PC CDS Planning, Implementation, and Reporting Checklist

➢ ***What is the Checklist's Purpose?*** The patient-centered clinical decision support (PC CDS) Planning, Implementation, and Reporting Checklist supports implementation teams and others in describing details of how they have addressed four key PC CDS implementation domains and associated patient-centered factors. We use the term "implementers" to encompass the team responsible for planning, developing, implementing, and evaluating a PC CDS intervention. 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.

➢ ***What is in the Checklist?*** There are separate sub-checklists for the four implementation domains—planning and needs assessment, design and development, implementation and adoption, and evaluation and impact—which are further organized by implementation subdomains and implementation tasks. Additionally, there is a separate table at the end of the checklist where users can indicate challenges and success factors within each implementation domain. The checklist provides a brief description of what implementation and patient-centered factors to consider for each task, 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 implementers to populate to describe their approach for completing the task.

➢ ***How and When Should You Use the Checklist?*** Implementation teams can use this checklist before implementation begins for planning purposes, during implementation to ensure key steps are being addressed, and/or after implementation to produce a comprehensive report that fosters best practice syntheses across efforts and facilitates replication of implementation successes by others. Implementation team members can collaborate to decide which implementation tasks are relevant for their PC CDS initiative. 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 or not the task was addressed, and by whom.

> **Additional detail on how to populate each section of the checklist and example approaches for reporting on each implementation task are provided in Sections 2 and 3 of the User Guide <u>here</u>.**

➢ **Please note: Implementation context will vary across PC CDS tools, and some implementation tasks in this checklist might not apply to all interventions or might not be feasible to complete. Users may not need to complete all the tasks in this checklist and can instead benefit from focusing on items they consider most valuable.**

Implementers can navigate to relevant sections of the checklist using the table of contents below:

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, implementation tasks cover four subdomains: 1) business case assessment, 2) user requirements gathering, 3) technical requirements gathering, and 4) planning for knowledge maintenance.

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities
Implementation Subdomain: Business Case Assessment				
Describe Identified Clinical Quality/Safety Goals and Opportunities for the PC CDS to Achieve the Goals Task Addressed? ☐ Who Addressed This Task?	• The issue the PC CDS aims 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.	• Performance measures related to patient/caregiver daily activities. • Patient and caregiver involvement in the PC CDS goal identification process.		
Summarize the Evidence Base for the PC CDS Task Addressed? ☐ Who Addressed This Task?	• The knowledge base that informed the PC CDS decision logic, including any frameworks, theories or models used to guide PC CDS development.	• Incorporation of patient-centered implementation frameworks 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? ☐ Who Addressed This Task?	• Anticipated costs, risks, and benefits of developing and implementing PC CDS. • Whether or not the PC CDS is financially feasible in a given setting.	• Anticipated costs, risks, and benefits incurred by patients.		
Describe the Process for Leveraging or Establishing Governance Mechanisms Specific to the PC CDS Task Addressed? ☐ Who Addressed This Task?	• Process for establishing/informing and maintaining governance bodies specific to the proposed PC CDS.	• Process to involve patients in PC CDS governance structures.		

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities
Implementation Subdomain: User Requirements Gathering				
Describe End-User Requirements Task Addressed? ☐ Who Addressed This Task?	• Processes to identify user requirements and the results of these processes. • Metrics needed to define the current state and opportunities for improvement.	• Incorporation of patient perspectives and needs.		
Describe Results of Workflow Compatibility Assessments Task Addressed? ☐ Who Addressed This Task?	• How the PC CDS will be integrated into end-user workflows.	• Compatibility of the proposed PC CDS with patient/caregiver daily activities (i.e., "lifeflows").		
Describe Results of System Readiness Assessments Task Addressed? ☐ Who Addressed This Task?	• System capabilities to implement the PC CDS and how much effort it will take the system to reach its goals.			
Implementation Subdomain: Technical Requirements Gathering				
Describe Results from Technical Feasibility Assessments Task Addressed? ☐ Who Addressed This Task?	• Existing technical infrastructure, application programming interfaces, and knowledge resources. • Existing data quality, local data availability, and additional data needs.			
Process for Developing PC CDS System Requirements Task Addressed? ☐ Who Addressed This Task?	• Process for identifying and developing software requirements for the PC CDS. • Process for reaching consensus on which information/guidelines to include within the PC CDS.			

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities
Implementation Subdomain: Preparing for Knowledge Maintenance				
Describe Procedures for Knowledge Maintenance Task Addressed? ☐ Who Addressed This Task?	• PC CDS types used within an organization and their relevant owners and creation dates. • Cadence for reviewing relevant metrics to assess PC CDS effectiveness. • Approach to establish and monitor a help desk or malfunction log where end users can report issues.			
Describe Approach for Updating the PC CDS Artifact Knowledge Base Task Addressed? ☐ Who Addressed This Task?	• Approach for updating the PC CDS when new clinical or technological evidence becomes available. • Formal software change control processes that guide PC CDS updates.			

2. Design & Development

We refer to *design and development* as 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 implementation domain are three implementation subdomains: 1) CDS Five Rights, 2) co-design, and 3) PC CDS usability.

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities
Implementation Subdomain: CDS Five Rights				
Describe How the PC CDS Design Addresses Each Component of the CDS Five Rights Task Addressed? ☐ Who Addressed This Task?	• PC CDS delivery method that is appropriate for the patient population and types of data available. • The choice of targeted user and PC CDS workflow.	• 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 PC CDS design so that information is delivered to the patient at the right time, in the right format.		
Report on the Accuracy, Availability, and Validation of Data used Within the PC CDS Task Addressed? ☐ Who Addressed This Task?	• Which data elements were used in the PC CDS and what, if any, standard terminologies were leveraged? • Approaches used to improve or validate PC CDS accuracy.	• Availability of patient-contributed information and the process of validating this information if incorporated into the PC CDS.		
Implementation Subdomain: Co-Design				
Describe Initial and Iterative User Input During Design Task Addressed? ☐ Who Addressed This Task?	• For initial and iterative stages, PC CDS design approach and the results of user-centered design practices. • Results of cognitive task load assessments. • How human-computer interaction design guidelines were followed.	• Patient participation in PC CDS co-design and cognitive task load assessments.		

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities
Describe Process for Decision Support Logic Validation Task Addressed? ☐ Who Addressed This Task?	• Translate information, clinical guidelines, and/or recommendations into computable knowledge in the PC CDS.	• Translate patient-contributed information into computable knowledge in the PC CDS.		
Implementation Subdomain: PC CDS Usability				
Prototype Development and Design Testing Task Addressed? ☐ Who Addressed This Task?	• Approaches used to conduct PC CDS prototype testing, the number of rounds of testing performed, who participated in testing, and activities to refine the prototype based on feedback. • Results of social acceptability testing.	• Patient involvement in prototype testing and social acceptability testing.		
Technical Acceptability Testing and Results Task Addressed? ☐ Who Addressed This Task?	• Whether or not the PC CDS software meets technical requirements.			
Initial Usability Testing and Results Task Addressed? ☐ Who Addressed This Task?	• Activities performed to assess initial usability of the designed tool. • The criteria used to inform the development of usability testing methods.	• Results of usability testing among patients.		

3. Implementation & Adoption

We define *implementation and adoption* as 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 implementation domain are five implementation subdomains: 1) preparing for deployment, 2) deployment, 3) adoption, 4) use, and 5) fidelity of implementation design.

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities
Implementation Subdomain: Preparing for Deployment				
Describe how Key Stakeholders were Engaged in Implementation Task Addressed? ☐ Who Addressed This Task?	• Process for identifying and engaging multidisciplinary stakeholders. • How buy-in was obtained from stakeholders.	• How patients were identified and engaged in PC CDS implementation, particularly patients representing vulnerable populations.		
Report on the Identification of End-User Champions Task Addressed? ☐ Who Addressed This Task?	• Process for identifying user champions to advocate for widespread use of the PC CDS.	• Process for identifying patient champions.		
Describe the Guidance and Training Provided on How to Use the PC CDS Task Addressed? ☐ Who Addressed This Task?	• Resources used to teach end users how to use the PC CDS and how personnel were trained to manage tool components. • Hands-on training sessions and tailored education provided for different user groups. • User documentation about the PC CDS and help topics related to the system functions.	• What patient training was provided for patient-facing tools and how this training was made accessible to patients.		
Describe the Study Design Selected for the Summative PC CDS Evaluation Task Addressed? ☐ Who Addressed This Task?	• Preparations to collect pre-/post-implementation data for mixed method studies utilizing qualitative assessments of user experience combined with usage data, or randomized controlled trials.	• Patient involvement in defining study approaches and incorporation of patients into each study arm.		

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities
Implementation Subdomain: Deployment				
Describe Approach for Deploying the PC CDS in a Stepwise Manner into Existing Workflows Task Addressed? ☐ Who Addressed This Task?	• Stepwise approach used to integrate the PC CDS into clinician workflows and patient lifeflows.	• Patient involvement in pilot testing of tools. For tools used outside of the healthcare setting, the process for incorporating the PC CDS into patient lifeflows.		
Implementation Subdomain: Adoption				
Report on the Extent of PC CDS Adoption Task Addressed? ☐ Who Addressed This Task?	• Measures used to assess PC CDS adoption.	• Measures to assess patient uptake of patient-facing tools. • Engagement trends among patients from patient user data.		
Implementation Subdomain: Use				
Report on Results of Social Implementation Assessments Task Addressed? ☐ Who Addressed This Task?	• Barriers and facilitators to implementation and how facilitators will be leveraged to encourage use of the PC CDS. • User data related to PC CDS usage patterns, engagement, and adherence.	• Engagement of patient champions in social implementation assessments.		
Report on Results of Post-Deployment Usability and User Adherence Testing With End Users Task Addressed? ☐ Who Addressed This Task?	• Approach for assessing usability of the tool after deployment and using results for iterative system enhancement. • Rank usability problems based on severity and their potential impact on patient safety.	• Results of usability testing among patients and process to address identified issues.		

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities
Implementation Subdomain: **Fidelity of Implementation Design**				
Describe how the PC CDS was Integrated Into Existing Systems Task Addressed? ☐ Who Addressed This Task?	• Process for integrating the PC CDS into existing systems, including actions taken to minimize burden on users.	• Efforts to reduce burden of the PC CDS on patient daily activities (lifeflows).		
Report on Results of Technical Implementation Assessments Task Addressed? ☐ Who Addressed This Task?	• Whether or not the PC CDS meets technical requirements in a real-world setting.			
Describe Environmental Factors Affecting Implementation Task Addressed? ☐ Who Addressed This Task?	• The effects of internal (e.g., within the implementation setting) and external (e.g., wider regulatory and policy structures) factors on PC CDS implementation.	• Internal (e.g., within healthcare setting or daily life) and external (e.g., power dynamics) factors patients encounter when using the PC CDS. Consider unique internal and external factors faced by vulnerable populations.		
Describe the Approach for Conducting Regular Audits and the Results Task Addressed? ☐ Who Addressed This Task?	• Process for regular testing of the PC CDS to identify misalignments with original intentions and implement solutions; specify the frequency of audits. • A plan to routinely collect user feedback and monitor system usage and performance.	• Test CDS rules against patient data to identify system performance issues. • Collect feedback from patients during regular audits.		
Report on the Extent of Fidelity to the Implementation Protocol Task Addressed? ☐ Who Addressed This Task?	• 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.	• Whether or not the PC CDS was used as intended by patients.		

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 PC CDS has achieved its defined objectives, and describing the short- and long-term effects of the PC CDS, including its sustainability. This implementation domain includes three subdomains: 1) summative evaluation, 2) sustainability, and 3) scalability.

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities	Describe what Performance Metrics You Will (or Did) Consider
Implementation Subdomain: **Summative Evaluation**					
Describe Assessments of PC CDS Process Impacts Task Addressed? ☐ Who Addressed This Task?	• Approach for assessing process impacts of the PC CDS (e.g., simplicity, flexibility, data quality, timeliness, acceptability). • Feedback collected from end users on their experience with the tool and perceived changes to workflows.	• Approach for collecting and reporting process outcomes relevant to patients (e.g., lifeflow burden, efficiency, usage, and patient/clinician communication).			
Report Results of User Experience and Challenges Encountered Task Addressed? ☐ Who Addressed This Task?	• Approach for gathering feedback from end users on their experience while using the tool.	• Results of user experience assessments with patients.			
Report Results of User Satisfaction Assessments Task Addressed? ☐ Who Addressed This Task?	• Process for conducting user satisfaction assessments. • Results from pre- and post-implementation user satisfaction surveys, including satisfaction with changes to workflow due to the tool.	• Patients and caregiver involvement in user satisfaction assessments.			
Report Changes in Clinical, Health System, and Related Outcomes Task Addressed? ☐ Who Addressed This Task?	• Changes in clinical (e.g., health outcomes, patient safety), health system (e.g., cost, provider burnout), and related outcome measures.	• Inclusion of patient-reported outcomes.			

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities	Describe what Performance Metrics You Will (or Did) Consider
Describe Implications for Conducting Quality Improvement Activities Task Addressed? ☐ Who Addressed This Task?	• Quality improvement activities undertaken or planned to improve PC CDS performance.	• Identification of unintended consequences of the PC CDS implementation within patient daily activities and approaches for amelioration.			
Report Results of a Full Program Evaluation of the PC CDS Task Addressed? ☐ Who Addressed This Task?	• Results from assessments of the overall value of the PC CDS. • If conducting a pilot study, feasibility estimates for a full trial. • Results of information quality management evaluations.	• Assessments of satisfaction, utility, engagement, and outcomes among patients. • Overall value of the PC CDS among patients. • Use of equity-relevant metrics to evaluate the PC CDS.			
Implementation Subdomain: **Sustainability**					
Describe the Approach to Monitoring and Managing the PC CDS Throughout its Lifecycle Task Addressed? ☐ Who Addressed This Task?	• Plan for continuous monitoring of PC CDS so it continues to deliver high value to end users, is modified when needed, and is retired when appropriate.				
Describe the Extent to Which the Tool has Become Part of Routine Organizational Practice and Culture Task Addressed? ☐ Who Addressed This Task?	• Long-term followup 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.	• Extent to which the tool has become embedded into patient daily activities/ "lifeflows."			
Report on Results of Ethics Assessments Task Addressed? ☐ Who Addressed This Task?	• Results of ethics risk-benefit assessments at the individual, organizational, and regulatory level.	• How ethical concerns related to patient privacy and transparency were addressed.			

Implementation Task	Implementation Task Description	Patient-Centered Implementation Activities	Describe How You Will (or Did) Address the Implementation Task	Describe How You Will (or Did) Address the Patient-Centered Implementation Activities	Describe what Performance Metrics You Will (or Did) Consider
Implementation Subdomain: Scalability					
Report Results of Cost-Effectiveness Evaluations Task Addressed? ☐ Who Addressed This Task?	• Results of cost-effectiveness evaluations. • Measures used to evaluate the direct or indirect costs of PC CDS development or use.	• Include patient cost considerations in cost-effectiveness evaluations of the PC CDS.			
Report Results of Technical Portability Assessments Task Addressed? ☐ Who Addressed This Task?	• Whether or not the PC CDS software can be deployed across health systems or, if applicable, EHR systems.				
Describe Approaches to Deploy the Tool Beyond the Host Organization Task Addressed? ☐ Who Addressed This Task?	• Take action to encourage wider dissemination of the PC CDS. • Provide information about the PC CDS so other organizations or implementers can use it.	• 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 with limited access to the healthcare system.			

5. Challenges and Success Factors

Within each implementation domain, PC CDS implementers may have encountered challenges and/or identified factors that led to successful completion of implementation tasks. This section provides a space for PC CDS implementation teams to document those challenges and success factors to support reporting and identify lessons learned to inform future PC CDS implementation activities.

Implementation Domain	What Challenges Did You Encounter?	What Factors Led to Success?
Planning & Needs Assessment		
Design & Development		
Implementation & Adoption		
Evaluation & Impact		