Scaling, Measurement, and Dissemination of CDS **Workgroup:** PC CDS Planning, Implementation, and Reporting User Guide

Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

www.ahrq.gov

Contract No: 75Q80120D00018

Prepared by:
Priyanka J. Desai, PhD, MSPH and Jerome A. Osheroff, MD, FACP, FACMI
Sofia Ryan, MSPH
Krysta Heaney-Huls, MPH
Frances Jiménez, MPH
Allison B. McCoy, PhD, ACHIP, FAMIA
Prashila M. Dullabh, MD, FAMIA
CDSiC Scaling, Measurement, and Dissemination of CDS Workgroup

AHRQ Publication No. 23-0066
August 2023

Agency for Healthcare Research and Quality

Clinical Decision Support Innovation Collaborative

PURPOSE

The Clinical Decision Support (CDS) Innovation Collaborative (CDSiC) Scaling, Measurement, and Dissemination of CDS Workgroup is charged with identifying measures of patient-centered clinical decision support (PC CDS) adoption, implementation, and use that can be used to scale safe and effective CDS tools beyond initial implementation sites. The Workgroup is comprised of 12 experts and stakeholders representing diverse perspectives related to CDS. This report is intended to be used broadly by those interested in planning, implementing, and reporting about PC CDS.

FUNDING STATEMENT

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

PUBLIC DOMAIN NOTICE

SUGGESTED CITATION

Desai PJ, Osheroff JA, Ryan S, Heaney-Huls K, Jiménez F, McCoy AB, Dullabh PM, CDSiC Scaling, Measurement, and Dissemination of CDS Workgroup. Scaling, Measurement, and Dissemination of CDS Workgroup: PC CDS Planning, Implementation, and Reporting User Guide. Prepared under Contract No. 75Q80120D00018. AHRQ Publication No. 23-0066. Rockville, MD: Agency for Healthcare Research and Quality; August 2023.

Contributors: CDSiC Scaling, Measurement, and Dissemination of CDS Workgroup

Members of the Scaling, Measurement, and Dissemination of CDS Workgroup who contributed to this report are listed below.

Name	Affiliation
Paul Dexter, MD	Regenstrief
Ben Hamlin, DrPH	National Committee for Quality Assurance (NCQA)
Christopher Harle, PhD	Indiana University
Polina Kukhareva, PhD, MPH	University of Utah
Tiffany Peterson	LupusChat
David M. Rubins, MD	Brigham & Women's Hospital
Dean F. Sittig, PhD	University of Texas
Christopher Tignanelli, MD, MS	University of Minnesota
Adam Wright, PhD	Vanderbilt University

Table of Contents

1. About This User Guide

Patient-centered clinical decision support (PC CDS) is one promising tool that 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] To be successful, PC CDS must be designed with patients in mind, accessible where and when providers and patients prefer to receive the support, implemented in a manner that is easy for them to understand, and evaluated using patient-centered outcome measures. PC CDS can accomplish these goals by leveraging information provided by the patient (e.g., patient-generated health data [PGHD], social determinants of health [SDOH] data, as well as findings from patient-centered outcomes research [PCOR]).[2,3]

Although there is a large body of literature on CDS, comprehensive guidance on reporting how CDS tools were implemented is lacking. An important cause of this challenge is the variety of approaches used to report and evaluate CDS implementations. For example, there are a numerous checklists, guides, and frameworks related to CDS development[4] and evaluation (e.g., GUIDES, ELICIT, STARE-HI).[5,6,7] Additionally, frameworks related to health information technology (IT) implementation,[8,9] as well as implementation science more broadly,[10,11] are common.

What is Patient-Centered Clinical Decision Support?

Patient-centered clinical decision support is defined as "tools that significantly incorporate patient-centered factors related to knowledge, data, delivery, and/or use."[3] Factors include:

- **Knowledge:** Based on comparative effectiveness research or patient-centered outcomes research that incorporates outcomes that are meaningful to patients.
- **Data:** Data that are generated directly from patients such as patient-generated health data, patient-reported outcomes, and/or nonclinical patient-centric data.
- **Delivery**: Directly engages patients and caregivers across a range of settings.
- **Use:** Supports direct patient and/or caregiver involvement in decision making and supports shared decision making.

Each of these guides, checklists, and frameworks address some key CDS implementation features, but none specifically address the patient-centered activities that distinguish PC CDS, nor do they capture the details needed to efficiently and fully compare implementation results across efforts. PC CDS, as defined in this report, is a relatively new field, which could be strengthened through tools to support robust, standardized documentation of PC CDS design, implementation, and evaluation processes. This user guide is intended to complement existing CDS reporting guidance and evaluation frameworks by providing a comprehensive PC CDS planning, implementation, and reporting checklist that robustly addresses patient-centered dimensions of the CDS lifecycle.

What Does the User Guide Cover?

The PC CDS Implementation, Planning, and Reporting User Guide is intended as a step toward a standard approach for comprehensively describing how PC CDS is designed, developed, deployed, used, maintained, and evaluated along four key implementation domains: 1) planning and needs assessment, 2) design and development, 3) implementation and adoption, and 4) evaluation and impact.

This user guide includes a fillable checklist (the PC CDS Planning, Implementation, and Reporting Checklist) that enables users to describe details of how each implementation domain was (or will be) addressed within their PC CDS approach. In doing so, the tool:

- Allows users reviewing (or planning) an implementation described using the checklist to fully understand (or address) the *'why, what, and how'* details for the PC CDS implementation.
- Ensures that the key dimensions that drive PC CDS success are described (or planned) in a complete and consistent way. This will provide a standardized *context* for related process and outcome measurement within and across PC CDS evaluation efforts.

What Gap Does the User Guide Fill?

This user guide aggregates guidance from a range of existing CDS implementation guidance and implementation science and evaluation frameworks to provide a unified resource for planning and reporting PC CDS implementations (a summary of methods used to develop the user guide is provided in **Appendix A**).

Details relevant to the patient-centered activities that are critical components of PC CDS, such as patient needs elicitation, patient co-design, incorporation of 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 (and addressing) them. 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 Checklist?

The intended users of the user guide and checklist include researchers, electronic health record (EHR) and app developers, implementers 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 reporting (and planning, development, implementation, and evaluation) of PC CDS. In this user guide, we use the term “implementers” to encompass the team responsible for planning, developing, implementing, and evaluating PC CDS. This can include, but is not limited to, health system leadership, researchers, members of the organization’s IT department, informaticians, clinical champions, clinicians, and patients/caregivers.

How Can You Use the User Guide and Checklist?

Implementation teams can use this user guide and accompanying checklist before implementation begins for planning purposes, during implementation to ensure key steps are being addressed, and after implementation to produce a comprehensive report. Such 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 (or address in implementation) every item listed in the user guide and checklist. These materials are intended to help surface important items that might otherwise be missed.

In Section 2, we describe how to use the PC CDS Planning, Implementation, and Reporting Checklist. Using the fillable checklist, implementers will be able to describe how they addressed each implementation task and the associated patient-centered activities for their specific PC CDS implementation. The checklist will also provide implementers with the ability to describe which performance measures they considered, challenges encountered, and factors that led to implementation success. The checklist is provided as a separate PDF document that accompanies this user guide.

In Section 3, we describe the PC CDS implementation domains and subdomains included within the user guide and checklist. For each subdomain, we outline specific tasks to consider when planning, implementing, or reporting about PC CDS. Additionally, in this section we synthesize guidance from the literature on what to consider—including example elements to consider—as well as patient-centered activities to prioritize for each implementation task.

2. PC CDS Planning, Implementation, and Reporting Checklist

The PC CDS Planning, Implementation, and Reporting Checklist can be accessed here. Below, we describe how to use the PC CDS Planning, Implementation, and Reporting Checklist. By completing this checklist, implementers will be able to describe details of how each PC CDS implementation dimension, including associated patient-centered activities, were (or will be) addressed by their PC CDS approach. This can help organizations ensure they have considered the key dimensions that drive PC CDS success, and for those who report results from their efforts, to do so in a manner that supports a robust and standardized evidence base for comparing and improving PC CDS implementation across organizations.

Implementation teams should meet at each stage of the implementation process (i.e., planning, design, implementation, evaluation) to determine which tasks in the checklist are appropriate to address for their PC CDS. Implementation teams can divide responsibility for addressing the tasks in the checklist based on individual roles within the project or expertise. Under each task, implementation teams can use the checkbox to indicate whether the task was addressed, and by whom. Given that implementation processes are iterative, implementation teams can choose to make adaptations to the checklist as needed for their specific project. Also, it might not be feasible for all organizations to

complete all tasks, given that implementation context will vary across PC CDS in terms of setting, target end users, software requirements, available resources, and other factors. As this checklist is refined and validated over time, and tools to support quality improvement initiatives mature, it should become more feasible for teams to fully report on the most important dimensions of their PC CDS implementation efforts.

The PC CDS Planning, Implementation, and Reporting Checklist is organized by the implementation domains, subdomains, and implementation tasks described in Section 3 of this user guide. The checklist provides a brief description of what implementation and patient-centered activities to consider for each task, as well as fillable sections for implementers to populate to describe their approach for completing the task and addressing the patient-centered activities. Additionally, at the end of the checklist is a separate table where implementation teams can describe challenges and success factors related to each implementation domain. The full checklist is provided as a separate PDF document, linked in the call-out box, to facilitate completion. Implementation teams can review the checklist alongside the implementation task descriptions provided in Section 3 of this user guide. The checklist contains five fillable sections for implementers to populate relevant to their specific PC CDS implementation.

Implementation teams can access the PC CDS Implementation, Planning, and Reporting Checklist here.

Describe how you will (or did) address the implementation task. This section applies to all implementation tasks. In this section, implementers can specify their approach for addressing the implementation task. The approaches can be unique or guided by the examples provided in Section 3 of the user guide.

Describe how you will (or did) address the patient-centered implementation activities. This section applies to all implementation tasks. In this section, implementers can describe how they prioritized patient-specific needs, preferences, and values for each applicable implementation task. Greyed out cells indicate an absence of patient-centered activities reported in the literature. However, given the nascency of PC CDS literature, implementers may identify patient-centered activities that were not initially included when this checklist was developed, and should describe them when possible.

Describe what performance metrics you will (or did) consider. This section only applies to tasks in the Evaluation and Impact domain.

Reporting Considerations for Implementers

- The amount of detail provided by implementation teams for each fillable section of the checklist will vary depending on the PC CDS, available resources, and purpose for completing the checklist (i.e., for planning versus reporting purposes). This user guide and checklist are versatile and intended to support a spectrum of reporting uses and audiences, ranging from published manuscripts to documents solely for internal use.
- Reporting on implementation challenges and success factors will also vary depending on the intervention. Responses to these sections of the checklist can range from anecdotal evidence discussed during team meetings to conducting a randomized trial to prove causality.

In this section, implementers can describe the specific metrics used within each implementation task, when applicable.

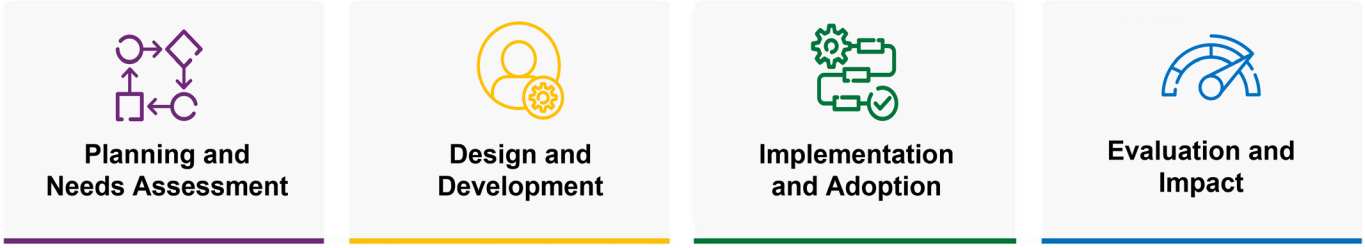
What challenges did you encounter? This section is provided in a separate table at the end of the checklist. In this section, implementers can report factors (e.g., resource availability, regulatory environment, software malfunctions, implementation setbacks) that arose during implementation that posed challenges to completing implementation tasks for each of the four implementation domains. When possible, implementers should describe how these challenges were addressed.

What factors led to success? This section is provided in a separate table at the end of the checklist. In this section, implementers can report factors (e.g., resource availability, leadership support, data collection methods, implementation approaches) that facilitated the successful completion of implementation tasks for each of the four implementation domains. If possible, implementers should provide additional guidance for other implementers to follow on how to acquire or achieve said factors.

3. PC CDS Implementation Domains and Subdomains

In this section, we describe the information implementers will need to know to use the checklist and apply it effectively. There are four key implementation domains relevant to PC CDS (Exhibit 1).

Exhibit 1. PC CDS Implementation Domains



Each of these domains can be further stratified into subdomains, which are organized into discrete implementation tasks. Within each domain and sub-domain, there are patient-centered activities implementers should consider when carrying out a PC CDS implementation. Below, we describe each domain and subdomain and provide example approaches to address the implementation tasks.

3.1 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 assessment implementation domain, we identified implementation tasks in four subdomains: 1) business case assessment, 2) user

Patient-Centered Activities to Address

Throughout Section 3, this patient icon delineates patient-centered activities to consider for each implementation task.

requirements gathering, 3) technical requirements gathering, and 4) planning for knowledge maintenance.

3.1.1 Business Case Assessment

The first step to planning a PC CDS implementation involves conducting a business case assessment, which is the process of justifying the need for a new PC CDS tool.[12] Implementers can consider the following tasks related to the business case assessment:

1. The clinical quality/safety goals and opportunities for the PC CDS to achieve the goals.
2. The evidence base for the PC CDS.
3. The anticipated costs, risks, and benefits of the PC CDS.
4. The process for leveraging or establishing governance mechanisms specific to the PC CDS.

Example approaches for addressing and reporting these tasks are described below.

Describe Identified Clinical Quality/Safety Goals and Opportunities for the PC CDS to Achieve the Goals. Implementers may consider conducting local needs assessments to identify issues that can be addressed by PC CDS. For example, implementers can develop questionnaires, interview target end users, and/or lead brainstorming and expert panel sessions with clinicians or other users of the PC CDS (i.e., patients, caregivers) to develop and validate a list of system requirements for the PC CDS to address stakeholder needs and improve performance.[13,14] Additionally, results of interviews with relevant stakeholders or observations of their workflows can be reported to assess their information needs, pain points, and relevant environmental factors (e.g., business drivers, cultural/organizational factors, resources, setting) that may affect PC CDS implementation.[7] Implementers should describe the performance or quality measures used to inform the decision to implement the PC CDS. Examples of information to consider include findings from a literature review, best practices gleaned from CDS case studies in similar settings, identification of clinical quality or performance measures, and input from stakeholders to set performance goals.[15] Particular attention should be paid to the automatic provision of CDS as part of clinician workflow or patient lifeflow, as this has been identified as a strong predictor of CDS success in the literature.[18] Within this task, implementers should also develop a process for obtaining buy-in from leadership or established governance committees to implement the PC CDS in order to fill the identified gaps.

Implementers should identify performance measures related to patient/caregiver daily activities and consider how the proposed PC CDS can reduce health disparities among these groups.[16] Implementers should also consider how patients and caregivers can be 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 providers that are passed on to implementation teams).[7]

Summarize the Evidence Base for the PC CDS. Implementers can synthesize the knowledge base that formed the basis of the PC CDS decision logic.[17] Example approaches used by implementers to identify an evidence base include meta-regression analyses, case studies of CDS implementations in similar settings, or systematic reviews of existing CDS tools or CDS success factors.[14,18,19] When

pertinent, implementers should identify the framework, theory, or model used to guide PC CDS development and justify that decision.[19] This can include disease-specific conceptual models or behavior change theories that guide design features of the PC CDS.


Implementers may consider how patient-centered implementation frameworks, such as the Analytic Framework for Action,[20] or patient-focused behavior change models can be incorporated into the PC CDS design.

Assess the Anticipated Costs, Risks, and Benefits of the PC CDS. Implementers can consider assessing the anticipated monetary costs, risks, and benefits of developing and implementing PC CDS in order to determine whether the project is financially feasible in a given setting.[7] While assessments can focus 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.[12]


Implementers can consider the anticipated costs, risks, and benefits, financial or otherwise, that patients may incur through the PC CDS.

Describe the Process for Leveraging or Establishing Governance Mechanisms Specific to the PC CDS. Implementers can consider implementing a process for establishing, informing, and maintaining formal CDS governance bodies specific to the proposed PC CDS to align leadership, end users, and IT.[5,21,22,23] This reporting step may not be necessary if CDS governance structures already exist. Implementers can follow Kawamoto and colleagues' guide to establishing CDS governance bodies when describing their approach to establishing their own governance mechanisms.[23]


When applicable, implementers can consider how to involve patients in PC CDS governance structures.

3.1.2 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. Implementers can consider the following tasks for user requirements gathering:

1. End-user requirements.
2. Results of workflow compatibility assessments.
3. Results of system readiness assessments.

Example approaches for addressing and reporting on these tasks are described below.

Describe End-User Requirements. Implementers should identify requirements from end users, such as information on user needs and decision and communication tasks, and the current (presumably suboptimal) results from these processes.[7] Additionally, implementers should identify the metrics

needed to define the current state and opportunities for improvement.[7] Examples of the types of information to describe include results from interviews conducted with clinicians using the think-aloud method[24] 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.[7,25]


Identifying patient user requirements can enhance patient-centered design of PC CDS. Implementers should describe the extent to which patient perspectives were collected as part of the user requirement gathering.

Describe Results of Workflow Compatibility Assessments. Implementers can consider conducting a workflow compatibility assessment with a focus on describing how the PC CDS will be integrated into end-user workflows. Workflow compatibility can be assessed via a Delphi process that rates compatibility of a proposed tool with clinical workflows and the potential impact of a tool to address performance gaps.[15] The results of workflow mapping to identify the current state of workflows and identify gaps can also be reported.[26]


Implementers can consider the potential workflow compatibility of the proposed PC CDS on patient/caregiver daily activities (i.e., “lifeflows”).

Describe Results of System Readiness Assessments. The results of system readiness assessments can be used to illustrate the system capabilities to implement the PC CDS and how much effort it will take to reach the identified goals. Example approaches to system readiness assessments include stakeholder completion of the Organizational Readiness for Implementing Change (ORIC) instrument,[27] which measures organizational change commitment and change efficacy, or strength, weaknesses, opportunity, and threat (SWOT) analysis of potential barriers and facilitators to implementation.[14] Models such as the Readiness Assessment and Maturity Model (RAMM) can guide reporting of system readiness assessment results.[28]

3.1.3 Technical Requirements Gathering

Technical requirements gathering refers to the process of assessing the current technological factors related to PC CDS to be implemented, such as usability, performance, adaptability and flexibility, dependability, information functionality, and cost.[29,30] Implementers can consider the following related to technical requirements gathering:

1. Results from technical feasibility assessments.
2. Developing system requirements guidelines for PC CDS software.

Example approaches for addressing and reporting on these tasks are described below.

Describe Results from Technical Feasibility Assessments. Implementers can consider exploring existing technical infrastructure, application programming interfaces (APIs), and knowledge resources, as well as input from stakeholders and end users on software performance, regulatory, and security

requirements.[7] Additionally, implementers can assess data quality (i.e., completeness and validity) and local data availability, and identify additional data collection needs.[31,32] This approach is particularly important given that the need for new data collection is predictive of lower implementation feasibility.[32]

Report Process for Developing System Requirements Guidelines for PC CDS Software. Implementers can consider identifying and 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]

3.1.4 Planning for Knowledge Maintenance

Knowledge maintenance planning refers to the process of organizing, disseminating, and updating the knowledge or information conveyed by a PC CDS.[33,21] Implementers should develop a plan for knowledge maintenance during the planning and needs assessment phase rather than waiting until the PC CDS is launched to avoid overlooking this task. Implementers can consider the following related to knowledge maintenance planning:

1. Procedures for knowledge maintenance.
2. Approach for updating the PC CDS artifact knowledge base.

Example approaches for addressing and reporting on these tasks are described below.

Describe Procedures for Knowledge Maintenance. Implementers may consider describing the PC CDS types used within their organization and their relevant owners and creation dates,[52] and specifying a regular cadence for reviewing relevant metrics to assess PC CDS effectiveness, such as alert firing and acceptance rates.[52,34] Implementers can also consider developing an approach to establish and monitor a help desk or malfunction log where end users can report issues with the PC CDS.[52]

Describe Approach for Updating PC CDS Artifact Knowledge Base. PC CDS artifacts need to be updated to ensure their utility for both patients and clinicians. Implementers can describe their approach to updating the PC CDS as needed when new clinical or technological evidence becomes available.[54] Implementers may consider specifying the formal software change control processes that will guide these updates.[52]

3.2 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.[7,10] We refer to *design and development* as the process of designing and building PC CDS such that it is easy to use and delivered at the right time and to the right person,[4] with the goal of ensuring its fit or effectiveness in a given context.[7] Within this implementation domain, we identified three implementation subdomains: 1) CDS Five Rights, 2) co-design, and 3) PC CDS usability.

3.2.1 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.[4] This framework was developed to help implementers consider approaches to make the right decisions and actions *easier* and decrease over-reliance on alerts and reminders as a primary mechanism for improving processes and outcomes. Implementers can consider the following tasks:

1. How the PC CDS design addresses each component of the CDS Five Rights to achieve the targeted results.
2. The accuracy, availability, and validation of data used within the PC CDS.

Example approaches for addressing and reporting on these tasks are described below.

Describe How the PC CDS Design Addresses Each Component of the CDS Five Rights. PC CDS designers should articulate how the 'who, what, when, where, how' CDS Five Rights dimensions for the PC CDS were determined. Implementers 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 times' components of the CDS Five Rights.[35,36] For example, implementers 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. Implementers can also specify how this approach allows clinicians to easily document why a recommended order was not heeded, thereby making the right patient-specific decisions/actions 'easy' and integrated into workflow.[31]

Implementers can specify what, if any, patient-contributed data (e.g., PROs or PGHD) were leveraged by the PC CDS. If relevant, implementers should report how they determined when to collect patient-contributed data. Implementers should note any patient-facing delivery methods (e.g., apps) used to make the PC CDS content more accessible to patients.[35] Implementers 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.

Report on the Accuracy, Availability, and Validation of Data Used Within the PC CDS. Implementers 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, implementers can consider approaches to improve or validate CDS accuracy and may consider quantifying this accuracy. For example, this may entail conducting chart audits to identify the proportion of charts missing important data that could affect the accuracy of clinical actions suggested by PC CDS.[18]


Implementers can consider incorporating patient-contributed information (e.g., PGHD, PROs, and SDOH data) into the PC CDS design, as well as how to ensure that this information is valid for use in the PC CDS.

3.2.2 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[37] and could provide a path forward for improving patient-centeredness in CDS design and deployment. Implementers can consider the following information related to co-design:

1. Initial and iterative user input during design.
2. Process for decision support logic validation.

Example approaches for addressing and reporting on these tasks are described below.

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. For both initial and iterative stages, implementers can describe the design approach and the results of 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.[29,38] Additionally, implementers may conduct cognitive task assessments with end users,[39] which can include interviews or observations that assess end-user goals, tasks, and mental models using critical incidence technique,[40] stimulated recall,[41] screen capture, or eye tracking.[7] Descriptions of how human-computer interaction design guidelines were followed can also be reported.[36]


Patient-centered co-design specifically involves patients in the conceptualization of a tool based on their needs, preferences, and values. 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.[42] Implementers should describe the extent to which patients participated in co-design and cognitive task load assessments, and note key facilitators and barriers to their engagement.

Describe Process for Decision Support Logic Validation. Implementers can translate information, clinical guidelines, and/or recommendations into computable knowledge, and describe how this translation was validated. Implementers may consider holding discussions among stakeholders to agree upon which information/guidelines to include within a tool and how to optimize clinical content to inform tool development.[43]


To encourage patient-centeredness in design, implementers can consider translating patient-contributed information into computable knowledge and describing the extent to which patients contributed to validating the decision support recommendations.

3.2.3 PC CDS Usability

PC CDS usability refers to the process of involving end users in the testing and evaluation of a prototype PC CDS to inform refinements prior to implementation.[7] Feedback from prototype and usability testing are utilized during CDS development to create a final PC CDS artifact that can be deployed in a production environment. Implementers can consider implementing the following tasks:

1. Prototype development and design testing.
2. Technical acceptability testing and results.
3. Initial usability testing and results.

Example approaches for addressing and reporting on these tasks are described below.

Prototype Development and Design Testing. Implementers should consider approaches 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,[44] and validation studies where a group testing the tool is compared with a "business-as-usual" control.[45] Implementers 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,[46] 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. Implementers 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 and Results. Implementers can conduct technical acceptability assessments and describe activities performed to determine whether the PC CDS software meets 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.[47]

Initial Usability Testing Results. 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. Implementers should conduct activities related to assessing usability of the designed tool, including cognitive load, user friendliness, and ease of use.[7] Example approaches commonly used by implementers for conducting usability testing include think-aloud interviews with end users regarding the prototype interface[25] and questionnaires, such as the Questionnaire for User Interface Satisfaction (QUIS).[48] Implementers should report the criteria used to inform the development of usability testing methods, such as the usability dimensions assessed (e.g., effectiveness, efficiency, and satisfaction),[49] Nielsen's usability principles,[50] or ease-of-use criteria (i.e., accessibility, automation, unconstraint, and user-friendly interface).[51]

Implementers should conduct usability testing and social acceptability testing among patients for patient-facing CDS and CDS for shared decision making, and report the results of these assessments.

3.3 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 the uptake, rollout, or sustainability of the PC CDS, including addressing barriers to this process.[5,7,10] Within this implementation domain, we identified five implementation subdomains: 1) preparing for deployment, 2) deployment, 3) adoption, 4) use, and 5) fidelity of implementation design.

3.3.1 Preparing for Deployment

Implementers should consider the following preparatory tasks to facilitate deployment and adoption of PC CDS within an organization or patients' daily life:

1. How key stakeholders were engaged in implementation.
2. The identification of end-user champions.
3. The guidance and training provided on how to use the PC CDS.
4. The study design selected for the summative PC CDS evaluation.

Example approaches for addressing and reporting on these tasks are described below.

Describe How Key Stakeholders were Engaged in Implementation. Implementers may consider describing the process for identifying and engaging multidisciplinary stakeholders (i.e., clinicians and other care team members, patients, IT staff, organizational leadership) and describing how buy-in for the PC CDS was obtained from these stakeholders. Example approaches include conducting meetings with organizational leadership to secure commitment to use the tool and establish a process for regular updates,[52,53] and coordinating conversations between clinical and IT staff to strengthen collaborations.[54]


Patient stakeholders should be identified and engaged in PC CDS implementation to facilitate adoption and acceptance within this group. In particular, implementers can engage patients representing vulnerable populations (e.g., racial/ethnic minorities, individuals affected by health inequities, sexual and gender minorities) in implementation efforts.[16]

Report on the Identification of End-User Champions. Implementers should describe the process for identifying and prioritizing clinical and patient champions to advocate for use of the PC CDS among their peers. Implementers may consider identifying at least two champions per end-user group who are dedicated to using the tool and available to troubleshoot questions or concerns with other users.[53]


A key dimension of patient-facing PC CDS utilization is patient empowerment to use the tool.[55] As such, implementers should describe their process for identifying patient champions for patient-facing tools and tools for shared decision making.

Describe the Guidance and Training Provided on How to Use the PC CDS. Implementers can describe what resources were employed to teach end users how to use the PC CDS, how personnel were trained to manage tool components, and whether or not clinicians and patients were trained on how to use the PC CDS.[36] Implementers can utilize approaches for ensuring firsthand experience with the tool through hands-on training sessions and tailored education for different user groups.[38] Implementers can also develop documentation about the PC CDS and helpful topics related to the functioning of the system.[5]


Implementers can describe what patient training was provided for patient-facing tools. Implementers can also indicate how this training was made accessible to patients, so that patients can easily access the training within their lifeflow, and it can be understood by patients without expertise in decision support systems.

Describe the Study Design Selected for the Summative PC CDS Evaluation. Common study designs used to evaluate PC CDS include mixed methods studies utilizing qualitative assessments of user experience combined with usage data or, less commonly, randomized controlled trials (RCTs). Prior to deployment, implementers should identify a study design and develop a plan for collecting pre- and post-implementation data related to the PC CDS. If designing an RCT, implementers can plan to follow Consolidated Standards of Reporting Trials (CONSORT) guidelines when reporting and use statistical methods that consider intracluster correlation.[18] If not conducting an RCT, implementers should plan to address the potential for confounding trends within results reporting.[18]


When appropriate, implementers can describe how patients will be included within the evaluation design (e.g., whether or not 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).

3.3.2 Deployment

Once the appropriate preparations have been made, implementers can consider deploying the PC CDS in a stepwise manner into clinician workflows and patient lifeflows. Example approaches for addressing and reporting on this task are described below.

Describe Approach for Deploying the PC CDS in a Stepwise Manner into Existing Workflows. Continued developments in PC CDS offer opportunities for new and improved clinician workflows and patient lifeflows. Implementers may consider utilizing a stepwise approach to facilitate the process of integrating PC CDS into clinician workflows and patient lifeflows, such as conducting pilot testing of the PC CDS, deploying the PC CDS to a small number of users to obtain feedback before broader implementation,[52] or implementing a short "grace period" during initial deployment, wherein users can log change requests, which can be implemented in real time.[56] 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.[55]

For patient-facing PC CDS or CDS for shared decision making, implementers can involve patients in pilot testing of tools. For tools used outside of the healthcare setting, implementers 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).[23]

3.3.3 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. Example approaches for assessing and reporting on PC CDS adoption are described below.

Report on the Extent of PC CDS Adoption. Implementers 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 use of the tool.[57]

Implementers should outline an approach for assessing patient adoption of patient-facing tools and tools for shared decision making. To the extent feasible, implementers should include data and describe details of when, how, and why patients and caregivers adopt PC CDS directed to them.

3.3.4 Use

Use of PC CDS refers to incorporation of a tool into clinical workflows or patient lifeflows. To understand the extent to which PC CDS is being used, implementers can consider:

1. Results of social implementation assessments.
2. Results of post-deployment usability and user adherence testing.

Example approaches for addressing and reporting on these tasks are described below.

Report on Results of Social Implementation Assessments. Implementers can use social implementation assessments to identify barriers and facilitators to implementation and determine how to leverage facilitators to encourage use of the PC CDS.[7] Implementers can describe the plan for conducting the assessments with clinical champions and, when applicable, the EHR team to understand implementation factors facilitating use of the tool. The Evaluation in Life Cycle of Information Technology (ELICIT) framework provides exemplar questions for social implementation assessments that explore innovation reach, adoption, usage patterns, adaptations over time, and readiness for wider clinical use. The exemplar questions also explore the effectiveness of innovation strategies and potential for long-term adoption, reach, and implementation fidelity.[7] Implementers can also utilize descriptive statistics of user data related to usage patterns, engagement, and adherence.[58] This can include reports of website metrics from web-based tools; for app-based tools, implementers can utilize feedback from an in-app widget.


To facilitate patient-centeredness, implementers can describe engagement of patient champions within social implementation assessments.

Report on Results of Post-Deployment Usability and User Adherence Testing with End Users. In addition to the initial usability testing described in the *Design and Development* section, implementers can conduct post-deployment usability testing of PC CDS with end users as a measure of implementation success and to leverage for iterative system enhancement. Presentation of assessment results can rank usability problems based on severity and their potential impact on patient safety.[59] Approaches to conducting usability assessments include conducting interviews and surveys,[58] using validated usability questionnaires such as the System Usability Scale (SUS),[60] performing benchmark analyses and technology assessments to understand alignment between the tool's features and users' needs,[58] and conducting workflow integration analyses.[53]


Implementers can include patients within usability assessments, report on the usability problems identified by patients, and describe approaches to ameliorate issues.

3.3.5 Fidelity of Implementation Design

To describe the degree to which PC CDS is delivered as intended,[61] implementers can consider:

1. How the PC CDS was integrated into existing systems.
2. Results of technical implementation assessments.
3. Environmental factors affecting implementation.
4. The approach for conducting regular audits and the results.
5. The extent of fidelity to the implementation protocol.

Example approaches for addressing and reporting on these tasks are described below.

Describe How the PC CDS was Integrated Into Existing Systems. Implementers can 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).[36] For example, implementers can take steps to reduce the volume of reminders[23] and familiarize end users (e.g., through trainings described in the *Preparation for Deployment* section) with the tool to facilitate incorporation into routine workflows.[54]

For patient-facing CDS and CDS for shared decision making, implementers should make efforts to reduce burden of the tool on patient daily activities (or lifeflows) and report the extent to which the PC CDS was made unobtrusive within patient lifeflows.[33]

Report on Results of Technical Implementation Assessments. Implementers can determine whether or not the PC CDS meets technical requirements in a real-world setting. To achieve this task, software development teams can report results from performance and uptime analyses to determine the success of tool integration, the adequacy of technical support infrastructure, and real-world technical performance.[7]

Describe Environmental Factors Affecting Implementation. Internal (e.g., within the implementation setting) and external (e.g., wider regulatory and policy structures) factors to explore at this stage can be gleaned from implementation frameworks such as the Consolidated Framework for Implementation Research (CFIR),[11] Cresswell and colleagues' framework for evaluating health IT implementations,[29] or Rippen and colleagues' organizational framework for health IT.[62] Additionally, implementers can 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.[36]

For patient-facing PC CDS and PC CDS for shared decision making, implementers can describe how patients are affected by internal (e.g., within healthcare setting or daily life) and external (e.g., policy, power dynamics) factors. In particular, implementers should consider reporting of unique internal and external factors faced by vulnerable populations as described by the Health Equity Implementation Framework, such as structural racism and power dynamics.[16,63]

Describe the Approach for Conducting Regular Audits and the Results. Implementers can conduct regular testing of the PC CDS to identify misalignments with original intentions and implement solutions, and should specify the frequency of audits (e.g., monthly, quarterly). For example, audits can describe whether patient-facing tools display accurate and relevant data, whether order sets are 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 patient's symptoms), whether processes were enhanced as intended, and whether the intended recipients had the knowledge, skills, and attitudes needed to benefit from the intervention. To support this process, implementers should describe a plan to routinely collect user feedback and monitor system usage and performance.[14,19]


Implementers can test 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.[18] Additionally, implementers should involve patients in identifying people and process issues and specify how feedback from patients will be collected during regular audits and addressed.

Report on the Extent of Fidelity to the Implementation Protocol. Implementers can report whether or not the PC CDS worked as designed or was used as intended by end users after accounting for confounding factors.[36] In order to measure whether the tool was delivered as intended, implementers can consider conducting evaluations that map current and desired process models for the tool.[58] Implementers can also describe how the results of fidelity assessments will be used to make changes to the tool using guiding frameworks such as the Plan-Do-Study-Act framework.[26,64]


Implementers can specify whether or not the PC CDS was correctly used as intended by patients and caregivers when pertinent.

3.4 Evaluation & Impact

We refer to *evaluation and impact* as the process of measuring or exploring properties of the PC CDS in a summative manner, determining whether or not the tool has achieved its defined objectives, and describing the short- and long-term effects of the tool, including its sustainability. [5,7,65] Within this implementation domain, we identified three implementation subdomains: 1) summative evaluation, 2) sustainability, and 3) scalability.

3.4.1 Summative Evaluation

To evaluate PC CDS performance in a summative manner, implementers can consider:

1. Assessments of PC CDS process impacts.
2. Results of user experience and challenges encountered.
3. Results of user satisfaction assessments.
4. Changes in clinical, health system, and related outcomes.
5. Implications for quality improvement activities.
6. Results of a full program evaluation of the PC CDS.

Example approaches for addressing and reporting on these tasks are described below.

Describe Assessments of PC CDS Process Impacts. Implementers can describe their approach for assessing process impacts of the PC CDS 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.[32] Implementers can collect feedback from end users and clinical champions via semistructured interviews and surveys regarding their experience with the tool and perceived changes to workflows. The ELICIT framework provides

exemplar questions to include in these assessments regarding process, health, and economic outcomes, as well as unintended consequences, health equity, and dissemination value.[7]


Implementers can 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.

Report Results of User Experience and Challenges Encountered. Implementers should develop an approach to gather feedback from end users on their experience while using the tool and any challenges experienced. An example organizing framework to develop materials for gathering this information is Rosembaum's adaptation of Morville's "honeycomb" of user experience, which encompasses accessibility, findability (i.e., whether users can locate what they are looking for), usefulness, usability, credibility (i.e., whether or not the tool and its content are trustworthy), desirability (i.e., whether or not the tool is something the user wants), and identification (i.e., whether or not the user feels like the tool was "designed for them").[66]


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

Report Results of User Satisfaction Assessments. PC CDS should ideally improve end users' satisfaction (and decrease burden) associated with the workflow or lifeflow activities targeted by the PC CDS. Implementers can conduct long-term user satisfaction assessments and describe whether or not users found the system to be enjoyable.[7] Implementers can consider reporting on the process for creating and deploying pre- and post-implementation user satisfaction surveys using tools such as the Clinical Information System Implementation Evaluations Scale (CISIES 2.0) System Usability Scale,[60] Net Promoter Score,[67] and/or the Meaningful Use Maturity-Sensitive Index (MUMS) to assess changes in satisfaction.[68] Implementers can also consider conducting semistructured interviews with end users to assess usability, user acceptance, and perceived effectiveness using exemplar questions from the ELICIT framework.[7] As an alternative or augment to surveys and interviews, implementers can also review software logs to determine changes in workflow due to the PC CDS.[7]


Implementers can describe how patients and caregivers were involved in user satisfaction assessments and report results relating to patient and caregiver satisfaction with the tool as appropriate.

Report Changes in Clinical, Health System, and Related Outcomes. To understand the effect of PC CDS on patient outcomes, implementers 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 of the tool. Example measures to report include mortality, hospital admissions or readmissions, effectiveness of care, adverse events, or disease-specific outcomes.


Implementers should prioritize inclusion of PROs within reporting when possible.

Describe Implications for Quality Improvement Activities. Implementers can describe the quality improvement activities they have undertaken or plan to undertake to improve tool performance, such as analyses of data quality and amelioration of unintended consequences of tool implementation.[36] Implementers can also discuss approaches to enhance the people and process dimensions associated with the tool to improve adoption, use, and value, such as exchange of best practices amongst tool users to facilitate system-wide quality improvement.[55]


For patient-facing tools, implementers can identify unintended consequences of tool implementation within patient activities and describe their approaches for amelioration.

Report Results of a Full Program Evaluation of the PC CDS. Implementers can consider all the tasks described in this user guide as they frame and address their program evaluation. Implementers should report results from assessments of the overall value of the PC CDS with regard to user engagement, adherence to guidelines or best practices, and clinical outcomes.[58] These assessments can 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.[69] If conducting a pilot study for PC CDS, implementers should report on the defined outcomes, implementation framework used, and feasibility estimates for a full trial.[70] Implementers can utilize the assessments described throughout this tool to guide their approach to conducting program evaluations, keeping in mind that pre- and post-implementation assessments are most beneficial to assess changes in user satisfaction, preparedness, perceived utility, and overall opinions about the tool, among other domains.[71] Additionally, implementers can conduct information quality management evaluations using evaluation criteria for each stage of the information life cycle as defined by Mohammed and Yusof: 1) requirements planning, 2) information acquisition, 3) information and systems maintenance, and 4) information application.[72]


Assessments of satisfaction, utility, engagement, 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. When appropriate, implementers should describe what equity-relevant metrics were used within evaluations to understand the effect of the tool on vulnerable populations.[73]

3.4.2 Sustainability

Sustainability is defined as "the extent to which an evidence-based intervention can deliver its intended benefits over an extended period of time".[74] Developing, deploying, and/or evaluating PC CDS requires significant time, expense, and effort. Implementers of PC CDS pilots or larger scale implementations can consider the following tasks related to sustaining their work:

1. The approach to monitoring and managing PC CDS throughout its lifecycle.

2. The extent to which the tool has become part of routine organizational practice and culture.
3. Results of ethics assessments.

Example approaches for addressing and reporting on these tasks are described below.

Describe the Approach to Monitoring and Managing the PC CDS Throughout its Lifecycle. Implementers should describe a plan for continuous monitoring of PC CDS throughout its lifecycle so that it continues to deliver high value to end users. This approach can include dimensions of knowledge maintenance, regular audits, and quality improvement activities that are described earlier in this user guide to ensure the PC CDS is managed appropriately, modified when needed, and retired as appropriate.

Describe the Extent to Which the Tool has Become Part of Routine Organizational Practice and Culture. Implementers can conduct long-term followup[19] to assess the extent to which the PC CDS has become a part of routine organizational practice and culture.[75] These approaches can be guided by success factors related to the maintenance domain of the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework (e.g., institutional culture, usefulness).[57] Implementers 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.[76] Other example approaches to completing this task include developing a benchmarking tool based on success.[57]


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

Report on Results of Ethics Assessments. Implementers can conduct ethics risk-benefit assessments at the individual, organizational, and regulatory levels and report results.[22]


Implementers can describe the tool's ability to address ethical concerns related to patient privacy and transparency, equity, and health disparities.[22]

3.4.3 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 in order to maximize impact.[77] Implementers can consider the following tasks to assess readiness of a PC CDS to be implemented on a larger scale:

1. Results of cost-effectiveness evaluations.
2. Results of technical portability assessments.
3. Approaches to deploy the tool beyond the host organization.

Example approaches for addressing and reporting on these tasks are described below.

Report Results of Cost-Effectiveness Evaluations. Implementers can conduct cost-effectiveness evaluations of PC CDS and describe whether or not the benefits of the tool outweigh the costs.[19,76]

Implementers can utilize measures relating to the cost of CDS development[78] (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.[79,80]

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 PC CDS app, time spent using the tool, time spent traveling to the healthcare facility).

Report Results of Technical Portability Assessments. Based on the results of technical portability assessments, implementers can consider whether or not 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]

Describe Approaches to Deploy the Tool Beyond the Host Organization. Implementers can take action to encourage wider dissemination of the PC CDS, such as the use of relevant interoperability standards (e.g., HL7 FHIR, HL7 Clinical Quality Language, HL7 CDS Hooks, HL7 SMART on FHIR, BPM+ Health) to support integration into other systems.[81] These standards should also be considered and incorporated into PC CDS during the initial design and development stage. Additionally, implementers can disseminate information about the tool so other organizations or implementers 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.[18,70]

For patient-facing tools, implementers may consider utilizing patient champions to disseminate information about the tool and encourage use among other relevant patient populations. Additionally, implementers 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).[73]

4. Conclusion

To improve PC CDS use and value in this growing field, it will become increasingly important to apply evidence-based, repeatable processes for implementing and describing PC CDS interventions. This PC CDS Planning, Implementation, and Reporting User Guide provides users with the information they need to plan, design, implement, and evaluate 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, Implementation, and Reporting Checklist to facilitate PC CDS-enabled care transformation—and reporting on these efforts—in a manner that ensures patient needs, values, and preferences are driving forces for change.

Appendix A. Scoping Review and Key Informant Interview Methodology

This tool was developed collaboratively through extensive interactions between the CDSiC Scaling, Measurement, and Dissemination Workgroup leads, Workgroup members, and the Workgroup support team. The methods that guided tool development within this collaboration are described below.

Research Questions

The following research questions informed tool development:

1. What is the current state of CDS implementation frameworks, checklists, or guides (e.g., use, purpose)?
2. How do existing CDS implementation frameworks, checklists, or guides describe/categorize CDS implementation dimensions (i.e., how these interventions are designed, developed, deployed, used, maintained, and evaluated)?
3. To what extent do these CDS implementation frameworks, checklists, or guides address PC CDS?
4. What are the gaps in implementation dimensions related to PC CDS?
5. What guidance is needed to encourage standardized reporting of PC CDS implementations?

Scoping 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 (See **Exhibit A1**). 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 (see **Exhibit A2**).

Records deemed *eligible* at the title/abstract level were screened again at the 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 Scaling, Measurement, and Dissemination Workgroup products, we also flagged articles relevant to this tool; we screened 18 peer-reviewed articles and included 16 of these articles from this mechanism.

In total, we screened 747 peer-reviewed journal articles and included 62 articles.

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 Scaling, Measurement, and Dissemination Workgroup products, we also flagged articles relevant to this tool; we screened 18 peer-reviewed articles and included 16 of these articles from this mechanism.

In total, we screened 747 peer-reviewed journal articles and included 62 articles.

Exhibit A1. Key Search Terms for the Scoping Literature Review

#1 CDS Search String	#2 Guideline/Checklist String	#3 Implementation String	#4 Health IT String
"clinical decision support"[tiab] OR "Decision Support Systems, Clinical"[Mesh] OR "Clinical Decision-Making"[Majr] OR "Decision Making, Computer-Assisted"[Majr] OR "Clinical Decision Rules"[Majr]	Practice Guidelines as Topic[Majr] OR guide[title] OR Checklist[Majr] or framework[title] OR checklist[title] OR Guidelines as Topic[Majr]	Implement*[tiab] OR design*[tiab] OR report*[tiab] OR evaluat*[tiab] OR "Implementation Science"[Mesh] OR "Process Assessment, Health Care"[Mesh]	“Health Information Systems”[Mesh] OR “health informatics”[tiab]

Exhibit A2. Literature Search Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Published/developed in 2012 or later. • Focuses on the use of CDS, health technology, or person-centered care implementation. • Peer-reviewed literature including literature reviews, qualitative studies, implementation studies, viewpoints, and commentaries. • Relevant to PC CDS interventions: targeted to patients or caregivers or created from patient-centered outcomes research (PCOR) and designed to facilitate shared decision making or target treatment based on patient-specific health data. • Discusses frameworks, checklists, and/or guidance relevant to developing, implementing, and evaluating PC CDS, including the design, development, adoption, maintenance, and evaluation of digital health interventions that are patient-facing or involve patients, collect data on patient preferences, social determinants of health, or patient reported outcomes, or support shared decision making.	• Does not address a CDS intervention or technologies that could be applied to improve PC CDS. • Does not include human patients (e.g., veterinary studies; algorithms or provider-focused tools that do not involve some element of patient interaction). • Blog, book, study protocol, news article, discussion forum, webinar.

Key Informant Interviews

We conducted key informant interviews with potential end users of the tool 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.

We developed semistructured discussion guides which allowed the interviewer to steer the conversation toward each key informant's expertise. Each interview was conducted via Zoom, audio recorded, and lasted approximately 60 minutes. Transcript-style notes were created for each interview to support analysis.

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.

References

1 Infographic: Patient-Centered Clinical Decision Support Explained | Clinical Decision Support Innovation Collaborative (ahrq.gov). https://cdsic.ahrq.gov/cdsic/patient-centered-clinical-cds-infographic

2 Patient-Centered Clinical Decision Support | CDS Connect (ahrq.gov)

3 Dullabh P, Sandberg SF, Heaney-Huls K, Hovey LS, Lobach DF, Boxwala A, Desai PJ, Berliner E, Dymek C, Harrison MI, Swiger J, Sittig DF. Challenges and opportunities for advancing patient-centered clinical decision support: findings from a horizon scan. J Am Med Inform Assoc. 2022 Jun 14;29(7):1233-1243.

4 Osheroff, Jerome A., Teich JM, Levick D, Saldana L, Velasco F, Sittig D, Rogers KM, and Jenders RA. Improving outcomes with clinical decision support: an implementer's guide. CRC Press, 2012.

5 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. doi: 10.1186/s13012-018-0772-3. PMID: 29941007; PMCID: PMC6019508.

6 Talmon J, Ammenwerth E, Brender J, de Keizer N, Nykanen P, Rigby M. STARE-HI - Statement on reporting of evaluation studies in Health Informatics. Int J Med Inform. 2009;78(1):1-9.

7 Kukhareva PV, Weir C, Del Fiol G, Aarons GA, Taft TY, Schlechter CR, Reese TJ, Curran RL, Nanjo C, Borbolla D, Staes CJ, Morgan KL, Kramer HS, Stipelman CH, Shakib JH, Flynn MC, Kawamoto K. Evaluation in Life Cycle of Information Technology (ELICIT) framework: Supporting the innovation life cycle from business case assessment to summative evaluation. J Biomed Inform. 2022 Mar;127:104014. doi: 10.1016/j.jbi.2022.104014. Epub 2022 Feb 12. PMID: 35167977; PMCID: PMC8959015.

8 Greenhalgh T, Abimbola S. The NASSS Framework - A Synthesis of Multiple Theories of Technology Implementation. Stud Health Technol Inform. 2019 Jul 30;263:193-204. doi: 10.3233/SHTI190123. PMID: 31411163.

9 DeLone, W. H., & McLean, E. R. (2003). The DeLone and McLean model of information systems success: a ten-year update. Journal of management information systems. 2003 Apr 1; 19(4), 9-30.

10 Moullin JC, Dickson KS, Stadnick NA, Rabin B, Aarons GA. Systematic review of the Exploration, Preparation, Implementation, Sustainment (EPIS) framework. Implement Sci. 2019 Jan 5;14(1):1. doi: 10.1186/s13012-018-0842-6. PMID: 30611302; PMCID: PMC6321673.

11 Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. Implement Sci. 2022 Oct 29;17(1):75. doi: 10.1186/s13012-022-01245-0. PMID: 36309746; PMCID: PMC9617234.

12 Bush, T. What is Business Case Analysis (BCA)? Pestle Analysis. Retrieved from: https://pestleanalysis.com/what-is-business-case-analysis/

13 Riazi H, Langarizadeh M, Larijani B, Shahmoradi L. Conceptual Framework for Developing a Diabetes Information Network. Acta Inform Med. 2016 Jun;24(3):186-92. doi: 10.5455/aim.2016.24.186-192. Epub 2016 Jun 4. PMID: 27482133; PMCID: PMC4949029.

14 Mosch LK, Poncette AS, Spies C, Weber-Carstens S, Schieler M, Krampe H, Balzer F. Creation of an Evidence-Based Implementation Framework for Digital Health Technology in the Intensive Care Unit: Qualitative Study. JMIR Form Res. 2022 Apr 8;6(4):e22866. doi: 10.2196/22866. PMID: 35394445; PMCID: PMC9034425.

15 Timbie JW, Damberg CL, Schneider EC, Bell DS. A conceptual framework and protocol for defining clinical decision support objectives applicable to medical specialties. BMC Med Inform Decis Mak. 2012 Sep 3;12:93. doi: 10.1186/1472-6947-12-93. PMID: 22943497; PMCID: PMC3536635.

16 Kerkhoff AD, Farrand E, Marquez C, Cattamanchi A, Handley MA. Addressing health disparities through implementation science-a need to integrate an equity lens from the outset. Implement Sci. 2022 Jan 31;17(1):13. doi: 10.1186/s13012-022-01189-5. PMID: 35101088; PMCID: PMC8802460.

17 Mouazer A, Tsopra R, Sedki K, Letord C, Lamy JB. Decision-support systems for managing polypharmacy in the elderly: A scoping review. J Biomed Inform. 2022 Jun;130:104074. doi: 10.1016/j.jbi.2022.104074. Epub 2022 Apr 22. PMID: 35470079.

18 Kawamoto K, McDonald CJ. Designing, Conducting, and Reporting Clinical Decision Support Studies: Recommendations and Call to Action. Ann Intern Med. 2020 Jun 2;172(11 Suppl):S101-S109. doi: 10.7326/M19-0875. PMID: 32479177.

19 Dowding D, Lichtner V, Closs SJ. Using the MRC Framework for Complex Interventions to Develop Clinical Decision Support: A Case Study. Stud Health Technol Inform. 2017;235:544-548. PMID: 28423852.

20 Marcial LH, Richardson JE, Lasater B, Middleton B, Osheroff JA, Kawamoto K, Ancker JS, van Leeuwen D, Lomotan EA, Al-Showk S, Blumenfeld BH. The Imperative for Patient-Centered Clinical Decision Support. EGEMS (Wash DC). 2018 May 30;6(1):12. doi: 10.5334/egems.259. PMID: 30094284; PMCID: PMC6078148.

21 Ash JS, Sittig DF, Guappone KP, Dykstra RH, Richardson J, Wright A, Carpenter J, McMullen C, Shapiro M, Bunce A, Middleton B. Recommended practices for computerized clinical decision support and knowledge management in community settings: a qualitative study. BMC Med Inform Decis Mak. 2012 Feb 14;12:6. doi: 10.1186/1472-6947-12-6. PMID: 22333210; PMCID: PMC3334687.

22 Amarasingham R, Audet AM, Bates DW, Glenn Cohen I, Entwistle M, Escobar GJ, Liu V, Etheredge L, Lo B, Ohno-Machado L, Ram S, Saria S, Schilling LM, Shahi A, Stewart WF, Steyerberg EW, Xie B. Consensus Statement on Electronic Health Predictive Analytics: A Guiding Framework to Address Challenges. EGEMS (Wash DC). 2016 Mar 7;4(1):1163. doi: 10.13063/2327-9214.1163. PMID: 27141516; PMCID: PMC4837887.

23 Kawamanto K, Flynn MC, Kukhareva P, ElHalta D, Hess R, Gregory T, Walls C, Wigren AM, Borbolla D, Bray BE, Parsons MH, Clayson BL, Briley MS, Stipelman CH, Taylor D, King CS, Del Fiol G, Reese TJ, Weir CR, Taft T, Strong MB. A Pragmatic Guide to Establishing Clinical Decision Support Governance and Addressing Decision Support Fatigue: a Case Study. AMIA Annu Symp Proc. 2018 Dec 5;2018:624-633. PMID: 30815104; PMCID: PMC6371304.

24 M.W. Jaspers, T. Steen, C. van den Bos, M. Geenen, The think aloud method: a guide to user interface design, Int. J. Med. Inf. 73 (2004) 781–795.

25 Kilsdonk E, Peute LW, Riezebos RJ, Kremer LC, Jaspers MW. Uncovering healthcare practitioners' information processing using the think-aloud method: From paper-based guideline to clinical decision support system. Int J Med Inform. 2016 Feb;86:10-9. doi: 10.1016/j.ijmedinf.2015.11.011. Epub 2015 Nov 26. PMID: 26725690.

26 Hoelscher SH, McBride S. Digitizing Infectious Disease Clinical Guidelines for Improved Clinician Satisfaction. Comput Inform Nurs. 2020 Jun;38(6):303-311. doi: 10.1097/CIN.0000000000000612. PMID: 32079814.

27 Wu RR, Myers RA, Sperber N, Voils CI, Neuner J, McCarty CA, Haller IV, Harry M, Fulda KG, Cross D, Dimmock D, Rakhra-Burris T, Buchanan AH, Ginsburg GS, Orlando LA. Implementation, adoption, and utility of family health history risk assessment in diverse care settings: evaluating implementation processes and impact with an implementation framework. Genet Med. 2019 Feb;21(2):331-338. doi: 10.1038/s41436-018-0049-x. Epub 2018 Jun 6. PMID: 29875427; PMCID: PMC6281814.

28 Readiness Assessment Maturity Model (RAMM). | BPM+ Health. https://www.bpm-plus.org/readiness-assessment-maturity-model.htm

29 Byrne CM, Pan EC, Russell C, Finley S, Rippen HE. Applying an organizational framework for health information technology to alerts. AMIA Annu Symp Proc. 2012;2012:67-76.

30 Cresswell K, Williams R, Sheikh A. Developing and Applying a Formative Evaluation Framework for Health Information Technology Implementations: Qualitative Investigation. J Med Internet Res. 2020;22(6):e15068. Published 2020 Jun 10. doi:10.2196/15068

31 Richesson RL, Staes CJ, Douthit BJ, Thoureen T, Hatch DJ, Kawamoto K, Del Fiol G. Measuring implementation feasibility of clinical decision support alerts for clinical practice recommendations. J Am Med Inform Assoc. 2020 Apr 1;27(4):514-521. doi: 10.1093/jamia/ocz225. PMID: 32027357; PMCID: PMC7075536.

32 Heidebrecht CL, Kwong JC, Finkelstein M, Quan SD, Pereira JA, Quach S, Deeks SL. Electronic immunization data collection systems: application of an evaluation framework. BMC Med Inform Decis Mak. 2014 Jan 14;14:5. doi: 10.1186/1472-6947-14-5. PMID: 24423014; PMCID: PMC3898919.

33 Shah H, Allard RD, Enberg R, Krishnan G, Williams P, Nadkarni PM. Requirements for guidelines systems: implementation challenges and lessons from existing software-engineering efforts. BMC Med Inform Decis Mak. 2012 Mar 9;12:16. doi: 10.1186/1472-6947-12-16. PMID: 22405400; PMCID: PMC3342141.

34 Wake DT, Smith DM, Kazi S, Dunnenberger HM. Pharmacogenomic Clinical Decision Support: A Review, How-to Guide, and Future Vision. Clin Pharmacol Ther. 2022 Jul;112(1):44-57. doi: 10.1002/cpt.2387. Epub 2021 Aug 29. PMID: 34365648; PMCID: PMC9291515.

35 Ivatury SJ, Hazard-Jenkins HW, Brooks GA, McCleary NJ, Wong SL, Schrag D. Translation of Patient-Reported Outcomes in Oncology Clinical Trials to Everyday Practice. Ann Surg Oncol. 2020 Jan;27(1):65-72. doi: 10.1245/s10434-019-07749-2. Epub 2019 Aug 26. PMID: 31452053; PMCID: PMC6925618.

36 Singh H, Sittig DF. A Sociotechnical Framework for Safety-Related Electronic Health Record Research Reporting: The SAFER Reporting Framework. Ann Intern Med. 2020 Jun 2;172(11 Suppl):S92-S100. doi: 10.7326/M19-0879. PMID: 32479184.

37 Kautz, K. (2010). Participatory Design Activities and Agile Software Development. In: Pries-Heje, J., Venable, J., Bunker, D., Russo, N.L., DeGross, J.I. (eds) Human Benefit through the Diffusion of Information Systems Design Science Research. TDIT 2010. IFIP Advances in Information and Communication Technology, vol 318. Springer, Berlin, Heidelberg.

38 Kilsdonk E, Peute LW, Jaspers MW. Factors influencing implementation success of guideline-based clinical decision support systems: A systematic review and gaps analysis. Int J Med Inform. 2017 Feb;98:56-64. doi: 10.1016/j.ijmedinf.2016.12.001. Epub 2016 Dec 5. PMID: 28034413.

39 Crandall B, Klein GA, Hoffman RR. Working minds: A practitioner's guide to cognitive task analysis. Mit Press; 2006 Jul 7.

40 Woolsey LK. The critical incident technique: An innovative qualitative method of research. Canadian Journal of Counselling and Psychotherapy. 1986;20(4).

41 Fox-Turnbull W. Stimulated recall using autophotography-A method for investigating technology education. Strengthening the position of technology education in the curriculum. Delft, The Netherlands: International Technology and Engineering Educators Association. 2009 Aug 24.

42 van Leeuwen D, Mittelman M, Fabian L, Lomotan EA. Nothing for Me or About Me, Without Me: Codesign of Clinical Decision Support. Appl Clin Inform. 2022 May;13(3):641-646. doi: 10.1055/s-0042-1750355. Epub 2022 Jun 29. PMID: 35768012; PMCID: PMC9242738.

43 Chung C, Patel S, Lee R, Fu L, Reilly S, Ho T, Lionetti J, George MD, Taylor P. Implementation of an integrated computerized prescriber order-entry system for chemotherapy in a multisite safety-net health system. Am J Health Syst Pharm. 2018 Mar 15;75(6):398-406. doi: 10.2146/ajhp170251. Erratum in: Am J Health Syst Pharm. 2018 Apr 15;75(8):504. PMID: 29523537.

44 Gance-Cleveland B, Leiferman J, Aldrich H, Nodine P, Anderson J, Nacht A, Martin J, Carrington S, Ozkaynak M. Using the Technology Acceptance Model to Develop StartSmart: mHealth for Screening, Brief Intervention, and Referral for Risk and Protective Factors in Pregnancy. J Midwifery Womens Health. 2019 Sep;64(5):630-640. doi: 10.1111/jmwh.13009. Epub 2019 Jul 26. PMID: 31347784.

45 Larsen K, Akindele B, Head H, Evans R, Mehta P, Hlatky Q, Krause B, Chen S, King D. Developing a User-Centered Digital Clinical Decision Support App for Evidence-Based Medication Recommendations for Type 2 Diabetes Mellitus: Prototype User Testing and Validation Study. JMIR Hum Factors. 2022 Jan 18;9(1):e33470. doi: 10.2196/33470. PMID: 34784293; PMCID: PMC8808349.

46 Hart, Sandra G., and Lowell E. Staveland. "Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research." In Advances in psychology, vol. 52, pp. 139-183. North-Holland, 1988.

47 Bates DW, Kuperman GJ, Wang S, Gandhi T, Kittler A, Volk L, Spurr C, Khorasani R, Tanasijevic M, Middleton B. Ten commandments for effective clinical decision support: making the practice of evidence-based medicine a reality. J Am Med Inform Assoc. 2003 Nov-Dec;10(6):523-30. doi: 10.1197/jamia.M1370. Epub 2003 Aug 4. PMID: 12925543; PMCID: PMC264429.

48 Norman K, Shneiderman B, Harper B. Quis: The questionnaire for user interaction satisfaction. HCIL Archive,[S. l.],[1999. 1995. http://www.cs.umd.edu/hcil/quis/

49 International Organization for Standardization. ISO 9241-11: Ergonomic requirements for office work with visual display terminals (VDTs): Part 11: Guidance on usability. 1998.

50 J. Nielsen, 10 Heuristics for User Interface Design, Nielsen Norman Group, Published 1994. Accessed February 10, 2023. https://www.nngroup.com/articles/ten-usability-heuristics/

51 Jia G, Yang P, Zhou J, Zhang H, Lin C, Chen J, Cai G, Yan J, Ning G. A framework design for the mHealth system for self-management promotion. Biomed Mater Eng. 2015;26 Suppl 1:S1731-40. doi: 10.3233/BME-151473. PMID: 26405941.

52 Wright A, Ash JS, Aaron S, Ai A, Hickman TT, Wiesen JF, Galanter W, McCoy AB, Schreiber R, Longhurst CA, Sittig DF. Best practices for preventing malfunctions in rule-based clinical decision support alerts and reminders: Results of a Delphi study. Int J Med Inform. 2018 Oct;118:78-85. doi: 10.1016/j.ijmedinf.2018.08.001. Epub 2018 Aug 2. PMID: 30153926; PMCID: PMC6128667.

53 Kannry J, McCullagh L, Kushniruk A, Mann D, Edonyabo D, McGinn T. A Framework for Usable and Effective Clinical Decision Support: Experience from the iCPR Randomized Clinical Trial. EGEMS (Wash DC). 2015 Jul 9;3(2):1150. doi: 10.13063/2327-9214.1150. PMID: 26290888; PMCID: PMC4537146.

54 Liberati EG, Ruggiero F, Galuppo L, Gorli M, González-Lorenzo M, Maraldi M, Ruggieri P, Polo Friz H, Scaratti G, Kwag KH, Vespignani R, Moja L. What hinders the uptake of computerized decision support systems in hospitals? A qualitative study and framework for implementation. Implement Sci. 2017 Sep 15;12(1):113. doi: 10.1186/s13012-017-0644-2. PMID: 28915822; PMCID: PMC5602839.

55 Ernst SK, Steinbeck V, Busse R, Pross C. Toward System-Wide Implementation of Patient-Reported Outcome Measures: A Framework for Countries, States, and Regions. Value Health. 2022 Sep;25(9):1539-1547. doi: 10.1016/j.jval.2022.04.1724. Epub 2022 May 21. PMID: 35610145.

56 Besiso A, Patrick JD, Dip G, Ho V, Cheng Y. The Impact of an Enterprise Electronic Medical Record (EEMR) Model vs a Clinical Information System (CIS) Model on Usability, Efficiency, and Adaptability. AMIA Annu Symp Proc. 2018 Dec 5;2018:242-251. PMID: 30815062; PMCID: PMC6371262.

57 Masterson Creber RM, Dayan PS, Kuppermann N, Ballard DW, Tzimenatos L, Alessandrini E, Mistry RD, Hoffman J, Vinson DR, Bakken S; Pediatric Emergency Care Applied Research Network (PECARN) and the Clinical Research on Emergency Services and Treatments (CREST) Network. Applying the RE-AIM Framework for the Evaluation of a Clinical Decision Support Tool for Pediatric Head Trauma: A Mixed-Methods Study. Appl Clin Inform. 2018 Jul;9(3):693-703. doi: 10.1055/s-0038-1669460. Epub 2018 Sep 5. PMID: 30184559; PMCID: PMC6125135.

58 Padman R, Jaladi S, Kim S, Kumar S, Orbeta P, Rudolph K, Tran T. An evaluation framework and a pilot study of a mobile platform for diabetes self-management: insights from pediatric users. Stud Health Technol Inform. 2013;192:333-7. PMID: 23920571.

59 Peute LW, Driest KF, Marcilly R, Bras Da Costa S, Beuscart-Zephir MC, Jaspers MW. A framework for reporting on human factor/usability studies of health information technologies. Stud Health Technol Inform. 2013;194:54-60. PMID: 23941930.

60 Brooke J. SUS-A quick and dirty usability scale. Usability evaluation in industry. 1996 Jun 11;189(194):4-7. https://digital.ahrq.gov/sites/default/files/docs/survey/systemusabilityscale%2528sus%2529_comp%255B1%255D.pdf

61 Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. Implement Sci. 2007 Nov 30;2:40. doi: 10.1186/1748-5908-2-40. PMID: 18053122; PMCID: PMC2213686.

62 Rippen HE, Pan EC, Russell C, Byrne CM, Swift EK. Organizational framework for health information technology. Int J Med Inform. 2013;82(4):e1-e13. doi:10.1016/j.ijmedinf.2012.01.012

63 Woodward EN, Singh RS, Ndebele-Ngwenya P, Melgar Castillo A, Dickson KS, Kirchner JE. A more practical guide to incorporating health equity domains in implementation determinant frameworks. Implement Sci Commun. 2021 Jun 5;2(1):61. doi: 10.1186/s43058-021-00146-5. PMID: 34090524; PMCID: PMC8178842.

64 Plan-Do-Study-Act (PDSA) Directions and Examples. Content last reviewed September 2020. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.html

65 Ammenwerth E, Brender J, Nykänen P, Prokosch HU, Rigby M, Talmon J; HIS-EVAL Workshop Participants. Visions and strategies to improve evaluation of health information systems. Reflections and lessons based on the HIS-EVAL workshop in Innsbruck. Int J Med Inform. 2004 Jun 30;73(6):479-91. doi: 10.1016/j.ijmedinf.2004.04.004. PMID: 15171977.

66 Meneses-Echavez JF, Rosenbaum S, Rada G, Flottorp S, Moberg J, Alonso-Coello P. Users' experiences with an interactive Evidence to Decision (iEtD) framework: a qualitative analysis. BMC Med Inform Decis Mak. 2021 May 25;21(1):169. doi: 10.1186/s12911-021-01532-8. Erratum in: BMC Med Inform Decis Mak. 2021 Jul 7;21(1):209. PMID: 34034723; PMCID: PMC8146986.

67 Owen R. Net promoter score and its successful application. Marketing wisdom. 2019:17-29.

68 McBride S, Tietze M, Hanley MA, Thomas L. Statewide Study to Assess Nurses' Experiences With Meaningful Use-Based Electronic Health Records. Comput Inform Nurs. 2017 Jan;35(1):18-28. doi: 10.1097/CIN.0000000000000290. PMID: 27655332.

69 Itchhaporia D. The Evolution of the Quintuple Aim: Health Equity, Health Outcomes, and the Economy. J Am Coll Cardiol. 2021 Nov 30;78(22):2262-2264. doi: 10.1016/j.jacc.2021.10.018. PMID: 34823665; PMCID: PMC8608191.

70 Patel D, Msosa YJ, Wang T, Mustafa OG, Gee S, Williams J, Roberts A, Dobson RJ, Gaughran F. An implementation framework and a feasibility evaluation of a clinical decision support system for diabetes management in secondary mental healthcare using CogStack. BMC Med Inform Decis Mak. 2022 Apr 14;22(1):100. doi: 10.1186/s12911-022-01842-5. PMID: 35421974; PMCID: PMC9009062.

71 Harry ML, Chrenka EA, Freitag LA, Saman DM, Allen CI, Asche SE, Truitt AR, Ekstrom HL, O'Connor PJ, Sperl-Hillen JAM, Ziegenfuss JY, Elliott TE. Primary care clinicians' opinions before and after implementation of cancer screening and prevention clinical decision support in a clinic cluster-randomized control trial: a survey research study. BMC Health Serv Res. 2022 Jan 6;22(1):38. doi: 10.1186/s12913-021-07421-0. PMID: 34991570; PMCID: PMC8739981.

72 Mohammed SA, Yusof MM. Towards an evaluation framework for information quality management (IQM) practices for health information systems--evaluation criteria for effective IQM practices. J Eval Clin Pract. 2013 Apr;19(2):379-87. doi: 10.1111/j.1365-2753.2012.01839.x. Epub 2012 Apr 15. PMID: 22502634.

73 Brownson RC, Kumanyika SK, Kreuter MW, Haire-Joshu D. Implementation science should give higher priority to health equity. Implement Sci. 2021 Mar 19;16(1):28. doi: 10.1186/s13012-021-01097-0. PMID: 33740999; PMCID: PMC7977499.

74 Hailemariam M, Bustos T, Montgomery B, Barajas R, Evans LB, Drahota A. Evidence-based intervention sustainability strategies: a systematic review. Implement Sci. 2019 Jun 6;14(1):57. doi: 10.1186/s13012-019-0910-6. PMID: 31171004; PMCID: PMC6554955.

75 Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, Ory MG, Estabrooks PA. RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review. Front Public Health. 2019 Mar 29;7:64. doi: 10.3389/fpubh.2019.00064. PMID: 30984733; PMCID: PMC6450067.

76 Christopoulou SC, Kotsilieris T, Anagnostopoulos I. Assessment of Health Information Technology Interventions in Evidence-Based Medicine: A Systematic Review by Adopting a Methodological Evaluation Framework. Healthcare (Basel). 2018 Aug 31;6(3):109. doi: 10.3390/healthcare6030109. PMID: 30200307; PMCID: PMC6165327.

77 Zamboni K, Schellenberg J, Hanson C, Betran AP, Dumont A. Assessing scalability of an intervention: why, how and who? Health Policy Plan. 2019 Sep 1;34(7):544-552. doi: 10.1093/heapol/czz068. PMID: 31365066; PMCID: PMC6788216.

78 Chen W, Howard K, Gorham G, et al. Design, effectiveness, and economic outcomes of contemporary chronic disease clinical decision support systems: a systematic review and meta-analysis. J Am Med Inform Assoc. 2022;29(10):1757-1772. doi:10.1093/jamia/ocac110

79 Fillmore CL, Bray BE, Kawamoto K. Systematic review of clinical decision support interventions with potential for inpatient cost reduction. BMC Med Inform Decis Mak. 2013;13:135. Published 2013 Dec 17. doi:10.1186/1472-6947-13-135

80 Klarenbeek SE, Weekenstroo HHA, Sedelaar JPM, Fütterer JJ, Prokop M, Tummers M. The Effect of Higher Level Computerized Clinical Decision Support Systems on Oncology Care: A Systematic Review. Cancers (Basel). 2020;12(4):1032. Published 2020 Apr 22. doi:10.3390/cancers12041032

81 Kawamoto K, Kukhareva PV, Weir C, Flynn MC, Nanjo CJ, Martin DK, Warner PB, Shields DE, Rodriguez-Loya S, Bradshaw RL, Cornia RC, Reese TJ, Kramer HS, Taft T, Curran RL, Morgan KL, Borbolla D, Hightower M, Turnbull WJ, Strong MB, Chapman WW, Gregory T, Stipelman CH, Shakib JH, Hess R, Boltax JP, Habboushe JP, Sakaguchi F, Turner KM, Narus SP, Tarumi S, Takeuchi W, Ban H, Wetter DW, Lam C, Caverly TJ, Fagerlin A, Norlin C, Malone DC, Kaphingst KA, Kohlmann WK, Brooke BS, Del Fiol G. Establishing a multidisciplinary initiative for interoperable electronic health record innovations at an academic medical center. JAMIA Open. 2021 Jul 31;4(3):ooab041. doi: 10.1093/jamiaopen/ooab041. PMID: 34345802; PMCID: PMC8325485.