Trust & Patient-Centeredness Workgroup: An Introductory Handbook for Patient Engagement Throughout the Patient-Centered Clinical Decision Support Lifecycle

AHRQ
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Clinical Decision Support
Innovation Collaborative

PURPOSE

The Trust and Patient-Centeredness Workgroup is charged with (1) supporting the design, implementation, and uptake of patient-centered clinical decision support (PC CDS)—to enhance trust, foster shared decision making, and engage patients and clinicians as partners alongside all members of the care team; (2) promoting and enabling the use of PC CDS and developing related outputs that can support clinicians and patients as partners in a care team, equally committed to creating effective treatment and care coordination plans; and (3) ensuring that PC CDS products are understandable by the care team, designed with end-users (including both clinicians and patients) in mind, and involving them from the very beginning in of PC CDS development. The Workgroup is composed of eleven experts and stakeholders representing a diversity of perspectives within the CDS community. This report is intended primarily for PC CDS tool developers and priority end-users.

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1.   Introduction

Clinical decision support (CDS) includes tools that provide timely, evidence-based information to inform patient, caregiver, and care team decision making.[1] To be patient-centered, CDS must significantly incorporate patient-centered factors. These factors can include using evidence that is based on patient-centered outcomes research (PCOR) that incorporates outcomes that are meaningful to patients (knowledge), incorporating data that are generated directly from, and meaningful to, patients (data), directly engaging patients and caregivers across a range of settings (delivery), and/or supporting patient and/or caregiver involvement in shared decision making (use).[2]

Established standards for ensuring patient-centeredness in research emphasize the importance of engaging individuals who represent the population of interest at each stage of the research process.[3] Within the context of patient-centered clinical decision support (PC CDS), involving patients, caregivers, and care teams in development and implementation can ensure that decision support tools are focused on critical information needs and that the delivery of information is in a manner and format that is most helpful to users. Engaging patients is especially important to creating CDS that is responsive to their needs.[4] While PC CDS continues to grow and evolve, the role of patient engagement in developing these tools remains limited. PC CDS researchers, developers, and implementers may require guidance on the best methods to engage patients, as well as easily accessible resources. The goal of this introductory handbook is to bridge this gap by providing guidance and resources.

1.1   About This Handbook

This brief handbook provides a practical resource to 1) understand how patient engagement fits into the stages of the PC CDS lifecycle and 2) learn about methods and resources that can be used to engage patients within these stages. While this handbook is not exhaustive, it serves as an introductory resource for the field.

How was this handbook developed? This handbook was developed through a targeted review of the peer-reviewed and grey literature for patient engagement methods and resources, as well as relevant examples of patient engagement throughout the PC CDS lifecycle. The literature findings were validated and supplemented with input from the Clinical Decision Support Innovation Collaborative (CDSiC) Trust & Patient-Centeredness Workgroup, which consists of experts in CDS, health information technology (IT), and patient engagement. The appendix provides additional information about our methods.

Who should use this handbook? Anyone interested in understanding what methods can be used to engage patients to develop or implement PC CDS may find the contents of this handbook useful. This handbook may be most useful to patient partners, researchers, and developers involved in the creation of PC CDS.

2.   Guidance: Engaging Patients Throughout the PC CDS Lifecycle

Four primary steps comprise the PC CDS lifecycle: 1) identifying and choosing evidence to inform PC CDS, 2) developing PC CDS, 3) implementing PC CDS, and 4) measuring PC CDS. Different methods can be used in each step to engage patients (Exhibit 1), which reflect unidirectional communication (e.g., patients provide input and information), bidirectional communication (e.g., patients serve as collaborative partners), or both.[4] Some methods can be adapted to be used in multiple steps of the lifecycle. Below, we briefly describe each step of the lifecycle, discuss why patient engagement is important for the step, and discuss methods that can be used to engage patients. Resources are provided for each method.

Exhibit 1.   Summary of Methods for Patient Engagement

Identifying and Choosing Evidence	Developing PC CDS	Implementing PC CDS	Measuring PC CDS
• Delphi consensus process • Priority setting partnership	• Consultative groups • Surveys • Interviews • Focus groups • Prototyping • Usability testing	• Patient pilot testing • Patient champions • Structured implementation assessments	• Delphi methods for outcomes selection • Community engagement studios • Group concept mapping

2.1   Identifying and Choosing Evidence to Inform PC CDS

The PC CDS lifecycle begins with identifying and prioritizing evidence-based findings (e.g., clinical guidelines based on research studies) that are transformed into decision support tools and disseminated to patients, caregivers, and/or care teams. Gathering and incorporating patient input in this step can set the groundwork for patient engagement throughout the PC CDS lifecycle and build trust in the final product. It can also ensure that PC CDS focuses on the decision-making needs of patients and the clinical outcomes that are most important to them.[5]

Methods for engaging patients in this stage of PC CDS development are not well established.[5] However, there are opportunities to adopt methods that have been used to engage patients and other stakeholders in consensus building, as well as patients in research priority setting.

Delphi Consensus Process

A Delphi consensus process, sometimes called a Delphi method or Delphi technique, is an approach that gains the collective opinion of a group of panel members. This method forecasts

group opinions by collecting individual anonymous feedback from each panel member and observing themes across responses to form a consensus. It can be a reliable method for gathering input because of the anonymity, which removes bias and the dominance of one opinion.[6]

In the context of decision support, this method has previously been used to engage patients, caregivers, clinicians, pharmacists, and other experts to assess evidence and identify priority areas for CDS development. [7,8,9] For example, the American College of Emergency Physicians used Delphi consensus process to assess the feasibility of translating their clinical policies into CDS.[9] For another study, researchers conducted a two-round online Delphi study to develop a CDS tool for palliative care. The panel, which included patient and/or caregiver representatives, assessed the appropriateness of clinical recommendations. [10] Delphi consensus processes have also been used to engage patients to generate recommendations, identify research priorities, and develop clinical guidance across a range of disciplines.[11,12,13]

Key Features. Delphi consensus processes can vary widely but generally include:[14,15]

- Identifying a problem area to explore. This can be done through literature reviews, group discussion among a defined group of experts or steering committee, and/or stakeholder discussion.[16]
- Selecting a group of panel members (e.g., patients, subject matter experts).
- Gathering panel member input through a series of questionnaires and structured feedback sessions. This usually involves at least two to three rounds, where the anonymized results of the previous round are shared back to the panel.
- Analyzing the panel member responses based on areas of agreement, disagreement, and consistency of responses across rounds to arrive at a group consensus.

Considerations. Due to the multiple rounds of consensus building, Delphi processes can be time consuming and resource intensive, often taking 4 to 6 months to complete.[17] They also offer limited opportunities for direct, shared discussion and idea generation among participants, given the desire for maintaining the anonymity of input.[16] Exhibit 2 provides resources for this method.

Exhibit 2.   Resources For Delphi Consensus Processes

Resources
- **Practical Considerations in Using Online Modified-Delphi Approaches to Engage Patients and Other Stakeholders in Clinical Practice Guideline Development**: This publication discusses how an online modified-Delphi approach can be used to engage patients and other stakeholders. While focused on clinical practice guideline development, the methods discussed here can be adopted for this stage of the PC CDS lifecycle.[18]
- **Delphi Methodology in Healthcare Research: How to Decide Its Appropriateness**: This study describes the key elements of the Delphi technique and offers a tool to evaluate the quality of Delphi methods in healthcare research.[16]

Priority Setting Partnerships

A Priority Setting Partnership (PSP) is a collaborative, consensus-based process that has been used to engage patients and other stakeholders to reach a consensus about research priorities. The UK-based James Lind Alliance has established PSP processes with oversight from the UK's National Institute for Health and Care Research.[19]

While this process has not been used to prioritize evidence for PC CDS development, it is a well-established method for engaging patients across a range of research areas.[20,21,22,23] This includes topics focused on patient-facing digital technologies such as mobile applications and patient portals.[24,25] PC CDS researchers and developers may be able to adapt this method for choosing health conditions for PC CDS development efforts and for prioritizing evidence in this step of the PC CDS lifecycle.

Key Features. These partnerships use a set of guiding principles to ensure consensus: equal involvement, inclusivity, transparency, and a commitment to using and contributing to the evidence base.[26] The PSP process includes:[27,28]

- Soliciting potential research needs using a survey with open-ended questions that focus on identifying areas of clinical uncertainty.
- Synthesizing open-ended survey responses via qualitative coding to generate an initial list of priorities.
- Conducting ranking exercises to narrow the initial list of priorities.
- Holding a face-to-face workshop for further refinement, resulting in a list of top ten priorities.

Considerations. The questionnaires used to generate research needs and the ranking exercises may be distributed across a larger group of patients, while the convening will involve a small group of participants.[29] Unlike Delphi processes, PSPs offer the opportunity for more direct engagement among participants during the workshop. The PSP process may be adapted to fit the needs of the patient group. For example, for patients unable to participate in face-to-face workshops, PSPs can instead convene a virtual workshop to narrow priority areas. These virtual workshops can help facilitate participation among underrepresented or underresourced groups.[30] Exhibit 3 provides resources for this method.

Exhibit 3.   Resources For Priority Setting Partnerships

Resources
- **PSP Guidebook**. Developed by the James Lind Alliance, this guidebook describes methods and provides a toolbox of key documents.[27]
- **Scoping Review on PSPs**. This scoping review summarizes processes across 37 studies conducted between 2010-2018 that used PSPs, including types of stakeholder participants and methods used for engagement.[28]

2.2 Developing PC CDS

Once evidence-based findings have been prioritized and selected, the next step is to translate these findings into computable clinical knowledge, develop the interface that will deliver decision support, and iteratively test and refine the PC CDS tool. Patient engagement is important in this step to ensure the CDS Five Rights—the right information is delivered to patients at the right time, and in the manner and format that they prefer.[31] This can also support trust in PC CDS by enhancing fairness, accountability, and transparency in the design process.[32,33] Methods for engaging patients in this step of the lifecycle are focused on codesign of PC CDS.

Codesign Processes

Patient-centered codesign specifically involves patients in the conceptualization of a tool based on their needs, preferences, and values. Codesign methods are well established in engaging clinicians in CDS development. For example, PC CDS developers and researchers have engaged clinicians to identify priority features for CDS, solicit feedback on CDS design elements, and assess the appropriateness of design features.[34, 35, 36,37] Engaging patients in PC CDS codesign is an emerging area;[3] however, these methods have been used to engage patients in the development of digital tools. For example, researchers have conducted patient focus groups in which patients were observed using a mobile application prototype, which was followed by facilitated focus group discussions to obtain input on the app design.[38]

Key Features. A range of methods can be used to support patient codesign of PC CDS tools. These can be quantitative, qualitative, or a combination of both. Below, we briefly summarize potential ways to engage patients in codesign.

- *Consultative groups.* Consultative groups include working groups, steering committees, patient and/or family advisory groups, and reactor panels.[39,40,41,42] These groups can be used in targeted ways to validate preliminary design ideas or evaluate PC CDS prototype designs, as well as for broader, sustained partnership throughout the PC CDS development process.

- *Surveys*. Surveys can gather information from patients to help PC CDS developers understand which information or features patients require to effectively use PC CDS and how patients would rank, prioritize, or interact with these PC CDS features. [43,35] Surveys can also be used to gather feedback on the effectiveness (e.g., usefulness, usability) of PC CDS prototypes.[44]

- *Focus Groups.* Focus groups are planned, facilitated discussions often focusing on a predetermined topic or product.[45] Often conducted as a series of discussions with the same or different participants, focus groups can highlight similarities and differences across patients' needs, values, perceptions, etc.[46] Focus groups can be held to understand how patients interact with PC CDS and which design elements facilitate or inhibit effective use.

- *Interviews.* Interviews with individual patients help PC CDS developers empathize with patients and better understand the needs, objectives, and challenges that dictate how

patients use PC CDS.[47] These interviews use unstructured or semistructured formats and open-ended questions to elicit stories about end users' past and personal experiences. When recruiting individuals to participate in interviews, it is important to ensure diverse representation reflective of the spectrum within the patient population of interest.[2] Consider the appropriate sample size and representativeness of the patient population to reflect the health condition and PC CDS topic area. In general, this is determined by reaching saturation (i.e., interviews are conducted until they yield no additional insights into the topic).[48]

- *Prototyping.* As part of prototyping, patients engage with low-resolution mockups or representations to solicit preliminary reactions or rapid feedback, often through iterative usability testing.[49] This provides direct input on design early in the PC CDS development process.[50,51,52]

- *Usability Testing.* Usability testing involves engaging patients during prototype interaction to assess PC CDS effectiveness in meeting their needs. This may involve conducting user interviews, observing patients interact with prototypes, and/or having patients document their experiences with the prototype.[53]

Considerations. There is no "one-size-fits-all" approach to codesign. PC CDS developers and researchers may find it helpful to consider using multiple codesign processes to engage patients in this step of the PC CDS lifecycle. In selecting methods, it is important to consider the intensity of engagement (e.g., commitment of time, depth of input), as well as the reach of the method.[54] Exhibit 4 provides resources for this method.

Exhibit 4. Resources For Codesign

Resources
• **Methods for Involving End Users in PC CDS Co-design**. Developed by the CDSiC, this report provides a detailed discussion of codesign methods including benefits, considerations, and examples in the literature.[54]
• **A Generative Codesign Framework for Healthcare Innovation**. This publication outlines a framework for engaging end users in healthcare innovation with three stages: predesign, codesign, and postdesign.[55]
• **Qualitative Usability Testing Guide**. Developed by the Nielsen Norman Group, this guide provides articles and videos that describe planning, conducting, and analyzing qualitative user testing.[56]
• **Patient Shark Tank®**. The Health Collaboratory, a global innovation hub, has created a Patient Shark Tank®, where developers can apply to receive feedback from a diverse group of patient representatives.[57]
• **Patient Experience Mapping Toolbox**. The National Health Council developed a set of publicly available resources to help researchers engage and document patients' experiences with chronic diseases more holistically and in a standardized way.[58]

2.3   Implementing PC CDS

Once PC CDS is developed, it is ready to be implemented into clinician-facing systems (i.e., electronic health record [EHR] environments), as well as patient-facing tools (e.g., mobile apps, patient portals, websites), for use. In this step of the lifecycle, patients should be engaged in PC CDS implementation to facilitate adoption and acceptance within this group. PC CDS implementers can engage patients representing underrepresented populations in implementation efforts. Patient engagement methods in this step of the lifecycle focus on patient codeployment of PC CDS.

Patient Codeployment

While codesign methods ensure that PC CDS is created based on needs of patient end users, engaging patients in PC CDS deployment provides real-time feedback during implementation, facilitating assessment and refinement of PC CDS.[59,60] For patient-facing PC CDS used outside of the healthcare setting, codeployment can be an opportunity to understand how decision support tools fit within patient life flows.[59,60]

Key Features. Codeployment requires that patients and PC CDS implementers develop a shared understanding about the goals of the PC CDS prior to implementation.[59] Methods used in codesign, such as surveys, interviews, and focus groups, may also be used throughout codeployment to gather patient input and feedback on PC CDS tools. Other methods that can be used for patient codeployment of PC CDS include patient participation in pilot testing, engaging patients as end-user champions and conducting implementation assessments with patients.

- *Patient Pilot Testing.* Pilot testing is a critical step in CDS implementation that has frequently been used to assess the functionality and acceptance of decision support tools among clinicians.[61] Similarly, patients can be part of pilot testing PC CDS, particularly tools that are patient facing. This method has frequently been used to gather patient input and feedback on disease- or condition-specific mobile applications.[62] Methods for collecting patient feedback as part of pilot testing can include questionnaires, interviews, workshops, and patient diaries.[62]

- *Patient Champions.* In healthcare settings, clinician champions are often used to support the adoption and uptake of new health IT systems and healthcare innovations, including CDS.[63,64,65] A key dimension of PC CDS, especially if it is patient facing, is patient uptake and adoption.[66] Engaging patients as end-user champions can help advocate for the uptake and use of the PC CDS tool within an organization and among other patients. While guidance is limited about engaging patients as champions for PC CDS, patient champions have a history of being used in healthcare for advocacy, peer support, adoption of resources, and patient empowerment.[67,68,69] In addition, engaging patients to provide peer support to encourage the adoption of digital tools among other patients is a well-established method.[70,71] PC CDS implementers should consider engaging at least two patient champions who are dedicated to using the proposed patient-facing tool, available to answer

questions, and encourage uptake within the organization.[72] Patient champions may also be part of consultative groups, such as steering committees and advisory panels.

- *Structured Implementation Assessments*. Implementation assessments can determine end-user satisfaction with PC CDS, identify barriers and facilitators to implementation, and determine how to leverage facilitators to encourage use of the PC CDS.[73] These assessments can systematically collect patient feedback through open-ended questionnaires, interviews, and consultative groups.[74] PC CDS implementers can also use available instruments such as the System Usability Scale (SUS) for post-deployment feedback, which includes 10 questions with response choices on a Likert scale (i.e., strongly disagree to strongly agree).[75]

Considerations: In engaging patients in codeployment and as end-user champions, PC CDS implementers should consider setting clear expectations about time commitments and compensation, providing training about the PC CDS tool, and, if applicable, training about effective peer support strategies.[70] Furthermore, it is important to explain that the deployment process may be iterative, with many updates made over time to improve a PC CDS tool. Sharing the full picture at the beginning of the process—specifically that PC CDS functionality keeps progressing with upgrades and that, in some cases, desired improvements are tabled until functionality permits it—will help set expectations with patient partners about how their feedback will be used and implemented. Exhibit 5 provides resources for this method.

Exhibit 5.   Resources For Patient Codeployment

Resources
- **Roadmap to Peer Support**. Developed by Johns Hopkins Medicine Armstrong Institute for Patient Quality and Safety, this roadmap can support PC CDS implementers looking to engage patient champions for peer support.[76]
- **Evaluation in Life Cycle of Information Technology (ELICIT) Framework**. The ELICIT Framework provides exemplar questions for implementation assessments.[73]
- **System Usability Scale**. Usability.gov provides an overview of the SUS as well as links to useful resources for using the scale.[75]

2.4 Measuring PC CDS Impact

The fourth step of the PC CDS lifecycle focuses on measuring the impact of implemented tools by the extent to which the PC CDS tool improves clinician and patient decision making, care processes, and outcomes. The results in this stage can inform improvements to the PC CDS tool as well as the development of new PC CDS, creating a continuous feedback loop.

Engaging patients in the selection of measures in this step is critical to ensuring that evaluation of PC CDS tools includes outcomes most relevant to patients.[77] This includes the selection of measures that assess PC CDS performance (e.g., patient acceptance and adoption, patient-reported outcomes, and clinical endpoints). Guidance for the development of core outcomes

emphasizes the importance of including individuals who have experienced or who are affected by the condition of interest (i.e., patients and caregivers).[78]

While there is a lack of literature on patient engagement in the selection of outcome measures for PC CDS,[5] there are opportunities to implement methods that have been used within other contexts. For example, modified Delphi processes and qualitative engagement activities have been used to identify outcomes that are most important to patients in other disciplines.

Delphi Methods for Outcomes Selection

In addition to being used as a method to prioritize evidence-based findings for PC CDS development, Delphi methods can be used to support the selection of outcome measures. Researchers have used these methods to engage patients in developing core outcomes sets for a range clinical areas.[79,80,81,82,] For example, researchers recruited a panel of 18 participants (including patients) to participate in a modified Delphi process to select measures reflective of value in care for inflammatory bowel disease. Selected measures focused on functional status, clinical status, and healthcare costs and utilization. [83] The International Consortium for Health Outcomes has used Delphi techniques to engage patient advocates and other stakeholders in developing standard outcomes sets across a range of clinical areas.[84,85] Similarly, within the context of PC CDS, a modified Delphi process can be used to identify and prioritize outcomes that are most important to patients.

Key Features. The core aspects of Delphi consensus methods are unchanged when applying the method to the selection of outcomes—select panel members, gather input through rounds of questionnaires, and analyze responses to determine areas of consensus. However, as an initial step, PC CDS researchers and implementers should gather patient perspectives on what outcomes are important to them to inform the Delphi questionnaire. Previous studies have used interviews, focus groups, surveys, and nominal group techniques to facilitate this initial engagement.[86]

Considerations. As previously noted, Delphi processes can be time-consuming and resource-intensive. Studies that have used Delphi methods to engage patients in outcome prioritization have had at least two rounds, with the majority reporting at least 2 to 4 weeks per round.[86] Exhibit 6 provides resources for this method.

Exhibit 6. Resources For Delphi Methods for Outcomes Selection

Resources
• **Systematic Review: Patient Participation in Delphi Surveys to Develop Core Outcome Sets**. This systematic review synthesizes practices across 78 studies that engaged patients using Delphi methods for outcomes prioritization.[86]
• **Participating in Core Outcome Set Development via Delphi Surveys: Qualitative interviews provide pointers to inform guidance**. This qualitative study identifies information that should be communicated to participants of a Delphi study focused on outcome selection.[87]

Community Engagement Studios

Community engagement studios bring together patients with lived experience for a condition or community of interest.[88] These studios can be especially informative in terms of providing opportunities to share patient stories that contextualize lived experiences and establish a mutual understanding among participants.[89]

Researchers have previously used this method to engage patients to help develop a digital equity screening tool,[90] create an app platform that allows patients to access and share their data,[91] and inform the feasibility of a portal to collect and display patient-reported outcomes.[92] While this method has not been used in PC CDS outcome measurement selection, it can serve as a valuable method to understand what success looks like for a specific disease or condition to inform the selection outcome measures.

Key Features: Unlike traditional focus groups, this engagement method emphasizes bidirectional communication and generating a structured discussion that is rooted in the lived experiences of patients.[93] Studios are typically held as in-person convenings for 90–120 minutes. The typical flow for the convenings includes:[93]

- An overview of the meeting's purpose and ground rules.
- A brief presentation from researchers regarding the topic of interest.
- A facilitated discussion among participants using prepared, structured key questions.
- A review and summary of recommendations and key points raised during the meeting.
- A post-meeting evaluation survey.

Considerations: Patients who participate in engagement studios should be treated as consultants who provide their input and experience, not as research subjects. As such, they should be offered a consulting fee. Meeting facilitators should be neutral, and not part of the CDS development or implementation team.[93] Exhibit 7 provides resources for this method.

Exhibit 7. Resources For Community Engagement Studios

Resources
• **Community Engagement Studio Toolkit 2.0**. The Meharry-Vanderbilt Community Engaged Research Core at the Vanderbilt Institute for Clinical and Translational Research was the first group to develop this method in 2009. They have developed a toolkit for community engagement studios.[93]
• **Community Engagement Studios: A Structured Approach to Obtaining Meaningful Input from Stakeholders to Inform Research**. This Innovation Report describes the characteristics of the 28 community engaged studios conducted by the Meharry-Vanderbilt group as well as the feasibility, acceptability, and benefits from using this methodology.[94]
• **Community Engagement Studio Toolkit**. This toolkit from Brandeis University builds on the Meharry-Vanderbilt toolkit and tailors it for researchers interested in maternal mental health and/or opioid use/recovery.[95]

Group Concept Mapping

Concept mapping is a structured exercise that can be used to engage patients in evaluation planning, including the selection of outcomes.[96,97,98] For example, researchers used group concept mapping to engage patients with diabetes mellitus in identifying patient-important outcomes for shared decision making, resulting in 41 outcomes within seven domains.[96,99] This method can similarly be applied to identify patient-important outcomes for PC CDS tools.

Key Features: While the steps of concept mapping can vary, the process general involves six steps:[100]

- *Preparation:* This step includes identifying the area of focus and selecting participants.
- *Generation:* This involves group brainstorming, which can be conducted virtually or in-person. This involves using structured prompts to solicit input. For example, "When you seek care for your condition, what are you hoping to improve or make happen?"[96]
- *Synthesis:* The results of the group brainstorming session are organized, refined, and ranked to determine importance.
- *Representation:* The ranked concepts are then represented in the form of a concept map (typically through statistical analysis).
- *Interpretation:* Participants then interpret the generated maps and provide additional feedback.
- *Utilization*: The resulting maps are then used for research or implementation.

Considerations. Patients may feel most comfortable with the generation step of the concept mapping process and may struggle with using web-based tools to complete the synthesis step.[101] PC CDS researchers, developers, and implementers should consider potential access issues with web-based tools and the needs of the patient population being engaged when choosing methods for concept mapping. Exhibit 8 provides resources for this method.

Exhibit 8. Resources For Group Concept Mapping

Resources
• **Patient Experience and Challenges in Group Concept Mapping for Clinical Research**. This publication describes patients' experiences with participating in group concept mapping, assessed through direct observation and surveys.[101]
• **Group Concept Mapping Resource Guide**. Groupwisdom™ is a web-based application designed for group concept mapping research. They developed this resource guide to consolidate basic information about group concept mapping to help researchers learn about the method.[102]
• **Concept Mapping Methodology and Community-Engaged Research: A Perfect Pairing**. This literature review of 103 articles highlights how concept mapping can be used in collaboration with communities and describes the benefits to researchers and participants.[103]

3.   Considerations: Engaging Patients in PC CDS

Patient engagement is a critical part of PC CDS development that can occur throughout the development and implementation. When engaging patients, it is important to foster a respectful, inclusive environment and establish trustworthiness. Below, we provide several considerations to keep in mind when engaging patients:

- **Clearly communicate expectations.** It is important that patients understand their role in engagement activities, as well as the time commitment for the activities.[104,105] Clearly communicating expectations at the beginning of the engagement activity helps establish a partnership dynamic and builds trust.

- **Treat patients as partners.** Patients participating in PC CDS development and implementation should be engaged as partners in the process, not research subjects.[106] It is important that patient engagement in PC CDS is not treated as simply checking boxes. PC CDS researchers, developers, and implementers should be intentional about establishing equitable, reciprocal relationships and encouraging co-learning between themselves and patient partners.[107]

- **Ensure diversity and inclusivity.** PC CDS researchers, developers, and implementers must be sensitive to and aware of the range of lived experiences and needs of patients who use PC CDS. It is important to ensure the engagement of diverse patient partners, including those from underrepresented groups. However, to be truly inclusive, individuals leading engagement activities must also create processes that consider cultural context and foster a sense of belonging among patient partners.[107]

- **Provide compensation**.[108,109] Providing compensation or other incentives (e.g., meals), particularly if engagement activities occur during business hours, removes barriers to participation, enabling a more diverse group of patients to participate throughout the PC CDS lifecycle.[110]

- **Share findings**. Fostering trust between patient partners and PC CDS researchers, developers, and implementers requires transparency throughout the process. Findings should be shared with patient partners so that they can see how their contributions have helped shape PC CDS tools.

- **Create feedback loops.** In addition to sharing findings related to PC CDS, it is important to create feedback opportunities so that patient partners can reflect on their experiences during engagement activities. These feedback loops help create accountability among PC CDS researchers, developers, and implementers to improve engagement practices.

Exhibit 9 provides resources focused on patient engagement practices including frameworks, rubrics, and guidance documents.

Exhibit 9.   Resources For Patient Engagement

Resources
• **Patient-Centered Outcomes Research Institute (PCORI) Engagement Rubric**. This rubric provides guidance on methods for engaging stakeholder partners in research. [106]
• **PCORI Compensation Framework**. This framework provides a sample model for determining compensation based on engagement level.[111]
• **PCORI Equity and Inclusion Guiding Engagement Principles**. This document provides principles for ensuring diversity, equity, and inclusion in health research partnerships.[107]
• **Practical Guidance for Involving Stakeholders in Health Research**. This publication draws on experts from four countries—Canada, Australia, the United Kingdom, and the United States—to provide practical guidance for engaging stakeholders in research activities.[112]
• **Patient Engagement In Research Scale (PEIRS)**. This 37-item patient self-reported questionnaire can be used to assess the quality of patient engagement in research.[113]
• **The National Health Council Rubric to Capture the Patient Voice**. This tool was developed to guide the healthcare community on meaningfully engaging patients and evaluating attributes of patient-centeredness.[114]

Appendix: Summary of Methods

In collaboration with the CDSiC Trust & Patient-Centeredness Workgroup, we did an initial mapping of potential patient engagement methods to each stage of the PC CDS life cycle based on the expertise and previous research activities of Workgroup leads and members. We then conducted a series of targeted searches of the peer-reviewed and grey literature to verify the mapping, find additional relevant patient engagement methods, and identify resources. Given that patient engagement is a developing area in PC CDS, we included literature from other topic areas, such as community-based participatory research, mobile application development, and patient engagement practices for research studies. The search process was iterative—once a potentially relevant method or resource was identified, additional searches were conducted to identify additional literature and resources. Exhibit A1 provides key search terms for PubMed.

Exhibit A1. Key PubMed Search Terms

Search Terms
("priority setting"[tiab] OR "Delphi Technique"[Mesh] OR "Health Priorities"[Mesh]) AND ("clinical decision support"[tiab] OR "Decision Support Systems, Clinical"[Mesh])
(Stakeholder Participation[Mesh] OR Patients[Mesh] OR Patient Participation[Mesh]) AND "priority setting"[tiab] AND ("research"[tiab] OR "guidance"[tiab] OR "guidelines"[tiab] OR "decision support"[tiab])
"Community-Based Participatory Research"[Mesh] AND "Research Design"[Majr]
(Decision Support Systems, Clinical [MeSH] OR Decision Support Techniques [MeSH] OR "Clinical Decision Support"[tw] NOT "decision aid"[tw]) AND ("Co-design*"[tw] OR "Codesign*"[tw] OR "Collaborative* design*"[tw] OR "Participatory design"[tw] OR "Partnered design"[tw])
"patient-important outcomes"[tiab] and (engage*[tiab] OR participat*[tiab] OR "select"[tiab])
("patient champion"[tiab] OR "peer support"[tiab]) AND ("decision support"[tiab] OR "mHealth"[tiab] OR "mobile app"[tiab])
"patient"[tiab] AND "concept mapping"[tiab] AND "outcomes"[tiab]
("Co-design*"[tw] OR "Codesign*"[tw] OR "Collaborative* design*"[tiab] OR "Participatory design"[tw] OR "Partnered design"[tiab]) AND (Decision Support Systems, Clinical [MeSH] OR "Decision Support System*"[tw] OR Decision Support Techniques [MeSH] OR "Clinical Decision Support"[tw] NOT "decision aid"[tw])

Search results were title/abstract reviewed for relevance. Literature that spoke to patient engagement practices relevant to PC CDS were full text reviewed. In addition to searching PubMed, we identified literature and resources through the PCORI Engagement in Health Research Literature Explorer, the PCORI Engagement Tool and Resource Repository, searching reference lists of included peer-reviewed literature, and recommendations from the CDSiC Trust & Patient-Centeredness Workgroup. For each identified method, we also conducted targeted searches for grey literature resources via Google. We included 71 peer-reviewed publications and 31 grey literature resources in the development of this handbook. Handbook guidance was reviewed and validated by the CDSiC Trust & Patient-Centeredness Workgroup.

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