

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

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PURPOSE

The Clinical Decision Support Innovation Collaborative (CDSiC) aims to advance the design, development, dissemination, implementation, use, measurement, and evaluation of evidence-based, shareable, interoperable, and publicly available patient-centered clinical decision support (PC CDS) to improve health outcomes of all patients by creating a proving ground of innovation. The Measurement and Outcomes Workgroup supports the measurement of PC CDS implementation and effectiveness to ensure that PC CDS works as intended. The Workgroup is comprised of 8 experts representing diverse perspectives related to CDS. All qualitative research activities conducted by the CDSiC are reviewed by the NORC at the University of Chicago Institutional Review Board (FWA00000142).

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PC CDS Planning & Reporting Tool

What is the Tool's Purpose? The Patient-Centered Clinical Decision Support (PC CDS) Planning & Reporting Tool supports research teams and others in describing how they addressed four key PC CDS life cycle phases and associated patient-centered factors when implementing a PC CDS. This tool allows users to document the “why, what, and how” details for their PC CDS implementation, ensures the key dimensions that drive PC CDS success are described in a complete and consistent way, and promotes patient-centeredness within the lifecycle of CDS.

We use the term “users” to encompass the team responsible for planning, developing, implementing, and evaluating a PC CDS intervention. This can include, but is not limited to, researchers, project managers, members of an organization’s IT department, informaticians, clinical champions, clinicians, and patient partners who are part of research teams.

What is in the Tool? There are four separate sections—1) planning and needs assessment, 2) design and development, 3) implementation and adoption, and 4) evaluation, maintenance, and sustainability— which are further organized by areas and tasks. The tool provides a brief description of what task and patient-centered factors to consider for each area, as well as fillable sections (i.e., how did you address the task, how did you address the patient-centered factors, what performance metrics were considered) for users to describe their approach for completing the task.

How and When Should You Use the Tool? Research teams can use this planning and reporting tool before, during, and after PC CDS implementation to document the information needed to produce a comprehensive report that fosters best practice syntheses across efforts and facilitates replication of implementation successes by others. Under each task, teams can use the checkbox to indicate whether the task was addressed.

Please note: Implementation context will vary across PC CDS research, and some tasks in this tool might not apply to all interventions. You may not need to complete all the tasks in this tool and can instead benefit from focusing on items you consider most valuable.

Tool at a Glance

- For reporting on 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 how the PC CDS meets these needs, navigate to [1. Planning & Needs Assessment](#) (page 3).
- For reporting on the process of designing and building effective PC CDS interventions, navigate to [2. Design & Development](#) (page 5).
- For reporting on methods used for deployment preparation and/or integration of PC CDS into clinical workflows or patient daily activities, navigate to [3. Implementation & Adoption](#) (page 7).
- For reporting on short- and long-term effects of your PC CDS intervention, including its sustainability, navigate to [4. Evaluation, Maintenance & Scalability](#) (page 9).

Each row in the tool represents an individual task. See below for a guide on how to complete the tool.

	Task	Task Description and Patient-Centered Activities	Describe How You Addressed the Task and Patient-Centered Activities
Task Area	Business Case Assessment		
Task	<p><i>Describe Identified Clinical Quality/Safety Goals and Opportunities for the PC CDS to Achieve the Goals</i></p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • The issue the PC CDS aimed to address. • The performance or quality measures used to inform the decision to implement the PC CDS. • The process for obtaining leadership buy-in to implement the PC CDS. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Performance measures related to patient/caregiver daily activities. • Patient and caregiver involvement in the goal identification process 	

Check the first box if you have results to report for this task. Check the second box if you did not perform activities related to this task.

Use these response field to provide details on how your project addressed the task and identified patient-centered activities.

Additional detail on how to populate each section of the tool and example approaches for reporting on each task are provided in Sections 2 and 3 of the User Guide.

1. Planning & Needs Assessment

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

Task	Task Description and Patient-Centered Activities	Describe How You Addressed the Task and Patient-Centered Activities
Business Case Assessment		
Describe Identified Clinical Quality/Safety Goals and Opportunities for the PC CDS to Achieve the Goals Task Addressed? <input type="checkbox"/> Not Applicable <input type="checkbox"/>	Task Description <ul style="list-style-type: none"> • The issue the PC CDS aimed to address. • The performance or quality measures used to inform the decision to implement the PC CDS. • The process for obtaining leadership buy-in to implement the PC CDS. Patient-Centered Activities <ul style="list-style-type: none"> • Performance measures related to patient/caregiver daily activities. • Patient and caregiver involvement in the goal identification process 	
Summarize the Evidence Base for the PC CDS Task Addressed? <input type="checkbox"/> Not Applicable <input type="checkbox"/>	Task Description <ul style="list-style-type: none"> • The knowledge base that informed the PC CDS decision logic, including any frameworks, theories, guidelines, or models used to guide PC CDS development. Patient-Centered Activities <ul style="list-style-type: none"> • Incorporation of patient-centered implementation frameworks, clinical guidelines/recommendations, or patient-focused behavior change models in the PC CDS design or logic. 	
Assess the Anticipated Costs, Risks, and Benefits of the PC CDS Task Addressed? <input type="checkbox"/> Not Applicable <input type="checkbox"/>	Task Description <ul style="list-style-type: none"> • Anticipated costs, risks, and benefits of developing and implementing the PC CDS. • Whether or not the PC CDS is financially feasible in a given setting. Patient-Centered Activities <ul style="list-style-type: none"> • Anticipated costs, risks, and benefits incurred by patients. 	

Task	Task Description and Patient-Centered Activities	Describe How You Addressed the Task and Patient-Centered Activities
<p>Describe the Process for Leveraging or Establishing Governance Mechanisms Specific to the PC CDS</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Process for establishing/informing and maintaining governance bodies specific to the proposed PC CDS. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Process to involve patients in PC CDS governance structures. 	
User Requirements Gathering		
<p>Describe the Process for User Requirements Gathering</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Processes to identify user requirements and the results of these processes. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Incorporation of patient perspectives and needs. 	
<p>Describe the Results of Workflow Compatibility Assessments</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • How the PC CDS will be integrated into end-user workflows. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Compatibility of the proposed PC CDS with patient/caregiver daily activities (i.e., “lifeflows”). 	
Technical Requirements Gathering		
<p>Describe Results from Technical Feasibility Assessments</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Existing technical infrastructure, application programming interfaces, and knowledge resources. • Existing data quality, local data availability, and additional data needs. • System capabilities to implement the PC CDS and how much effort it will take the system to reach its goals. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Incorporation of patient perspectives and needs. 	

2. Design & Development

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

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
Co-Design		
<p>Describe Initial and Iterative User Input During Design</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • PC CDS design approach and the results of user-centered design practices during initial and iterative stages. • Results of cognitive task load assessments. • How human-computer interaction design guidelines were followed. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Patient participation in PC CDS co-design and cognitive task load assessments. 	
<p>Describe the Process for Developing the PC CDS System and Addressing End-User Requirements</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Process for identifying and developing software requirements from end-user requirements. • Metrics needed to describe the current state of the PC CDS and identified opportunities for improvement. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Incorporation of patient perspectives and needs. 	

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
Prototype Testing		
<p>Describe How the PC CDS Design Addresses Each Component of the CDS Five Rights (right information, right people, right format, right channel, and right times in the workflow)ⁱ</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • PC CDS delivery method appropriate for the patient population and types of data available. • The choice of targeted user and PC CDS workflow. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Patient-contributed data that were used, barriers to capturing these data, and the optimum time to collect patient-contributed data. • Incorporation of patient preferences into design so that information is delivered to the patient at the right time, in the right format. 	
<p>Report on the Accuracy, Availability, and Validation of Data Used within the PC CDS</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Data elements that were used in the PC CDS and what, if any, standard terminologies were leveraged. • Approaches used to improve or validate accuracy. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Availability of patient-contributed information and the process of validating this information if incorporated. 	
<p>Describe the Process for Decision Support Logic Validation</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Translate information, clinical guidelines, and/or recommendations into computable knowledge in the PC CDS. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Translate patient-contributed information into computable knowledge in the PC CDS. 	

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
<p>Describe how PC CDS Usability was Addressed.</p> <p>Check the activities that were completed:</p> <p><input type="checkbox"/> Prototype Development and Design Testing</p> <p><input type="checkbox"/> Technical Acceptability Testing</p> <p><input type="checkbox"/> Initial Usability Testing</p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Approaches used to conduct PC CDS prototype testing (number of testing rounds, testing participants, social acceptability testing, etc.). • Whether or not the PC CDS software meets technical requirements. • Activities performed to assess initial usability of the designed tool. • The criteria used to inform the development of usability testing methods. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Patient involvement in prototype testing and social acceptability testing. • Results of usability testing among patients. 	

3. Implementation & Adoption

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

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
Preparing for Deployment		
<p>Describe how Key Stakeholders were Engaged in Implementation</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Process for involving and engaging multidisciplinary stakeholders for adoption of tool. • Process for identifying user champions to advocate for widespread use of the PC CDS. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • How patients were identified and engaged in PC CDS implementation, particularly patients representing vulnerable populations. • Process for identifying patient champions. 	
<p>Describe the Study Design Selected for the Implementation Evaluation</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Preparations to collect pre-/post-implementation data for mixed method studies, such as assessments of user experience combined with usage data. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Patient involvement in defining study approaches and incorporation of patients into each study arm 	

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
Deployment		
Describe the Guidance and Training Provided on How to Use the PC CDS Task Addressed? <input type="checkbox"/> Not Applicable <input type="checkbox"/>	Task Description <ul style="list-style-type: none"> Resources used to teach end users how to use the PC CDS, and how personnel were trained to manage the tool. Hands-on training sessions and tailored education provided to different user groups. User documentation about the PC CDS and topics related to how the system functions. Patient-Centered Activities <ul style="list-style-type: none"> Patient training provided for patient-facing tools and how this training was made accessible to patients. 	
Describe Approach for Deploying the PC into Existing Workflows Task Addressed? <input type="checkbox"/> Not Applicable <input type="checkbox"/>	Task Description <ul style="list-style-type: none"> Approach used to integrate the PC CDS into clinician workflows and patient daily activities (lifeflow). Patient-Centered Activities <ul style="list-style-type: none"> Patient involvement in pilot testing of patient-facing tools used outside of a clinical encounter. Process for incorporating the PC CDS into patient lifeflows. 	
Adoption		
Report the Extent of PC CDS Adoption Task Addressed? <input type="checkbox"/> Not Applicable <input type="checkbox"/>	Task Description <ul style="list-style-type: none"> Measures used to assess PC CDS adoption. Patient-Centered Activities <ul style="list-style-type: none"> Measures to assess patient uptake of patient-facing tools. Engagement trends among patients from patient user data. 	
Fidelity of Implementation Design		
Describe Environmental Factors Affecting Implementation Task Addressed? <input type="checkbox"/> Not Applicable <input type="checkbox"/>	Task Description <ul style="list-style-type: none"> The effects of internal (e.g., within the implementation setting) and external (e.g., wider regulatory and policy structures) factors on the implementation of the tool. Patient-Centered Activities <ul style="list-style-type: none"> Internal and external factors patients encounter when using the PC CDS. Consider unique internal and external factors faced by vulnerable populations. 	

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities
<p>Report the Extent of Fidelity to the Implementation Protocol</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Whether or not the PC CDS worked as designed and/or was used as intended by end users, after accounting for confounding factors. • How the results of fidelity assessments will be used to make changes to the tool. • Process for integrating the PC CDS into existing systems, including actions taken to minimize burden on users. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Efforts to reduce burden of the PC CDS on patient daily activities. • Whether or not the PC CDS was used as intended by patients. 	

4. Evaluation, Maintenance, & Scalability

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

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities and Performance Metrics Used
Evaluation of Process Changes		
<p>Assessments of PC CDS Process Impacts</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Approach for assessing impacts of the PC CDS on clinical workflow processes (e.g., simplicity, flexibility, timeliness, acceptability, etc.) and results. • Information quality management evaluation activities and results. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Approach for collecting, evaluating, and reporting process outcomes relevant to patients (e.g., lifeflow burden, efficiency, usage, and patient/clinician communication). • Identification of unintended consequences of the PC CDS on patient daily activities and approaches for improvement. 	
<p>PC CDS Assessments</p> <p>Check the assessments that were completed:</p> <p><input type="checkbox"/> Ethics Assessments</p> <p><input type="checkbox"/> User Satisfaction Assessment</p> <p><input type="checkbox"/> User Experience and Challenges Encountered</p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Ethics: Approach and results of ethics risk-benefit assessments at the individual, organizational, and regulatory level. • User Satisfaction: Process, approach for, and results of conducting pre- and post-implementation user satisfaction assessments, including satisfaction with changes to workflow due to the tool. • User Experience/Challenges Encountered: Process and results of gathering user feedback on their experience using the tool and any challenges (e.g., accessibility, findability, usefulness, credibility, desirability, and identification). <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Ethics: How ethical concerns related to patient privacy, consent, transparency, equity, and health disparities were addressed. 	

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities and Performance Metrics Used
	<ul style="list-style-type: none"> • User Satisfaction: Patients and caregiver involvement in follow-up user satisfaction assessments. • User Experience/Challenges Encountered: Results of user experience assessments with patients. 	
Evaluation of Outcomes and Impacts		
<p>Outcomes Evaluation</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Changes in clinical (e.g., health outcomes, patient safety), health system (e.g., cost, provider burnout), and related outcome measures. • Results from assessments of the overall value of the PC CDS. • If conducting a pilot study, feasibility estimates for a full trial. • Approach and measures used to evaluate the direct or indirect costs of PC CDS development or use. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Changes in patient-reported outcomes pre-to post-implementation and results from assessments of patient health journey measures and outcomes. • Overall value of the PC CDS among patients. • Use of equity-relevant metrics to evaluate the effectiveness of PC CDS. • Include patient cost considerations in assessing cost of PC CDS. 	
Maintenance		
<p>Approach to Monitoring and Managing the PC CDS Throughout its Lifecycle</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Plan for continuous monitoring of PC CDS so it continues to deliver value to end users, is modified when needed, and is retired when appropriate. May include quality improvement activities undertaken or planned to improve PC CDS performance. • Process for regular testing of the PC CDS to identify changes from the original intention and implement solutions. Specify the frequency of audits. • Plan for routinely collecting user feedback and monitoring system usage and performance. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Test PC CDS rules against patient data to identify system performance issues. • Collect feedback from patients during regular audits. 	

Task	Task Description	Describe How You Addressed the Task and Patient-Centered Activities and Performance Metrics Used
<p>Extent to Which the Tool has Become Part of Routine Organizational Practice and Culture</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Long-term follow up approaches to assess the extent to which the PC CDS has become a part of routine organizational practice, and the measures used to assess this. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Extent to which the tool has become embedded into patient daily activities/ “lifeflows.” 	
<p>Procedures for Knowledge Maintenance</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • PC CDS types used within an organization and their relevant owners and creation dates. • Approach for updating the PC CDS when new clinical or technological evidence becomes available. • Formal software change control processes that guide updates. 	
Scalability		
<p>Approaches to Deploy the Tool Beyond the Host Organization</p> <p>Task Addressed? <input type="checkbox"/></p> <p>Not Applicable <input type="checkbox"/></p>	<p>Task Description</p> <ul style="list-style-type: none"> • Action taken to encourage wider dissemination of the PC CDS (e.g., dissemination strategies). • Information provided about the PC CDS so other organizations or implementers can use it. • If technical portability assessment was conducted, report whether the PC CDS software can be deployed across health systems or, if applicable, EHR systems. <p>Patient-Centered Activities</p> <ul style="list-style-type: none"> • Partnering with patient champions to disseminate information about the tool and encourage use among other patients. • Deployment of patient-facing tools outside of healthcare settings to reach underserved patients. 	

¹ NIH Pragmatic Trials Collaboratory. 5 Rights of CDS - Definitions and uses. Rethinking Clinical Trials. October 24, 2022. Accessed June 5, 2024. <https://rethinkingclinicaltrials.org/chapters/conduct/real-world-evidence-clinical-decision-support/definitions-and-uses-for-cds/#:~:text=The%205%20rights%20of%20CDS%20are%20as%20follows%3A,user%20of%20the%20CDS%20tool>