results from these processes.[7] Examples of the types of information to describe include results from interviews conducted with clinicians using the think-aloud method[17] to understand workflows and current methods for processing/using information, scenarios based on user stories, and

descriptions of salient needs gathered from advisory groups via nominal group techniques or other methods.[7,18]

Identifying patient user requirements can enhance patient-centered design of PC CDS. Users should describe the extent to which patient perspectives were collected as part of the user requirements gathering, for example, by engaging a patient advisory group. (Learn more here.)

Task: Describe Results of Workflow Compatibility Assessments. Users should report if they conducted a workflow compatibility assessment with a focus on describing how the PC CDS would be integrated into end-user workflows. The results of workflow mapping are used to identify the current state of workflows and identify gaps can also be reported.[19]

Users should report if the potential workflow compatibility of the proposed PC CDS on patient/caregiver daily activities (i.e., "lifeflows")[20] was considered. Reflecting on how well the proposed PC CDS can be integrated into patients' or caregivers' daily routine and activities can help identify gaps.

1.3 Technical Requirements Gathering

Technical requirements gathering refers to the process of assessing the current technological factors relevant to PC CDS, such as usability, performance, adaptability and flexibility, dependability, information functionality, and cost.[21,22]

Task: Describe Results from Technical Feasibility Assessments. Users may have conducted assessments of existing technical infrastructure, application programming interfaces (APIs), or knowledge resources, and gathered input from stakeholders and end users on software performance and regulatory and security requirements.[7] Additionally, users may have assessed data quality (i.e., completeness and validity) and local data availability, and identified additional data collection needs.[23,24] Users may report the results of system readiness assessments to illustrate the system capabilities to implement the PC CDS and how much effort it would take to reach the identified goals.

Identifying technical feasibility requirements can enhance patient-centered design of PC CDS. Users should describe the extent to which patient perspectives were collected as part of the technical requirements gathering, for example, by engaging a patient advisory group.

2. Design & Development

The design and development phase constitutes software (and related process change) design and development, as well as user testing to identify and address needed people (e.g., training), process, and technology changes prior to implementation.[7,25] We refer to *design and development* as the process of designing and building PC CDS such that it is easy to use and is delivered at the right times and to the right people,[26] with the goal of ensuring its fit or effectiveness in a given context.[7] Within this section, we identified two areas: 1) co-design, and 2) prototype testing.

2.1 Co-design

CDS co-design consists of the intentional engagement of diverse stakeholders in collaborative design and development activities. Patients and caregivers in particular should be involved in the design and development of PC CDS, since they are the ultimate beneficiaries. This approach has been successfully applied to software design[27] and could provide a path forward for improving patient-centeredness in CDS design and deployment.

Task: Describe Initial and Iterative User Input During Design. Gathering user input, both at the initial design stage and iteratively throughout development, is a key implementation task within PC CDS co-design. Users should describe the design approach and the results of any user-centered design practices, such as pilot testing, satisfaction assessments, and mapping of end-user doubts or negative beliefs about the tool to address in future implementation plans.[21,28] Additionally, users should report if cognitive task assessments with end users[29] were conducted, such as interviews or observations that assessed end-user goals, tasks, and mental models using critical incidence technique,[30] stimulated recall,[31] screen capture, or eye tracking.[7] Descriptions of how human-computer interaction design guidelines were followed can also be reported.[35]

> Patient-centered co-design specifically involves patients in the conceptualization of a tool based on their needs, preferences, and values (learn more here). Strategies to support patient-centered co-design include holding focus groups with patient advocates, utilizing social media to gather patient feedback, including patients in software development activities, and paying attention to privacy and cybersecurity issues that may be of concern for patients.[32] Users should describe the extent to which patients participated in co-design and note key facilitators and barriers to their engagement.

Task: Describe Process for Developing PC CDS System & Addressing End-User Requirements. Users should report considerations they identified for developing the software requirements for the PC CDS, such as knowledge representation, parameterization, extensibility mechanisms, coordination with workflow systems, execution, editability, use of standards to integrate into existing systems, and knowledge maintenance.[33]

> Developing PC CDS systems that address end-user requirements can enhance patient-centered design of PC CDS. Users should describe the extent to which patient perspectives were considered as part of the process for addressing identified end-user software requirements.

2.2 Prototype Testing

The process of involving end users in the testing and evaluation of a prototype PC CDS to inform refinements prior to implementation is vital for optimizing usability.[7] Feedback from prototype and usability testing is used during CDS development to create a final PC CDS tool that can be deployed in a production environment

Task: Describe How the PC CDS Design Addresses Each Component of the CDS Five Rights (right information, right person, right format, right channel, and right time in the workflow). Users should articulate how the CDS Five Rights dimensions, "who, what, when, where, how," for the PC CDS were determined. Users should provide justifications for the tool type, choice of delivery method, targeted user, and workflow given the patient population and types of data available to satisfy the "right people" and "right time" components of the CDS Five Rights.[34,35] For example, users could report on the approach used to translate a clinical guideline into a risk-organized order set that lists orders that are appropriate for patients falling into different risk categories.[23]

> **CDS Five Rights**
>
> A pillar of prototype testing is evaluating the CDS Five Rights. The CDS Five Rights is a framework that provides a foundation for designing CDS tools that effectively improve targeted care processes and outcomes. To achieve these goals, CDS tools must provide the right information, to the right people, in the right formats, through the right channels, at the right times.[26]

Users can specify what, if any, patient-contributed data (e.g., patient-report outcomes [PROs] or PGHD) were leveraged by the PC CDS. If relevant, users should report how they determined when to collect patient-contributed data. Users should note any patient-facing delivery methods (e.g., apps) used to make the PC CDS content more accessible to patients.[34] Users can also provide information describing how patient preferences were incorporated into the design or decision support logic for the PC CDS to ensure that helpful information is delivered to the patient at the right time, in the right manner.

Task: Report on the Accuracy, Availability, and Validation of Data Used Within the PC CDS. Users can specify which data elements were used and which, if any, standard terminologies were leveraged (e.g., International Classification of Diseases [ICD] codes, Logical Observation Identifiers Names and Codes [LOINC], Systematized Nomenclature of Medicine Clinical Terms [SNOMED-CT]). Additionally, users should report any approaches to improve or validate CDS accuracy and quantify this accuracy. For example, this may include conducting chart audits to identify the proportion of charts missing important data that could affect the accuracy of clinical actions suggested by the PC CDS.[9]

Users should report if they incorporated patient-contributed information (e.g., PGHD, PROs, social determinants of health [SDOH], or Health Related Social Needs [HRSN] data) into the PC CDS.

Task: Describe the Process for Decision Support Logic Validation. Users may have translated information, clinical guidelines, and/or recommendations into computable knowledge, and should report how this translation was validated. Users should also report discussions with stakeholders to agree upon which information/guidelines to include within a tool and how to optimize clinical content to inform tool development, if applicable.[36]

To encourage patient-centeredness in design, users should report if they translated patient-contributed information into computable knowledge and describe the extent to which patients contributed to validating the decision support recommendations.

Task: Describe How PC CDS Usability was Addressed. Users should report the method(s) used to address the usability of the PC CDS, which may include prototype development and design testing, technical acceptability testing, and initial usability testing.

Prototype Development and Design Testing. Users should report approaches taken to conduct prototype testing and specify the number of rounds of testing performed on a PC CDS prototype, who participated in testing, and activities to refine the prototype based on feedback. Example approaches for prototype testing include process mapping conducted through qualitative observations, alpha testing and subsequent focus group discussions with end users,[37] and

> **Usability Assessments**
> ► Prototype Testing
> ► Technical Acceptability Testing
> ► Initial Usability Testing (think aloud interviews, surveys)

validation studies in which a group of users testing the tool is compared with a "business-as-usual" control.[38] Users can also report results of social acceptability testing, which focuses on determining whether it is "worth" deploying the PC CDS in a given environment.[7] Exemplar methods for conducting social acceptability testing include formative evaluations in simulated settings with comparisons to business-as-usual; end-user cognitive load assessment using tools such as the NASA Task Load Index;[39] or task-based efficiency assessments that compare time required for PC CDS management versus a control (e.g., mouse clicks, keystrokes, and screen changes).[7]

To facilitate patient-centered design, patients and caregivers should be involved in prototype testing and social acceptability testing to provide design feedback based on their needs and preferences. Users should describe to what extent patients were involved in prototype testing. Even when other care team members are the intended PC CDS recipients, patients should be involved, as appropriate, to ensure that recommendations are likely to be consistent with differing patient values and preferences.

Technical Acceptability Testing. Users should report if they conducted technical acceptability assessments and describe the activities performed to determine whether the PC CDS software met technical requirements (e.g., data readiness, functional requirements, software performance, interoperability, and regulatory compliance).[7] Exemplar methods include performance testing of load and response times with beta testers, assessments of PC CDS integration into EHR and other software interfaces,[7] and technical peer review of the tool, with emphasis on privacy and security vulnerability testing.[43]

> **Usability Dimensions to Assess**
> ► Effectiveness, efficiency, and satisfaction[40]
> ► Nielsen's usability principles (e.g., visibility of system status, error prevention, flexibility, and efficiency of use) [41]
> ► Ease-of-use criteria (i.e., accessibility, automation, unconstraint, and user-friendly interface)[42]

Initial Usability Testing. Intertwined with prototype testing is the process of testing the initial usability of the PC CDS at the beginning stages of development to ensure human-centered design of the tool. Users should report if they conducted activities related to assessing usability of the designed tool, including cognitive load, user friendliness, and ease of use.[7] Common approaches used for usability testing include think-aloud interviews with end users regarding the prototype interface[18] and

questionnaires, such as the Questionnaire for User Interface Satisfaction (QUIS).[44] Users should report the criteria used to inform the development of usability testing methods.

Users should conduct usability testing with patients for patient-facing CDS and CDS for shared decision making and report the results of these assessments.

3. Implementation & Adoption

We define *implementation and adoption* as the deployment of PC CDS into clinical workflows or patients' daily activities and the actions taken to enhance its uptake or rollout, including addressing barriers to this process.[45,7,25] Within this section, we identified five areas: 1) preparing for deployment, 2) deployment, 3) adoption, and 4) fidelity of implementation design.

3.1 Preparing for Deployment

Users should report if they conducted the preparatory tasks to facilitate the deployment and adoption of PC CDS within an organization or patients' daily life, as detailed below.

Task: Describe How Key Stakeholders were Engaged in Implementation. Users should describe the processes undertaken to identify and engage multidisciplinary stakeholders (i.e., clinicians and other care team members, patients, IT staff, organizational leadership, end-user champions) and describe how they obtained buy-in for the PC CDS. Users may have identified champions who are dedicated to using the tool and available to troubleshoot questions or concerns with other users.[47] Example approaches include conducting meetings with organizational leadership to secure commitment and establish a process for regular updates,[46,47] and coordinating conversations with clinical and IT staff to strengthen collaborations.[48]

Patient stakeholders should be identified and engaged in PC CDS implementation to facilitate adoption and acceptance of the tool.[6]

Task: Describe the Study Design Selected for the Implementation Evaluation. Common study designs used to evaluate PC CDS include mixed methods studies utilizing qualitative methods (e.g., key informant interviews, focus groups) to explore user experience combined with usage data. While less common, randomized controlled trials (RCTs) can also be used.

When appropriate, users should describe how patients were included within the evaluation design (e.g., if and how patients were incorporated into each study arm, which patient-centric confounding factors were considered, and how patients contributed to defining study approaches and outcomes).

3.2 Deployment

Deployment of PC CDS may include providing guidance and training on how to use the tool, as well as processes for deploying the tool into existing workflows. Below are example approaches for assessing and reporting on the deployment process.

Task: Describe the Guidance and Training Provided on How to Use the PC CDS. Users should describe what resources were employed to teach end users how to use the PC CDS and how personnel were trained to manage tool components. Users should additionally report if end users were trained on how to use the PC CDS,[35] either through hands-on training sessions or tailored education for different user groups.[28]Users should report if they developed documentation about the PC CDS and topics related to the functioning of the system. [45]

> Users should report what patient training was provided for patient-facing tools and indicate if and how this training was made accessible to patients so that patients can easily access it within their lifeflow.

Task: Describe Approach for Deploying the PC CDS into Existing Workflows. Continued developments in PC CDS offer opportunities for new and improved clinician workflows and patient lifeflows, and the tool may have been implemented in a way that facilitated information gathering. Users may have conducted pilot testing of the PC CDS, deployed the PC CDS to a small number of users to obtain feedback before broader implementation,[46] or implemented a short "grace period" during initial deployment during which users could log change requests.[49] The five dimensions of patient-reported outcome measures (PROMs) implementation outlined in the PROM healthcare system implementation framework (PROM-HCSIF) offer a structure to report on stepwise deployment: first experimentation, early adoption, scaling, wider adoption, and system-wide adoption.[50]

> For patient-facing PC CDS or CDS for shared decision making, users may have involved patients in pilot testing of tools. For tools used outside of the healthcare setting, users should describe the process for incorporating the PC CDS into patient lifeflows, as well as processes for gathering patient feedback (e.g., in-app feedback widget).[16]

3.3 Adoption

PC CDS adoption refers to the frequency with which end users initiate use of the tool or are given the opportunity to do so. Below are example approaches for assessing and reporting on PC CDS adoption.

Task: Report on the Extent of PC CDS Adoption. Users should describe the extent of PC CDS adoption within the targeted setting. This reporting can utilize measures such as the absolute number, proportion, and representativeness of users who were willing to initiate the tool or actually initiated its use.[51]

> Users should detail their approach for assessing patient adoption of patient-facing tools and tools for shared decision making. To the extent feasible, users should include data and describe details of when, how, and why patients and caregivers adopted PC CDS directed to them.

3.4 Fidelity of Implementation Design

To describe the degree to which PC CDS was delivered as intended,[52] users should report on several factors, as described below.

Task: Describe Environmental Factors Affecting Implementation. Users should describe the internal organizational features (e.g., capacity for change, technical capacity, communication), organizational processes/policies, and external or regulatory factors that form the context for PC CDS implementation.[35] Internal (e.g., within the implementation setting) and external (e.g., wider regulatory and policy structures) factors to report at this stage can be gleaned from implementation frameworks such as the Consolidated Framework for Implementation Research (CFIR),[53] the Systems Engineering Initiative for Patient Safety (SEIPS),[54] Cresswell and colleagues' framework for evaluating health IT implementations,[21] Sittig's and Singh's socio-technical model,[55] or Rippen and colleagues' organizational framework for health IT.[56] Users should consider describing internal organizational features (e.g., capacity for change, technical capacity, communication), organizational processes/policies, and external or regulatory factors that form the context for PC CDS implementation.[35]

> For patient-facing PC CDS and CDS for shared decision making, users should describe how patients are affected by internal (e.g., within healthcare setting or daily life) and external (e.g., policy, power dynamics) factors. Users should consider reporting unique internal and external factors faced by vulnerable populations as described by the Health Equity Implementation Framework, such as structural racism and power dynamics.[6,57]

Task: Report on the Extent of Fidelity to the Implementation Protocol. Users should report whether or not the PC CDS worked as designed or was used as intended by end users after accounting for confounding factors.[35] This may include reporting the results of evaluations that map current and desired process models for the tool.[58] Users should also describe how the results of fidelity assessments were used to make changes to the tool, if any were made, using guiding frameworks such as the Plan-Do-Study-Act framework.[19,59] Users should describe the process for integrating the PC CDS into existing systems, including actions taken to minimize burden on users (e.g., automation of manual, tedious, or repetitive steps, pre- and post-implementation changes to workflow processes).[35]

> Users should specify whether the PC CDS was correctly used as intended by patients and caregivers when pertinent. Users should also make efforts to reduce the tool's burden on patient daily activities (or lifeflows) and report the extent to which the PC CDS was made unobtrusive within patient lifeflows.[33]

4. Evaluation, Maintenance, & Scalability

We refer to *evaluation, maintenance, and scalability* as the process of measuring or exploring properties of the PC CDS in a summative manner, determining whether or not the tool achieved its defined objectives and describing the short- and long-term effects of PC CDS.[45,7,60] Within this section,

tasks are grouped into four areas: 1) evaluation of processes, 2) evaluation of outcomes and impacts, 3) maintenance, and 4) scalability. Example approaches for addressing and reporting on these tasks are described below.

In the PC CDS Reporting & Planning Tool, users should report any performance metrics used in the evaluation of the PC CDS. Performance metrics can be quantitative or qualitative measures of the PC CDS's impact on processes and outcomes.

Exhibit 2.   Example Quantitative and Qualitative Measures for PC CDS Evaluation

Quantitative Measures *The "what"*	**Qualitative Measures** *The "why" or "how"*
• Numerical measures related to adoption and use (e.g., adoption and utilization rates) • Clinical outcomes (e.g., readmission rates, proportion of settings still delivering the PC CDS after a set amount of time)	• Open-ended survey data, interview/focus group findings, or other written or verbal information (e.g., user satisfaction or experience with the PC CDS)

4.1 Evaluation of Process Changes

Task: Describe Evaluations of PC CDS Process Impacts. Users should describe how they assessed impacts of the PC CDS on individual, organization, and system processes related to simplicity (i.e., ease of operation), flexibility (i.e., ability to adapt to changing requirements and needs), data quality (i.e., data completeness and suitability for research purposes), timeliness, and acceptability of the tool.[24] This may have included feedback collected from end users and

> **Evaluation in Life Cycle of Information Technology (ELICIT) Framework**
>
> The ELICIT framework provides exemplar questions regarding process outcomes, as well as other areas such as unintended consequences, health equity, and dissemination value.[7]

clinical champions via semistructured interviews and surveys regarding their experiences with the tool and perceived changes to workflows.

Users should also discuss approaches they took to transparently report data to end users on tool adoption, use, and value of data across a health system/clinical setting, and any impacts on how users exchange best practices to facilitate system-wide quality improvement.[50] This task may also include evaluations of information quality management practices that are designed to check that the quality of information fits users' needs. Typically, information quality management practices are performed organization-wide. These evaluations should be conducted at each stage of the lifecycle of producing information used to support decision making and planning: 1) requirements planning, 2) information acquisition, 3) information and systems maintenance, and 4) information application. Mohammed and Yusof outline criteria for evaluating information quality management practices at each stage of the information lifecycle that can support users in such an evaluation.[61]

Users should describe their approach to collecting and reporting on process outcomes relevant to patients, such as lifeflow burden, efficiency, usage, and patient/clinician

communication, both inside and outside healthcare encounters. For patient-facing tools, users should also identify unintended consequences of tool implementation within patient activities and describe how they approached them.

Task: Describe and Report Results of PC CDS Assessments.
Users should report the assessments conducted during the PC CDS evaluation. PC CDS assessments include: ethics assessments, user experience and challenges encountered, and user satisfaction assessments.

> **PC CDS Assessments**
> ► Ethics Assessments
> ► User Experience
> ► User Satisfaction

Ethics Assessments. Users can conduct ethics risk-benefit assessments at the individual, organizational, and regulatory levels to inform how and when PC CDS should be adopted to support decision making for both patients and clinicians.[15] The benefits of any interventions should outweigh the risks, and risks should not affect patient populations disproportionately. Users should report any results from ethics assessments.

> Users can describe the tool's ability to address ethical concerns related to patient privacy, consent, and transparency, equity, and health disparities. Users should describe any processes for communicating risks and benefits of using the PC CDS to patients.[15]

User Experience and Challenges Encountered. Users should report on their approach to gathering feedback from end users on their experience while using the tool and any challenges experienced. An example organizing framework is Rosembaum's adaptation of Morville's "honeycomb" of user experience, which includes aspects like accessibility, findability (i.e., whether users can locate what they are looking for), usefulness, credibility (i.e., whether the tool and its content are trustworthy), desirability (i.e., whether the tool is something users wants), and identification (i.e., whether users feel like the tool was "designed for them").[62]

> For patient-facing tools and tools for shared decision making, users should report results from user experience assessments with patients.

User Satisfaction Assessments. PC CDS should ideally improve end users' satisfaction (and decrease burden) associated with the workflow or patient lifeflow activities targeted by the PC CDS. Users may have conducted long-term user satisfaction assessments and should describe whether or not users found the system to be engaging.[7] Users should report the results of any pre- and post-implementation user satisfaction surveys, semistructured interviews with end users, additional surveys, or review of software logs that were conducted.

> Users should describe how patients and caregivers were involved in user satisfaction assessments and report results relating to patient and caregiver satisfaction with the tool, if applicable.

4.2 Evaluation of Outcomes and Impacts

Evaluations of an intervention's outcomes and impacts are conducted after a program is well established to understand the short-to-long-term health and clinical effects and implications.[63] Results

of a full program evaluation of a PC CDS tool can include changes in clinical, health system, and related outcomes as well as cost assessments.

Task: Describe Evaluation of PC CDS Outcomes.
Users should report results from assessments of the overall value of the PC CDS with regard to adherence to guidelines or best practices and clinical outcomes.[58] These assessments could be guided by frameworks such as the Institute for Healthcare Improvement's "quintuple aim," which focuses on improved patient experience, better outcomes, lower costs, clinician well-being, and health equity.[64] To understand the effect of PC CDS on patient outcomes, users should report changes in clinical (e.g., health outcomes, patient safety), health system (e.g., cost, provider burnout), and related outcome measures by comparing data collected pre- and post-implementation. Example measures include mortality, hospital admissions or readmissions, effectiveness of care, adverse events, or disease-specific outcomes.

> **Defining Patient Health Journey Measures**
>
> The CDSiC previously defined patient health journey measures as process and outcome measures that capture the experiences a patient has accessing and receiving healthcare, including interactions and engagement with clinicians and health systems, patient decision making, and their experience living with a health condition(s).[65]

Assessments of patient health journey measures[65] and outcomes among patients should be highlighted when reporting results from program evaluations to determine the overall value of the PC CDS to this population. Users should prioritize inclusion of PROs within reporting when possible. When appropriate, users should describe the equity-relevant metrics used within evaluations to understand the effect of the tool on vulnerable populations. Measures that are relevant to assessing an intervention's impact on equity should account for indicators of health or determinants of health, indicators of social status, and "methods for comparing health or a health determinant across social strata."[66]

Cost Evaluations. Cost impact is one component of health system outcomes that users can report if conducted. Users may conduct cost evaluations of PC CDS to describe whether the benefits of the tool outweigh the costs.[10,74] Users can utilize measures relating to the cost of CDS development [67] (e.g., hardware and software development costs, utilization and maintenance costs) or changes in healthcare costs resulting from the tool using direct (e.g., cost of care, facility cost savings) or indirect (e.g., resource utilization, readmission rates) measures.[68,69]

Patient cost considerations, both financial and time, can be considered within cost-effectiveness evaluations for patient-facing CDS and CDS for shared decision making (e.g., costs of healthcare visits, cost of the PC CDS app to the patient, time spent using the tool, less time needed during the visit to provide background information, fewer emails back and forth due to upfront communication of needs the needs and information time spent traveling to the healthcare facility, time taken off from work).

4.3 Maintenance

Maintenance refers to the sustainability of the PC CDS, which is defined as "the extent to which an evidence-based intervention can deliver its intended benefits over an extended period of time."[71] Developing, deploying, and/or evaluating PC CDS requires significant time, expense, effort, and knowledge maintenance. Knowledge maintenance planning refers to the process of organizing, disseminating, and updating the knowledge or information conveyed by a PC CDS tool.[33,14]

> **PC CDS Lifecycle Phases**
>
> 1. Knowledge Generation
> 2. Clinical Decision Support
> 3. Healthcare Delivery
>
> Across the phases, the lifecycle further divides into eight stages: 1) Computable Clinical Knowledge, 2) Patient-specific Inference, 3) Information Delivery, 4) Clinical Decision, 5) Patient Behaviors, 6) Health Outcomes, 7) Aggregate Data, and 8) PCOR Evidence.[70]

Task: Describe the Approach to Monitoring and Managing the PC CDS Throughout its Lifecycle.

The CDSiC previously described a PC CDS lifecycle in which activities to design, develop, implement, use, and evaluate PC CDS are categorized into three phases where patient and/or caregiver participation can be incorporated. Users should describe the plan for continuous monitoring of the PC CDS throughout its lifecycle so that it continues to deliver high value to end users.

This approach can include dimensions of routine auditing and quality improvement activities to ensure the PC CDS is managed appropriately, modified when needed, and retired as appropriate. Users should report if they conduct regular testing of the PC CDS for reviewing relevant metrics to identify misalignments with original intentions and implement solutions, and should specify the frequency of audits (e.g., monthly, quarterly).[46,72] For example, audits can describe whether patient-facing tools displayed accurate and relevant data, whether order sets were deployed at the appropriate time in the workflow and correctly (e.g., reminders to order tests presented at the correct time, correct orders displayed given patients' symptoms), whether processes were enhanced as intended, and whether the intended recipients had the knowledge, skills, and attitudes needed to benefit from the intervention. Users should have a plan to routinely collect user feedback and monitor system usage and performance.[4,10] This can be monitored through a help desk or malfunction log where end users can report issues with the PC CDS.[46] Quality improvement activities undertaken to improve tool performance may include analyses of data quality and efforts to prevent or lessen the impact of unintended consequences resulting from PC CDS implementation.[35]

Users should report if they tested PC CDS rules against patient data to detect unexpected PC CDS behavior (e.g., due to changes in data definitions) and identify potential system performance issues.[9] Additionally, if users involved patients in identifying people and process issues, they should report how feedback from patients was collected and addressed.

Task: Describe the Extent to Which the Tool has Become Part of Routine Organizational Practice and Culture. Users can conduct long-term followup[10] to assess the extent to which the PC CDS has become a part of routine organizational practice and culture.[73] These approaches can be guided by success factors related to the maintenance domain of the Reach Effectiveness Adoption

Implementation Maintenance (RE-AIM) framework, including institutional culture and usefulness.[51] Users can describe the measures used to assess the degree to which the PC CDS has been integrated into regular practice beyond the research phase, such as the proportion of settings still delivering the PC CDS after a set amount of time.[74] Another example approach to measuring and encouraging routine adoption of PC CDS includes developing a way to track and visualize individual utilization against set benchmarks as a way to let end users know where their use ranks against other users.[51]

For patient-facing tools, users can assess the extent to which the tool has become embedded in patient lifeflows.

Task: Describe Procedures for Knowledge Maintenance. Users should consider describing the PC CDS types used within their organization.[46] Examples may include patient-facing CDS, clinician-facing CDS, or CDS for shared decision making.[75] Additionally, PC CDS artifacts need to be updated to ensure their utility for both patients and clinicians. Users should report the approach used to update the PC CDS when new clinical or technological evidence becomes available.[48] This should include specifying the formal software change control processes that guide these updates.[46]

> **Technical portability** is the ability of PC CDS software to be deployed across different health systems and EHR systems. Assessments of technical portability can include evaluation of how easily the software can be disseminated to multiple EHR developers and assessment of the required resources and time to implement the software in settings other than the one(s) for which it was developed.[7]

4.4 Scalability

Scalability refers to the readiness of a successfully tested PC CDS to be implemented in organizations beyond the one in which it was originally implemented. Scalability can maximize the impact of any given PC CDS.[76]

Task: Describe Approaches to Deploy the Tool Beyond the Host Organization. Users can take action to encourage wider dissemination of the PC CDS, such as the use of relevant interoperability standards (e.g., Health Level Seven [HL7] Fast Healthcare Interoperability Standards [FHIR], HL7 Clinical Quality Language, HL7 CDS Hooks, HL7 SMART on FHIR, Business Process Management for Healthcare Plus (BPM+) Health) to support integration into other systems.[77] These standards should be considered and incorporated into PC CDS during the initial design and development stage. Additionally, users can disseminate information about the tool so other organizations or users can use it, such as detailed descriptions of the intervention itself, step-by-step instructions on how to use it, and details about its implementation context.[9,78]

If a technical portability assessment was conducted, users should report findings (see box figure above for more information). Based on the results of technical portability assessments, users can consider whether the PC CDS software can be deployed across health systems or, if applicable, EHR systems.[7] The ELICIT framework provides exemplar questions to consider when developing technical portability assessments regarding interoperability and integration requirements.[7]

For patient-facing tools, users may consider using patient champions to disseminate information about the tool and encourage use among other relevant patient populations.

Additionally, users may consider approaches to deploy patient-facing tools outside of healthcare settings (e.g., schools, neighborhoods, workplaces) to reach underserved patients with limited access to the healthcare system.[66]

D. Conclusion

This PC CDS Planning & Reporting Tool User Guide provides users with the information they need to report on PC CDS in a manner that supports successful scaling and improvement of PC CDS efforts across health systems and other organizations and patient populations. Using this comprehensive guidance, users will be able to complete the accompanying PC CDS Planning & Reporting Tool to facilitate reporting on PC CDS-enabled care transformation.

Appendix A. Tool Development Methodology

The PC CDS Planning & Reporting Tool was adapted from a previously developed CDSiC resource, the PC CDS Planning, Implementation, and Reporting Checklist.[79] Below, we describe the development methods for this initial checklist, user testing activities that informed the development of the current tool, and the changes made based on user testing.

Initial Checklist Development

The development of the PC CDS Planning, Implementation, and Reporting Checklist was informed by a targeted literature review and key informant interviews. These activities took place from 2022-2023 and are summarized below. For a full description of the checklist development methodology, please refer to the PC CDS Planning, Implementation, and Reporting User Guide.[80]

Literature Review

We searched PubMed to identify peer-reviewed literature in a multi-phased approach. We conducted two searches related to CDS implementation frameworks and guidance and health information technology (IT) implementation frameworks and guidance. After deduplication, our search yielded 726 peer-reviewed articles. We conducted two levels of screening—a title/abstract review and a full-text review. At each level, we assessed whether the reviewed records appeared to meet our eligibility criteria. Records deemed *eligible* at the title/abstract level were screened again through full-text review. We conducted a full-text review of 92 peer-reviewed articles identified from the PubMed searches. We then determined the final list of eligible records for data abstraction, and for ineligible records, documented the reason(s) they were excluded. In total, 43 articles were included from the literature searches performed.

Additionally, we reviewed articles that were recommended by Workgroup members and CDSiC project team members. We included three recommended articles after screening. During the literature review process for two other CDSiC products, we also flagged articles relevant to this tool; we screened 18 peer-reviewed articles and included 16 of those articles. In total, we screened 747 peer-reviewed journal articles and included 62 articles.

Key Informant Interviews

We conducted key informant interviews with potential end users of the checklist to support development of the PC CDS Planning, Implementation, and Reporting Checklist. Key informants reviewed an initial draft of the checklist and provided input on the content, design, and potential usefulness to end users. Key informants also tested the checklist on case examples of PC CDS implementation efforts from their own work. In April 2023, we gathered feedback from five researchers and/or experts in CDS development, implementation, and evaluation and adjusted the PC CDS Planning, Implementation, and Reporting Checklist accordingly.

Analysis and Synthesis

Three independent reviewers extracted the following data from the included literature from the scoping review: implementation setting, users (e.g., CDS developers, clinicians, patients, researchers), implementation domain, implementation subdomains and associated implementation tasks, implementation guidance, performance metrics, and patient-centered factors.

After abstracting data from the literature, we qualitatively synthesized literature review findings using qualitative content analysis to identify key domains and components to inform the development of the draft tool. We captured relevant implementation tasks, examples of items to consider, and patient-centered factors for the following implementation domains: 1) planning and needs assessment, 2) design and development, 3) implementation and adoption, and 4) evaluation and impact. We synthesized input from key informant interviews to refine the content and structure of the draft PC CDS Planning, Implementation, and Reporting Checklist.

User Testing and Refinement

To refine the existing checklist, we conducted additional key informant interviews to identify initial areas for refinement, tested an updated version of the tool with novice and expert PC CDS researchers, and then synthesized a list of priority updates based on the feedback received during user testing. Additional detail about these activities is provided below.

Preliminary Key Informant Interviews

We conducted two interviews with PC CDS experts in order to gather preliminary feedback regarding how potential end-users prefer to use the checklist. All interviews were conducted using a semistructured interview guide, conducted virtually, and lasted 60-minutes. Preliminary interviews indicated that the checklist needed more linkages to the user guide, that the tool used jargon that could potentially be confusing for more novice users, and that the column organization could be re-organized for better usability. Interviewees also noted that focus of the tool—which originally spanned planning, implementation, and reporting— could be streamlined. Based on this preliminary feedback, we refined the tool to focus on reporting, made some initial adjustments to language, and also eliminated a "challenges and successes" section that interviewees indicated was not necessary for reporting. The tool was renamed the PC CDS Planning & Reporting Tool.

User Testing

For user testing of the modified tool, we sought "novice" and "expert" PC CDS users to ensure that the tool was useful and understandable to individuals with a range of experience with PC CDS. Using convenience sampling (i.e., engaging others within the CDSiC community, soliciting recommendations from Workgroup leads and members), we recruited 8 testers. Three testers were PC CDS novices and five were PC CDS experts.

Testers were sent the tool, user guide, and a brief feedback form to complete, and were also given the option of annotating the tool and returning it to the CDSiC team to provide direct edits and comments.

Testers were asked to review and complete the tool using a current or previous PC CDS project as an example. For each section of the tool, the feedback form asked testers to share what they would recommend changing, what they found challenging in using the tool and user guide, and what additional suggestions they had for the tool. Each tester was also asked how long it took them to complete the tool.

Testers were also asked to participate in virtual interviews (individual or small group) post-testing to reflect on their experience using the tool. Each virtual interview was 60-minutes and guided by a semistructured interview guide. The interview guide was customized based on the initial written feedback that was received by each tester. Interviews were recorded for notetaking purposes with participant consent.

We received 6 responses to the feedback form and 3 annotated planning & reporting tool (two testers provided both an annotated tool and completed the feedback form). Seven testers completed a follow-up interview. One tester did not complete the feedback form or participate in an interview, noting that the time it took to complete the tool was longer than expected. Of the five testers who reported completion times, two reported taking 30 to 60 minutes to complete the tool, while three reported taking up to 2 hours to complete the tool.

Analysis, Synthesis, and Tool Refinement

Three CDSiC team members reviewed feedback form responses, annotated tools, and interview notes to code thematic areas and identify commonly noted areas for improvement across user feedback. User feedback indicated that the tool was comprehensive in that it covered most of the key aspects of PC CDS reporting. Exhibit A1 summarizes common areas for improvement identified by users.

Exhibit A1. Summary of Common Areas for Improvement from User Testing

Area	User Recommendations
Language	• Refine phrasing to remove complex or ambiguous language in tool and user guide
Content	• Refine questions to mitigate redundancy in responses • Re-evaluate the need for "Who Addressed This" option • Add "N/A" option and more clarifying language to only complete sections/tasks that pertain to CDS intervention
Level of Information	• Create more direct linkages between the user guide and tool • Add examples for how to fill out the tool
Burden	• Consider formatting changes to reduce the cognitive load of working with tool

Based on the feedback, we streamlined language throughout the tool, combined content in some sections to reduce potential redundancies, added checkbox options for some activities and assessments to allow users to easily indicate what was applicable to their PC CDS implementation, and combined columns to reduce the cognitive load of working with the tool. The updated tool was shared with the CDSiC Measurement & Outcomes Workgroup for additional feedback.

Appendix B. Examples of a Completed PC CDS Planning & Reporting Tool

1. Planning & Needs Assessment

Planning and needs assessment is the process of identifying the needs of the organization (e.g., to improve care quality and/or safety) and intended end users (e.g., clinicians, patients, and caregivers), and describing how the proposed PC CDS will meet these needs. Within this section, tasks are grouped into three areas: 1) business case assessment, 2) user requirements gathering, and 3) technical requirements gathering. **See the user guide for more information.** Please note that not all tasks in this section will be applicable to each PC CDS intervention. When marking tasks as "Not Applicable, it may be helpful to provide additional context for your fellow collaborators.

Task	Task Description and Patient-Centered Activities	Describe How You Addressed the Task and Patient-Centered Activities
Business Case Assessment		
Describe Identified Clinical Quality/Safety Goals and Opportunities for the PC CDS to Achieve the Goals Task Addressed? ☒ Not Applicable ☐	**Task Description** • The issue the PC CDS aimed to address. • The performance or quality measures used to inform the decision to implement the PC CDS. • The process for obtaining leadership buy-in to implement the PC CDS. **Patient-Centered Activities** • Performance measures related to patient/caregiver daily activities. • Patient and caregiver involvement in the goal identification process	The lung cancer screening (LCS) PC CDS project aimed to improve early lung cancer detection rates, facilitate shared decision making, and address patient barriers and preferences through the implementation of clinician- and patient-facing CDS tools integrated into EHRs. The project included 3 phases: 1) clinician-facing interventions in 2020-2021, 2) adding patient-facing reminders in 2021-2022, and 3) adding patient-facing education tools in 2024. We conducted focus groups with 23 individuals with high risk for lung cancer to explore patient perspectives related to LCS.
Summarize the Evidence Base for the PC CDS Task Addressed? ☒ Not Applicable ☐	**Task Description** • The knowledge base that informed the PC CDS decision logic, including any frameworks, theories, guidelines, or models used to guide PC CDS development. **Patient-Centered Activities** • Incorporation of patient-centered implementation frameworks, clinical guidelines/recommendations, or patient-focused behavior change models in the PC CDS design or logic.	PC CDS logic was based on USPSTF guidelines and the Life-Years Gained From Screening-CT (LYFS-CT) Model. We used the Evaluation in Life Cycle of Information Technology (ELICIT) framework to guide the development and refinement of the PC CDS interventions. We used Unified Theory of Acceptance and Use of Technology (UTAUT) to explore the theoretical determinants of behaviors associated with LCS implementation.

Task	Task Description and Patient-Centered Activities	Describe How You Addressed the Task and Patient-Centered Activities
Assess the Anticipated Costs, Risks, and Benefits of the PC CDS Task Addressed? ☒ Not Applicable ☐	**Task Description** • Anticipated costs, risks, and benefits of developing and implementing the PC CDS. • Whether or not the PC CDS is financially feasible in a given setting. **Patient-Centered Activities** • Anticipated costs, risks, and benefits incurred by patients.	For patients, the anticipated costs and risks included potential adverse events from invasive procedures to evaluate false-positive tests, radiation from the CT screening, and the need to adapt to new technology. However, for most patients the benefits of more informed decision making, early cancer detection, and personalized healthcare support significantly outweighed these costs, making the implementation of PC CDS advantageous for improving patient outcomes.
Describe the Process for Leveraging or Establishing Governance Mechanisms Specific to the PC CDS Task Addressed? ☒ Not Applicable ☐	**Task Description** • Process for establishing/informing and maintaining governance bodies specific to the proposed PC CDS. **Patient-Centered Activities** • Process to involve patients in PC CDS governance structures.	Tool development was performed within the ReImagine EHR initiative, an enterprise initiative aimed at enhancing healthcare delivery through the development and implementation of interoperable EHR innovations, launched in 2016. PC CDS tools were approved by the University of Utah Health CDS Committee and underwent security review. Patients were involved in the design through participation in focus groups, but were not involved in the governance structures.
User Requirements Gathering		
Describe the Process for User Requirements Gathering Task Addressed? ☒ Not Applicable ☐	**Task Description** • Processes to identify user requirements and the results of these processes. **Patient-Centered Activities** • Incorporation of patient perspectives and needs.	The process to identify user requirements involved conducting in-depth workflow assessments, focus groups, and interviews with end users, including clinicians and patients. The iterative feedback collected from these activities informed the design and customization of the PC CDS tools to ensure they met the specific needs of the users.
Describe the Results of Workflow Compatibility Assessments Task Addressed? ☒ Not Applicable ☐	**Task Description** • How the PC CDS will be integrated into end-user workflows. **Patient-Centered Activities** • Compatibility of the proposed PC CDS with patient/caregiver daily activities (i.e., "lifeflows").	The PC CDS tools were integrated into end-user workflows through a user-centered design process that included iterative feedback from clinicians (n=14) and patients (n=23), ensuring that the tools fit seamlessly into routine clinical activities and patient lifeflows.

Task	Task Description and Patient-Centered Activities	Describe How You Addressed the Task and Patient-Centered Activities
Technical Requirements Gathering		
Describe Results from Technical Feasibility Assessments Task Addressed? ☒ Not Applicable ☐	**Task Description** • Existing technical infrastructure, application programming interfaces, and knowledge resources. • Existing data quality, local data availability, and additional data needs. • System capabilities to implement the PC CDS and how much effort it will take the system to reach its goals. **Patient-Centered Activities** • Incorporation of patient perspectives and needs.	The results of system readiness assessments indicated that the system capabilities required to implement the PC CDS tools were in place, leveraging existing EHR infrastructure and interoperability standards such as FHIR and SMART on FHIR.

2. Design & Development

Design and development is the process of designing and building PC CDS that is easy to use and delivered at the right time and to the right person, with the goal of ensuring its fit or effectiveness in a given context. Within this section, tasks are grouped within two areas: 1) co-design, and 2) prototype testing. **See the user guide for more information.** Please note that not all tasks in this section will be applicable to each PC CDS intervention. When marking tasks as "Not Applicable, it may be helpful to provide additional context for your fellow collaborators.

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
Co-Design		
Describe Initial and Iterative User Input During Design Task Addressed? ☒ Not Applicable ☐	**Task Description** • PC CDS design approach and the results of user-centered design practices during initial and iterative stages. • Results of cognitive task load assessments. • How human-computer interaction design guidelines were followed. **Patient-Centered Activities** • Patient participation in PC CDS co-design and cognitive task load assessments.	The PC CDS design approach followed a user-centered design methodology involving initial and iterative stages of feedback from end-users, including clinicians and patients, to ensure the tools met their needs and integrated seamlessly into clinical workflows.
Describe the Process for Developing the PC CDS System and Addressing End-User Requirements Task Addressed? ☒ Not Applicable ☐	**Task Description** • Process for identifying and developing software requirements from end-user requirements. • Metrics needed to describe the current state of the PC CDS and identified opportunities for improvement. **Patient-Centered Activities** • Incorporation of patient perspectives and needs.	Our user-centered approach ensured that the gathered requirements were accurately translated into technical specifications, which were then iteratively refined based on continuous feedback and usability testing to develop the PC CDS system.

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
Prototype Testing		
Describe How the PC CDS Design Addresses Each Component of the CDS Five Rights (right information, right person, right format, right channel, and right time in the workflow)[81] Task Addressed? ☒ Not Applicable ☐	**Task Description** • PC CDS delivery method appropriate for the patient population and types of data available. • The choice of targeted user and PC CDS workflow. **Patient-Centered Activities** • Patient-contributed data that were used, barriers to capturing these data, and the optimal time to collect patient-contributed data. • Incorporation of patient preferences into the design so that information is delivered to the patient at the right time, in the right format.	Right Information: Our tools provide patient-specific, evidence-based information using validated risk prediction models. Right Person: Our tools target both clinicians and patients with clinician-facing reminders and patient-facing educational materials and reminders through the patient portal. Right Format: Our tools deliver information in accessible formats, including EHR-integrated prompts for clinicians and clear educational content for patients. Right Channel: Our tools use EHR-integrated prompts for clinicians and patient portal notifications for patients. Right Time: Our tools provide information at critical points in the clinical workflow, such as before and during patient visits.
Report on the Accuracy, Availability, and Validation of Data Used within the PC CDS Task Addressed? ☒ Not Applicable ☐	**Task Description** • Data elements that were used in the PC CDS and what, if any, standard terminologies were leveraged. • Approaches used to improve or validate accuracy. **Patient-Centered Activities** • Availability of patient-contributed information and the process of validating this information if incorporated.	Inaccuracies in EHR-documented smoking data—such as missing packs-per-day, years smoked, or outdated information—can lead to underestimation of screening eligibility. Our data quality study found that using longitudinal EHR data, which includes historical smoking records, significantly improves the identification of patients eligible for lung cancer screening, addressing the high prevalence of data inaccuracies seen in over 80 percent of evaluated records.
Describe the Process for Decision Support Logic Validation Task Addressed? ☒ Not Applicable ☐	**Task Description** • Translate information, clinical guidelines, and/or recommendations into computable knowledge in the PC CDS. **Patient-Centered Activities** • Translate patient-contributed information into computable knowledge in the PC CDS.	We conducted extensive logic validation using synthetic test cases.

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
Describe how PC CDS Usability was Addressed **Check the activities that were completed:** ☐ **Prototype Development and Design Testing** ☐ **Technical Acceptability Testing** ☒ **Initial Usability Testing** Not Applicable ☐	**Task Description** • Approaches used to conduct PC CDS prototype testing (number of testing rounds, testing participants, social acceptability testing, etc.). • Whether or not the PC CDS software meets technical requirements. • Activities performed to assess initial usability of the designed tool. • The criteria used to inform the development of usability testing methods. **Patient-Centered Activities** • Patient involvement in prototype testing and social acceptability testing. • Results of usability testing among patients.	Initial usability assessments involved iterative feedback sessions that refined the tools' interfaces and functionality to minimize cognitive load and improve user satisfaction.

3. Implementation & Adoption

Implementation and adoption covers the deployment of PC CDS into clinical workflows or patient daily activities and the actions taken to enhance the uptake, rollout, or sustainability of the PC CDS, including addressing barriers to this process. Within this section, tasks are grouped within four areas: 1) preparing for deployment, 2) deployment, 3) adoption, and 4) fidelity of implementation design. **See the user guide for more information.** Please note that not all tasks in this section will be applicable to each PC CDS intervention. When marking tasks as "Not Applicable, it may be helpful to provide additional context for your fellow collaborators.

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
Preparing for Deployment		
Describe how Key Stakeholders were Engaged in Implementation Task Addressed? ☒ Not Applicable ☐	**Task Description** • Process for involving and engaging multidisciplinary stakeholders for adoption of tool. • Process for identifying user champions to advocate for widespread use of the PC CDS. **Patient-Centered Activities** • How patients were identified and engaged in PC CDS implementation, particularly patients representing vulnerable populations. • Process for identifying patient champions.	Clinician champion was participating in the regalar team meetings. Patients were not involved in implementation planning.
Describe the Study Design Selected for the Implementation Evaluation Task Addressed? ☒ Not Applicable ☐	**Task Description** • Preparations to collect pre-/post-implementation data for mixed method studies, such as assessments of user experience combined with usage data. **Patient-Centered Activities** • Patient involvement in defining study approaches and incorporation of patients into each study arm.	We have used interrupted time series design for phases 1 and 2, and patient-randomized controlled trial for phase 3. Data were collected on patients who had visits during the study period.

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
Deployment		
Describe the Guidance and Training Provided on How to Use the PC CDS Task Addressed? ☒ Not Applicable ☐	**Task Description** • Resources used to teach end users how to use the PC CDS, and how personnel were trained to manage the tool. • Hands-on training sessions and tailored education provided to different user groups. • User documentation about the PC CDS and topics related to how the system functions. **Patient-Centered Activities** • Patient training provided for patient-facing tools and how this training was made accessible to patients.	To improve scalability and reduce burden, we aimed to provide only minimal training. The updates related to these tools were described in emails to clinicians and in a video that could be watched on demand.
Describe Approach for Deploying the PC into Existing Workflows Task Addressed? ☒ Not Applicable ☐	**Task Description** • Approach used to integrate the PC CDS into clinician workflows and patient daily activities (lifeflow). **Patient-Centered Activities** • Patient involvement in pilot testing of patient-facing tools used outside of a clinical encounter. • The process for incorporating the PC CDS into patient lifeflows.	Invitation to use the educational tool (phase 3) was sent to patients prior to their scheduled visits.
Adoption		
Report the Extent of PC CDS Adoption Task Addressed? ☒ Not Applicable ☐	**Task Description** • Measures used to assess PC CDS adoption. **Patient-Centered Activities** • Measures to assess patient uptake of patient-facing tools. • Engagement trends among patients from patient user data.	The tool was adopted by all participating clinics because the go-live decision was made centrally. Uptake was measured through system logs.
Fidelity of Implementation Design		
Describe Environmental Factors Affecting Implementation Task Addressed? ☒ Not Applicable ☐	**Task Description** • The effects of internal (e.g., within the implementation setting) and external (e.g., wider regulatory and policy structures) factors on the implementation of the tool. **Patient-Centered Activities** • Internal and external factors patients encounter when using the PC CDS. Consider unique internal and external factors faced by vulnerable populations.	During the study, USPSTF guidelines were updated to include more at risk patients.

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
Report the Extent of Fidelity to the Implementation Protocol Task Addressed? ☒ Not Applicable ☐	**Task Description** • Whether or not the PC CDS worked as designed and/or was used as intended by end users, after accounting for confounding factors. • How the results of fidelity assessments will be used to make changes to the tool. • Process for integrating the PC CDS into existing systems, including actions taken to minimize burden on users. **Patient-Centered Activities** • Efforts to reduce burden of the PC CDS on patient daily activities. • Whether or not the PC CDS was used as intended by patients.	The tools provided an opportunity for end users to provide feedback to the development team. Issues were addressed as soon as they were identified.

4. Evaluation, Maintenance, & Scalability

Evaluation, maintenance, and scalability is the process of measuring or exploring properties of the PC CDS in a summative manner, determining whether the PC CDS has achieved its defined objectives, and describing the short- and long-term effects of the PC CDS. Within this section, tasks are grouped into four areas: 1) evaluation of processes, 2) evaluation of outcomes and impacts, 3) maintenance, and 4) scalability. **See the user guide for more information and examples of performance metrics to include in your reporting.** Please note that not all tasks in this section will be applicable to each PC CDS intervention. When marking tasks as "Not Applicable, it may be helpful to provide additional context for your fellow collaborators.

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities and Performance Metrics Used
Evaluation of Process Changes		
Assessments of PC CDS Process Impacts Task Addressed? ☒ Not Applicable ☐	**Tak Description** • Approach for assessing impacts of the PC CDS on clinical workflow processes (e.g., simplicity, flexibility, timeliness, acceptability, etc.) and results. • Information quality management evaluation activities and results. **Patient-Centered Activities** • Approach for collecting, evaluating, and reporting process outcomes relevant to patients (e.g., lifeflow burden, efficiency, usage, and patient/clinician communication). • Identification of unintended consequences of the PC CDS on patient daily activities and approaches for improvement.	The tools were associated with increased screening rates and care-gap closures. 22.8 percent of eligible individuals (278 out of 1219) were screened with LDCT PC CDS tools in phase 1 (clinician-facing interventions) and 23.7 percent of eligible individuals (298 of 1255) were screened with LDCT in phase 2 (clinician-facing interventions and patient-reminders).
PC CDS Assessments **Check the assessments that were completed:** ☐ **Ethics Assessments** ☒ **User Satisfaction Assessment** ☐ **User Experience and Challenges Encountered** Not Applicable ☐	**Task Description** • Ethics: Approach and results of ethics risk-benefit assessments at the individual, organizational, and regulatory level. • User Satisfaction: Process, approach for, and results of conducting pre- and post-implementation user satisfaction assessments, including satisfaction with changes to workflow due to the tool. • User Experience/Challenges Encountered: Process and results of gathering user feedback on their experience using the tool and any challenges (e.g., accessibility, findability, usefulness, credibility, desirability, and identification). **Patient-Centered Activities** • Ethics: How ethical concerns related to patient privacy, consent, transparency, equity, and health disparities were addressed. • User Satisfaction: Patients and caregiver involvement in follow-up user satisfaction assessments. • User Experience/Challenges Encountered: Results of user experience assessments with patients.	System Usability Scale (SUS) was used to assess user satisfaction. Users reported good usability.

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities and Performance Metrics Used
Evaluation of Outcomes and Impacts		
Outcomes Evaluation Task Addressed? ☒ Not Applicable ☐	**Task Description** • Changes in clinical (e.g., health outcomes, patient safety), health system (e.g., cost, provider burnout), and related outcome measures. • Results from assessments of the overall value of the PC CDS. • If conducting a pilot study, feasibility estimates for a full trial. • Approach and measures used to evaluate the direct or indirect costs of PC CDS development or use. **Patient-Centered Activities** • Changes in patient-reported outcomes pre- to post-implementation and results from assessments of patient heath journey measures and outcomes. • Overall value of the PC CDS among patients. • Use of equity-relevant metrics to evaluate the effectiveness of PC CDS. • Include patient cost considerations in assessing cost of PC CDS.	We did not measure patient number of cancer diagnoses or patient deaths as the study was not powered for detect differences in such outcomes.
Maintenance		
Approach to Monitoring and Managing the PC CDS Throughout its Lifecycle Task Addressed? ☒ Not Applicable ☐	**Task Description** • Plan for continuous monitoring of PC CDS so it continues to deliver value to end users, is modified when needed, and is retired when appropriate. May include quality improvement activities undertaken or planned to improve PC CDS performance. • Process for regular testing of the PC CDS to identify changes from the original intention and implement solutions. Specify the frequency of audits. • Plan for routinely collecting user feedback and monitoring system usage and performance. **Patient-Centered Activities** • Test PC CDS rules against patient data to identify system performance issues. • Collect feedback from patients during regular audits.	The use of the tools is monitored through automated reports.

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities and Performance Metrics Used
Extent to Which the Tool has Become Part of Routine Organizational Practice and Culture Task Addressed? ☒ Not Applicable ☐	**Task Description** • Long-term follow up approaches to assess the extent to which the PC CDS has become a part of routine organizational practice, and the measures used to assess this. **Patient-Centered Activities** • Extent to which the tool has become embedded into patient daily activities/ "lifeflows."	The tools were used for over three years and continue to be used in the present.
Procedures for Knowledge Maintenance Task Addressed? ☒ Not Applicable ☐	**Task Description** • PC CDS types used within an organization and their relevant owners and creation dates. • Approach for updating the PC CDS when new clinical or technological evidence becomes available. • Formal software change control processes that guide updates.	The tools will be updated if USPSTF guidelines change.
Scalability		
Approaches to Deploy the Tool Beyond the Host Organization Task Addressed? ☒ Not Applicable ☐	**Task Description** • Action taken to encourage wider dissemination of the PC CDS (e.g., dissemination strategies). • Information provided about the PC CDS so other organizations or implementers can use it. • If technical portability assessment was conducted, report whether the PC CDS software can be deployed across health systems or, if applicable, EHR systems. **Patient-Centered Activities** • Partnering with patient champions to disseminate information about the tool and encourage use among other patients. • Deployment of patient-facing tools outside of healthcare settings to reach underserved patients.	The tools is in the process of being deployed in multiple external organizations. An implementation guide is provided. A technical portability assessment was conducted and showed that the tool could be sussesfully deployed externally.

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