Trust & Patient-centeredness Workgroup: Methods for Involving End-users in PC CDS Co-design

Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract No: 75Q80120D00018

Prepared by:
Prashila Dullabh, MD, FAMIA, and Rachel Dungan, MSSP
Minakshi Raj, PhD
Marley Catlett, MPH
Sarah Weinberg
Frances Jimenez, MPH
Elizabeth Cope, PhD, MPH
Priyanka Desai, PhD, MSPH
Angela Dobes, MPH
Tonya Hongsermeier, PhD, MSPH
CDSiC Trust and Patient-centeredness Workgroup

AHRQ Publication No. 23-0079
August 2023

Agency for Healthcare Research and Quality

Clinical Decision Support Innovation Collaborative

PURPOSE

The Clinical Decision Support Innovation Collaborative (CDSiC) 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 involves them from the very beginning 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.

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.

SUGGESTED CITATION

Dullabh P, Dungan R, Raj M, Catlett M, Weinberg S, Jimenez F, Cope E, Desai P, Dobes A, Hongsermeier T and the Trust and Patient-Centeredness Workgroup: Methods for Involving End-users in PC CDS Co-design. Prepared under Contract No. 75Q80120D00018. AHRQ Publication No. 23-0079. Rockville, MD: Agency for Healthcare Research and Quality; August 2023.

Contributors: CDSiC Trust & Patient-centeredness Workgroup

Members of the Trust & Patient-centeredness Workgroup are listed below.

Name	Affiliation
Deborah Collyar, MBA	Patient Advocates in Research
Catherine M. DesRoches, DrPH	Harvard University
Sarah Krug, MS	Cancer101
Elisabeth Oehrlein, PhD, MS	Applied Patient Experience
Jodyn Platt, PhD, MPH	University of Michigan
James Ralston, MD, MPH	Kaiser Permanente Washington Health Research Institute
Thomas Reese, PharmD, PhD	Vanderbilt University
Joshua Richardson, PhD, MS, MLIS, FAMIA	Research Triangle Institute
Danny Sands, MD, MPH	Consultant
Michael Valenti, PhD	Pressley Ridge
Jonathan Wald, MD, MPH	InterSystems

Table of Contents

Table of Exhibits

1. Introduction

Patient-centered care, an essential component of health system quality improvement,[1] reflects care that is "respectful of and responsive to individual patient preferences, needs, and values, and ensures that patient values guide all clinical decisions."[1,2,3] Clinical decision support (CDS) has historically been clinician-facing and is often delivered through reminders, alerts, order sets, or guidelines that are used for diagnostic and/or treatments at the point-of-care.[4] While it is important that CDS naturally align with clinicians' needs and workflows, it is also important for it to be used in patient-centered ways that can support informed decision making by patients and their caregivers.

Patient-centered Clinical Decision Support

Aligned with the ethos for patient-centered care, patient-centered (PC) CDS encompasses tools and processes for enhancing health-related decisions and actions using evidence-based information that incorporates outcomes and measures of importance to patients. PC CDS is specifically built on a knowledge base that includes patient-centered (e.g., patient-reported or patient-generated) data. Additionally, patients are directly engaged in the delivery of care and in the process of decision making for developing and implementing CDS.[5,6] PC CDS has the potential to improve quality of care across various disease contexts,[7] and some suggest the added benefits of involving end-users in upstream design processes. Evidence suggests that involving end-users (e.g., patients, caregivers, clinicians) and other key stakeholders (e.g., health system decision-makers) can help reduce barriers to effective PC CDS by:[8]

- accounting for a holistic view on how clinical decision making occurs;[9]
- yielding PC CDS that is easy to use, aligned with clinical workflows and schedules, or relevant to end-users' needs and priorities.[10]

Defining PC CDS Co-design and its Significance

CDS development has historically been spearheaded by health systems leaders, electronic health record (EHR) developers, and informaticians.[11] These entities translate clinical practice guidelines into the CDS tools, alerts, systems, etc. that deliver recommendations for clinician or patient end-users. For this guidance to be delivered in user-centered ways (for patients and clinicians), designers should account for characteristics of those end-users and the contexts where they use PC CDS.[5] Unless CDS developers prioritize end-user needs and preferences or invite end-user input during design, PC CDS may not align with clinician workflows or patient "lifeflows". To effectively engage end-users (patients and caregivers) in meaningful and sustainable co-design of PC CDS, designers should prioritize:[12]

- relationships between developers and end-users,
- solicitation of iterative and sustained feedback from end-users, and
- empathy for end-users' expertise and life experience.

In contrast, when CDS design fails to consider end-user perspectives, unintended consequences (e.g., alert fatigue, content inaccuracies, system inflexibility within the constraints of busy clinical schedules) can erode clinicians' trust and acceptance of CDS.[13] Co-design may help to prevent such unintended consequences by:

- **Deepening developers' understanding** of the needs and challenges PC CDS end-users face in their roles as clinicians, patients, caregivers, or other clinical decision making partners.[14,15,16]
- **Inviting perspectives** from other key stakeholders (e.g., health system leaders, vendor representatives) in the ecosystem, so that PC CDS design accounts for feasibility or other context considerations.[9]
- **Integrating different forms of knowledge** (e.g., experiential vs research expertise), and/or vantage points on PC CDS (e.g., clinician vs. patient perspectives) that each design partner can bring.[9,17]

Accordingly, co-design can help improve the patient-centeredness of CDS by accounting for clinician and patient end-users' needs, and then facilitating shared decision making and tailoring clinical recommendations to these needs.[14,16] Co-design may also potentially reinforce overall trust in PC CDS by enhancing fairness, accountability, and transparency in the design process.[18,19]

Despite the suggested benefits, there is limited documentation of ways that patients, clinicians, and other PC CDS end-users have been involved in co-design. A critical reason for this is that patients are rarely involved in this process.[5] Co-design with patients can support the development of PC CDS by ensuring that patient-centered factors are incorporated into the final product. However, using co-design approaches in and of itself will not result in PC CDS. PC CDS needs to account for other patient-centered factors (i.e., utilizing PCOR-derived evidence and/or the inclusion of patient-provided information, for example, patient-generated health data).

About This Resource

To address this gap, this resource focuses on co-design involving end-users and other stakeholders as partners in developing, refining, and testing patient- and clinician-facing PC CDS interfaces. This resource is primarily intended for those involved in designing and developing PC CDS interfaces. It can guide those seeking to use or promote patient-centered PC CDS co-design by:

- **Identifying** and describing PC CDS co-design methods and their defining features.
- **Describing** tradeoffs (i.e., benefits vs. limitations), and the utility of each method during different phases of co-design (i.e., pre-design, design) to elicit information.
- **Highlighting** and sharing considerations for involving end-users in PC CDS co-design.

Methods Informing This Resource

We conducted a scoping review of the literature on co-design in PC CDS and broader patient-centered healthcare contexts. A total of 68 articles from our search of PubMed were included in our full-text review along with 18 additional articles sourced from members of the CDSiC Trust and Patient-Centeredness Workgroup, key informants, and targeted searches.

Results of the review were validated through four key informant interviews (KIIs), conducted in May 2023. Informants included individuals who have led or participated in co-design activities; one of these informants also identified as a patient advocate. Two informants were members of the CDSiC Trust and Patient-centeredness Workgroup. A full description of the methods that informed development of this report have been detailed in the **Appendix**.

2. Findings

The literature review generated information, validated through KIIs, regarding the fundamental phases by which co-design occurs (Section 2.1). It also helped us to identify a range of co-design methods, as described in Section 2.2 in which we outline the defining features and benefits of each method, as well as key considerations when implementing co-design principles. We summarize this range of methods in Section 2.3, which presents a table and series of prompts that developers can consider when choosing methods that best meet their information needs and navigate their constraints throughout co-design.

2.1 Phases of Co-design

Generally, co-design proceeds in a sequence of Pre-design, Design, and Post-design phases (**Exhibit 1**),[20,21] as described in the Generative Co-Design Framework for Healthcare Innovation.[20] Below, we have adapted descriptions of each co-design phase from the Generative Co-design Framework and include additional research-informed sub-phases of co-design.[22]

Pre-design. This phase encompasses activities conducted before any design work occurs. It often involves background research to help developers learn about the needs, settings, and end-users for which PC CDS is designed. It also includes planning steps to select, train, and/or prepare co-design partners for involvement.

Design. This phase involves activities to create the interface and/or other elements of PC CDS that end-users interact with. Design sub-phases include:

1. **Generative Design**: preliminary activities used to frame the issue, determine the vision for the design, and generate or select ideas (e.g., features, functionality) to build into sample or draft designs known as prototypes.
2. **Evaluative Design**: various forms of testing such as usability testing (Section 2.2.6) that evaluate aspects of the draft design (or prototype) and the extent to which it addresses

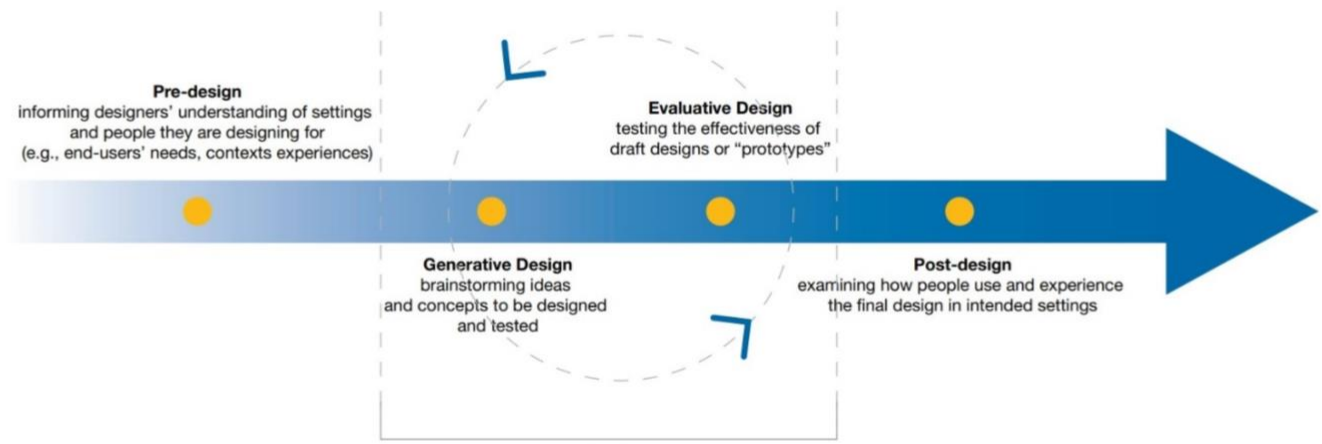
Co-design methods can serve different purposes at distinct points in the process.

- During **Pre-design**, developers may want to understand the context in which end-users will use PC CDS, end-users' needs (including features and functions), how and when they plan to use the PC CDS, and if others (e.g., caregivers) may also need access to it.
- During **Design**, the developer may again conduct surveys once a prototype is designed. These survey questions may ask end-users to react to features and functions presented in the prototype to generate feedback on whether end-users think the design can be effective.

end-users' needs. Feedback generated through these tests informs iterative revision of the prototype and improvement to PC CDS features or functionalities. Such user-informed design revisions to a PC CDS tool can improve favorability and usability among end-users, which may ultimately improve tool use.[23]

3. **Post-design.** Following design, additional evaluation and ongoing revision may occur. For example, once PC CDS is deployed in a healthcare delivery setting, ongoing monitoring can indicate whether and how design must be further adapted to best serve patient and clinician end-users in that setting.[6] Notably, this resource does not address methods for end-user involvement in Post-design (i.e., once PC CDS has been implemented and is being used by patients and clinicians). It focuses on methods for involving end-users in Pre-design and Design (e.g., Generative Design and Evaluative Design) phases.

Exhibit 1. General Sequence of Co-design Phases



Adapted from existing co-design frameworks for healthcare innovation[20] and digital or mobile health service delivery contexts.[21,22]

While several co-design frameworks have been developed, each using their own labels for co-design phases and individual methods, the following section uses discipline-agnostic terms to present and describe methods identified through the scan.

2.2 Co-design Methods

This section introduces six overarching methods that can be used individually or synergistically to involve patients, clinicians, and other stakeholders in PC CDS co-design. These methods include (1) consultative groups; (2) surveys; (3) focus groups; (4) empathy interviews; (5) prototypes; and (6) usability tests. Below, we describe each method and its defining features. We also detail the benefits of using methods in relevant co-design phases and summarize key considerations for doing so.

2.2.1 Consultative Groups (e.g., steering committees, advisory boards)

Consultative groups provide a structure and schedule for eliciting targeted input, as well as sustained involvement in governance or leadership, from PC CDS co-design partners, including patients, caregivers, and clinicians. Based on the roles they are expected to play and the guidance they are invited to provide, these groups can have different:[24,25,26]

- Goals and objectives (e.g., providing feedback on the design itself vs. on the co-design process).
- Forms (e.g., working groups, steering committees, communities of practice, study management groups, working groups, patient and/or family advisory groups, or reactor panels).[16,24]

Defining Features

Consultative groups can be charged with having influence over different kinds of decisions made throughout the co-design process: those solely focused on PC CDS design; or those broadly focused on the co-design process made in the Pre-design and Design phases.

- To validate preliminary design ideas or evaluate PC CDS prototype designs, developers may invite consultation on design decisions. Given their limited scope, these consultative groups may be (1) comprised primarily of PC CDS end-users, and (2) convened only during **Generative and Evaluative Design** phases.
- To invite broader partnership throughout co-design, developers may invite consultation on process and leadership decisions. Given their extended scope, these consultative groups may be (1) representative of diverse stakeholders,[27,28] and (2) convened regularly throughout **Pre-design and Design** phases.

The intended charge of a consultative group can inform developers' choices about who to include (i.e., group composition) and when to convene (i.e., frequency or duration of involvement).

Group Composition**.** Single- and multistakeholder groups each produce different types of information, and thus serve different purposes in co-design. **Single-stakeholder groups** can reveal variance in group members and their opinions, which enables PC CDS to be tailored or accommodative of different end-users. These groups also ensure that one individual is not assumed to represent a category of people. For example, instead of inviting one person to speak for all patient end-users, Patient Advisory Groups can invite multiple, diverse patient members to shape PC CDS. Single-stakeholder groups also highlight design elements deemed important across end-users, regardless of their individual differences. **Multistakeholder groups** represent a diverse range of perspectives by virtue of including stakeholders from varying backgrounds. They are useful for informing macro-level decisions regarding how PC CDS will be used in a health delivery system, or regarding planning for co-design.

Exhibit 2. Examples of Consulting Stakeholder Groups

Category	End-user	Description
Single-stakeholder Group	**Patient-facing**	Single-stakeholder groups consist of people with shared experiences or characteristics (e.g., mothers of children with complex medical needs), who can be consulted on co-design decisions important to the end-user, as well as activities supporting the broader co-design process (e.g., grant writing).[20]
Multistakeholder Group	**Patient- and Clinician-facing**	Multistakeholder engagement can include convening a “community of practice” throughout CDS co-design that includes participants who represent a range of backgrounds and perspectives (e.g., patients, clinicians, researchers, specialists, delivery system leaders). Such groups can be engaged at various points throughout the co-design process to provide input on activities (i.e., evidence synthesis and idea generation during Generative Design; participate in focus groups, usability testing during Evaluative Design).[24]

Frequency and Duration of Involvement. Decisions about how long or often to convene a consultative group can be based on the group’s role or charge. Consultative groups intended to oversee the co-design process may be engaged at project onset, when key decisions are being made; they may then be convened either on a regular schedule, or on an “as needed” basis at key decision making points. In contrast, other groups may provide consultation only at specific points in co-design. For example, the Health Collaboratory Patient Shark Tank® events invite patient panels to react to a series of developer prototypes.[29] Events like these may convene a group only once to solicit feedback at a single point in time. If appropriate, these one- or low-touch consultations can supplement other ongoing consultations. In such a scenario, feedback from a panel of reactors or judges could be shared with a standing project steering committee tasked with voting to select the final design.

Benefits

Since these consultative groups can be composed differently or convened on different schedules, developers have the flexibility to structure involvement to best meet their information needs.

Single-stakeholder groups offer the benefits of:

- Generating deep or nuanced information from one priority population.
- Leveraging in-group comfort and reinforcing group members’ confidence as co-design contributors. Some individuals may feel comfortable arguing for particular design

decisions if speaking as representatives of a patient committee, rather than solely sharing their personal opinions or advocating on their own behalf.
- Providing safe spaces where members are likely to talk more openly and honestly among themselves than they might if others were present. For example, patients may respond more honestly to questions about their mistrust in clinicians and/or PC CDS when among other patients, rather than as part of a group in which clinicians are also present.

In contrast, multistakeholder groups offer the benefits of:
- Enhancing developers' broader awareness of the ecosystems in which PC CDS is deployed—potentially enabling development of PC CDS with broader acceptance.[30]
- Improving awareness, communication, and understanding across stakeholders with different roles and objectives in healthcare settings.[31] Structuring multistakeholder groups to include patient, clinician, caregiver, and EHR developers can promote consideration and integration of input from diverse stakeholders—with different needs and vantage points on PC CDS.[27] Including delivery system leaders can increase their awareness of patient and clinician end-user needs, as well as the design elements created to address these. This can position system leaders to champion or advocate for PC CDS piloting and adoption, once design is complete.[22,32]

When convened regularly, developers benefit from a group's informed and holistic view of the co-design process and objectives. When needing rapid input on a focused question, however, developers can benefit from one-touch consultations; these can generate needed feedback, without requiring the time and effort necessary to prepare people for ongoing involvement.

Considerations

When deciding if and how to implement consultation, developers should consider:
- the nature of input and duration of commitment requested from co-design partners;
- the importance of setting and communicating expectations, in light of pre-existing commitments; and
- the need to optimize value of input, while minimizing developers' administrative burden in planning and hosting convenings.

Some of these approaches are more time- and resource-intensive than others for PC CDS developers. For example, convening multistakeholder groups involves up-front time and effort for introductions and level-setting across diverse participants. Convening groups that include patients or other stakeholders with limited health, digital, or PC CDS literacy requires preparing orientation materials or discussions to prime group members for their role in consultation.

Additionally, steps can be taken to offset barriers inhibiting involvement. For example, co-design partners may face constraints (e.g., time, cost, comfort) in traveling to meeting locations most convenient for developers, such as research or academic settings. Thus, hosting co-design sessions or advisory group meetings in these settings may prevent some from participating; this can lead to attrition and limit the reliability or representativeness of input. Developers can mitigate barriers by providing compensation for travel, hosting meetings in mutually convenient settings, or convening people virtually—to ensure easy, equitable access.

2.2.2 Surveys

Surveys can gather information from a target audience, to help PC CDS developers understand end-users' or other stakeholders' problems or challenges and how these may be addressed. They can provide insight into (1) which information or features end-users require to effectively use PC CDS, and (2) how end-users would rank, prioritize, or interact with these PC CDS features.

Defining Features

During **Pre-design,** surveys can help developers understand how PC CDS will be used: to meet which needs, in which settings, and by whom. Specifically, surveys are helpful in collecting information regarding end-users':[33]

- characteristics (e.g., age, education level);
- goals, needs, preferences, and values;
- challenges to be addressed through PC CDS; and
- contexts for which PC CDS design may need to be tailored.

Surveys can also be used during **Design** phases, to determine which features should be included in PC CDS.[34] Once ideas are incorporated into an initial design, surveys or questionnaires can be used during **Evaluative Design** to solicit data on the effectiveness (e.g., usefulness, usability) of the PC CDS prototype.[35]

Benefits

Surveys (which can be disseminated online or by paper) tend to require relatively limited time, cost, and effort from both developers and other co-design partners. Since this reduces barriers to participation, surveys can often be used to generate information from large, diverse, or potentially representative samples of end-users.

Considerations

As noted, surveys can be used to collect important information about target end-users' needs, preferences, priorities, or experiences. However, they offer:

- Limited channels for collecting nuanced or detailed input. Even when space is designated for respondents' open-ended comments, a fixed survey format limits the potential for responsive questioning that is adjusted based on respondents' answers.
- Limited influence on PC CDS design. Survey respondents have indirect influence on PC CDS design, by sharing information for others' (i.e., developers') use rather than having direct involvement in design-related decisions (e.g., playing roles in the synthesis, interpretation, or decisions about how that information gets used to inform design choices).[34,36]

Exhibit 3. Examples of Generating or Prioritizing Ideas with Surveys During Design

Category	End-user	Description
Pre-design	**Patient-facing**	Surveys can support needs assessments conducted prior to prototype development to help researchers understand the knowledge and information needs of target users and their preferences for display formats, helping to inform the content and visual presentation of the CDS.[37]
Generative Design	**Clinician-facing**	Surveys can be used to understand potential end-users' interest and subsequent uptake of a PC CDS tool, promising use cases, and specific features that would increase chances for wide adoption. For example, researchers surveyed clinicians about their interest in using CDS to support glaucoma patients' treatment and used results to identify priority CDS features that could help them identify and track the glaucoma progression.[14]
Evaluative Design	**Clinician-facing**	In this phase, surveys support soliciting feedback on PC CDS design elements and the tool overall. Researchers have used surveys with interface design experts to assess the appropriateness of design features (e.g., layout, visuals, amount of content) for key tasks performed while using a tool by end-users.[34]
	Patient-facing	Surveys provide an efficient opportunity for gathering feedback from patients on components of the tool using standardized scales, like usability. Online surveys have been used to assess CDS usability using the System Usability Scale, while also providing space for open-ended feedback.[38,39,40]

Thus, while surveys afford efficient means of reaching and involving multiple stakeholders, they limit the depth of input and extent of influence from each individual. Limitations of this method can be offset by pairing it with other co-design methods such as usability testing or prototyping, which directly involve end-users in making or reviewing design choices.

2.2.3 Focus Groups

Focus groups are planned, facilitated discussions often inviting input (from five to ten end-users or other key stakeholders) on a pre-determined topic or product.[41] Often conducted as a series of discussions with the same or different participants, focus groups can highlight similarities and differences across end-users' needs, values, perceptions, etc.[42] Depending on the nature of feedback sought, focus groups can be conducted virtually or in person.

Defining Features

Focus groups enable getting quick, simultaneous input from multiple end-users; this helps identify points of resonance as participants build on each other's comments. The interactive format of focus groups allows conversation to evolve and generates insight difficult to capture using, for example, surveys with fixed questions or prompts. Notably, since focus groups involve interaction between participants, this approach can simulate elements of discussion and decision making processes during clinical encounters, highlighting additional needs or gaps.

As with consultative groups, developers can determine who to involve and when to convene focus groups based on their information needs at different points in co-design.

Group Composition. Developers may host single-stakeholder focus groups (e.g., exclusively including patients) or multistakeholder focus groups (e.g., including both patients and clinicians). Choices about whom to involve in these groups may depend on where developers are in the co-design process.

Timing of Involvement. During **Pre-design,** focus groups can give PC CDS developers insight into how end-users would use PC CDS and how it might fit into clinician workflows and patient lifeflows. Focus groups provide a unique opportunity to gather patient and clinician perspectives around how PC CDS can support shared decision making, as well as end-user perceptions and experiences with PC CDS. Focus groups can be held during both **Generative** and **Evaluative Design** phases to help developers understand (1) how end-users interact with PC CDS and (2) which design elements facilitate or inhibit effective use.

Benefits

Focus group members' roles and responsibilities are clear (i.e., participate and provide input in a facilitated discussion) and time-bound (i.e., confined to periods of real-time participation). Relative to other engagement approaches, focus groups can limit the time developers must invest in:

- Level-setting, trust building, or maintaining bidirectional communication, as is often recommended for ongoing partnerships.
- Equipping co-design partners to share input on governance, leadership, and less personally informed guidance.

For example, it may be necessary to provide consultative groups with informational materials or an orientation to help them make leadership or governance decisions. This is not always necessary when inviting focus group members' input based on personal opinion or experience.

Exhibit 4. Examples of Focus Groups to Obtain Input

Category	End-user	Description
Pre-design	**Clinician-facing**	Conducting focus groups may be helpful to increase understanding of the challenges clinicians face in recommending treatment options. As one example, researchers conducted multiple focus groups with clinicians to explore questions (developed with patient input) about such difficulties. Next, insights generated through focus groups informed work done in the Design phase to create prototypes.[43]
Generative Design	**Clinician-facing**	In CDS for disease management, researchers often create a conceptual model of a particular disease, informed by the literature and subject matter experts, to develop the tool. Focus groups can be used to generate information about clinicians' perspectives on the model, as well as key features and functions that clinicians would want in a working prototype.[44] Researchers can then use the focus group findings to make necessary model modifications and build a working prototype.
Evaluative Design	**Patient- and Clinician-facing**	Focus groups can also support refinement of prototypes by asking end-users, such as patients and clinicians, to provide feedback on prototype features, appearance, and suggested revisions.[16] In addition to facilitating group conversations around a prototype, developers can combine observation and focus group testing to obtain feedback from end-users. For example, researchers have conducted focus groups where patients were instructed to watch a recorded demonstration on how to use a mobile application prototype and were then observed by developers while using the prototype. Facilitated focus group discussions were then conducted to obtain input that was integrated into subsequent iterations of the design.[45]

Considerations

While this method can be less intensive than some others, developers should consider that hosting focus groups (whether virtual or in person) can require:

- Additional planning and resources to ensure inclusivity and accessibility for all participants. This includes accessibility in terms of physical access to virtual or in-person venues, accessibility of content to accommodate participants with different reading and health/digital literacy levels, as well as learning or communication styles.

- Preparation to invite and integrate equal contributions from diverse participants (rather than allowing only the most senior, vocal, or naturally outgoing participants to dominate discussions).

Additionally, soliciting end-user feedback in this way provides a point-in-time “snapshot” of people’s impressions or interactions with a prototype. Comments shared in conversation may not wholly or accurately reflect the ways end-users would realistically interact with PC CDS. Since focus group participants provide information solely during a discussion (rather than being involved in the synthesis, interpretation, or decision regarding how that information gets used to inform design choices),[46] they have indirect influence on design decisions made by developers.[16] Limitations of this method can be offset by combining it with methods that invite end-users’ direct involvement in making or reviewing design choices (e.g., consultative groups).

2.2.4 Empathy Interviews

Interviewing is commonly used in design processes to solicit qualitative information about end-users’ experiences, beliefs, or values. Empathy interviews help developers better understand end-users for whom they are designing PC CDS as well as the needs, objectives, and challenges that will dictate how clinicians or patients ultimately use PC CDS.[47] These interviews help developers empathize with end-users: preparing them to design responsive PC CDS likely to address needs and, therefore, be more frequently used and effective. Notably, interviews are also commonly used to solicit information during usability testing (described in Section 2.2.5); those interviews, however, are often more structured and focused on a specific prototype.

Defining Features
While empathy interviews can be conducted throughout co-design, their main purpose is to help developers develop an accurate preliminary understanding (and ability to empathize with) end-users.[48] These interviews use unstructured or semi-structured formats and open-ended questions to elicit stories about end-users’ past and personal experiences. This approach can reveal stakeholders’ overt and unmet, or unanticipated, needs and priorities.[47]

During **Pre-design,** empathy interviews help developers gather insight into how end-users interact with their environment or encounter problems that PC CDS is designed to solve. This information can help developers build tools that appropriately address needs surfaced by end-users, while not being too disruptive to existing workflows and lifeflows. One form of empathy interviewing, based on the Jobs to be Done (JTBD) framework,[49,50] helps developers transition from **Pre-design** into **Generative Design** phases. As with other forms of empathy interviewing, JTBD interviews are designed to elicit personal stories. JTBD interviews, however, use sequential questions to guide end-users toward articulating the root cause of problems or needs.[51] For instance, end-users may not specifically *need* an app or an intelligent computerized system, but rather PC CDS that does the “job” of (1) generating evidence-based clinical recommendations, and (2) presenting these in digestible formats that facilitate understanding and using the information for clinical decision making. Thus, JTBD interviews reveal end-users’ fundamental need, which then guides Generative Design of PC CDS to be responsive to that need.

Exhibit 5. Example Use of Empathy Interviews to Understand Users' Context

Category	End-user	Description
Pre-design	**Clinician-facing** 	Developers have used empathy interviews to better understand an existing issue and potential contributing factors prior to designing new CDS or modifying an existing tool. Empathy interviews may reveal barriers to CDS use due to perceived interface design issues, challenges with navigating tool content due to usability challenges, behavioral barriers such as being overburdened, and potential solutions to address these barriers. For example, researchers described using empathy interviews with clinicians to understand the high rates of clinician override for drug-drug interaction alerts prior to redesigning CDS and clinician prescribing behaviors.[52] This information was subsequently used to involve clinicians as co-design partners in developing prototypes (see Section 2.2.5) for CDS that would address surfaced needs.

Benefits

Empathy interviews may be initiated and guided using prepared questions; however, allowing interviews to evolve organically can yield end-users' unbiased opinions and information difficult to gather via other methods.[47] This interview format allows developers, having encouraged interviewees to discuss topics of personal salience or resonance, to:

- Observe how individuals choose to direct the conversation. Subsequently, existing pain points and priorities are highlighted without using questions that prime people based on developers' own assumptions, priorities, or preconceived notions.[47]
- Learn how key stakeholders or end-users perceive or describe PC CDS.

Considerations

Empathy interviews require time (e.g., for scheduling, discussion, follow-up) and resources (e.g., development of guiding questions, time for meeting virtually or in person) from all co-design partners. As a one-touch form of involvement, an interview requires a brief and focused commitment from the person being interviewed. For the co-design team, however, interviews can be costly relative to other methods for collecting information simultaneously from multiple people (e.g., surveys, focus groups). The investment required may limit the number of interviews that can be conducted and, thus, whether results can be thought of as representative or generalizable.

While empathy interviews can provide useful insights into end-users' experiences and needs, they provide limited opportunities to directly shape PC CDS design.[16,53] Unless also involved in design decisions, empathy interview participants provide information only in response to specific questions, during time- and scope-bound discussions. As with previous methods, this limitation can be offset by pairing empathy interviews with other co-design methods that invite direct involvement in design choices (e.g., prototype testing).

2.2.5 Prototypes

Generative Prototype Activities Include:

- ***Idea Generation and Grouping:*** Brainstorming activities to prompt creative thinking and organize ideas.
- ***Mental Modeling:*** Activities to explain end-users' understanding of how PC CDS-relevant processes and ecosystems work.
- ***Prototype Building:*** Co-creation and iterative testing of a mock-up of the product design.

A critical design step, prototyping is the process by which generated ideas are translated into low-resolution mockups or representations (i.e., "prototypes"). Until a product is developed enough to take its final form (i.e., with working features and full functionality), low-resolution prototypes can be used to solicit early input from end-users. Prototypes are intended to be sufficiently concrete and tangible to solicit preliminary reactions or rapid feedback, often through iterative usability testing (Section 2.2.6).[54]

Defining Features

An inherently creative exercise, prototyping begins during **Generative Design** and can be done through various activities. These serve different but distinct purposes of generating, organizing, and voting on ideas; these ideas get translated into the design during prototype building activities. Notably, Idea Generation and Grouping, Mental Modeling, and Prototype Building activities may be built into the same convening or conducted separately such that end-users are involved in only some activities.

Idea Generation and Grouping. These activities prompt creative thinking about key features or functionalities to build into the design. For instance, brainstorming invites end-users to quickly generate original design ideas, which may be captured on post-it notes or using virtual platforms that mimic collaborative workspaces. Aside from more traditional brainstorming sessions, other activities used to prompt creative thinking include, but are not limited to, using games and role plays.[55]

End-users may then be involved in organizing ideas, through activities whereby similar ideas are grouped (i.e., clustering) and then prioritized (i.e., voting). This process allows quick visualization of how individual ideas are related or similar. It also enables identification of group priorities through simple voting systems (e.g., placing a "dot" vote on each idea or cluster). One alternative to clustering involves co-creating **affinity diagrams**, or visuals used to thematically organize details and insights gathered through interviews, surveys, or observations. Whereas clustering and capturing ideas in real-time on post-it notes can facilitate soliciting original information, affinity diagrams facilitate the organization of collected information and the validation of how that information is interpreted and translated into the diagram.

An alternative to having end-users generate original ideas involves using **issue cards** that show a word, phrase, or image.[56] Subsequently, end-users can be involved in clustering activities called **card sorts** that involve ranking, prioritizing, or grouping issue cards.[56]

Exhibit 6. Example of Prototyping to Understand User Needs and Generate Ideas

Category	End-user	Description
Generative Design	**Patient- and Clinician-facing** 	Card sorting is a useful activity to understand how end-users organize and categorize CDS tool content and ultimately structure the tool in a way that is meaningful to users. For example, developers of a shared decision making tool employed card sorting during prototype development, asking groups of end-users to sort cards into categories based on existing conceptual models and frameworks or by developing their own categories. After each group presented its model for categorizing the cards, end-users voted on the model they felt most accurately reflected patient experiences using dot stickers.[57] Results from such activities are then used to inform prototype development.

***Mental Modeling*.** These activities can also be used to determine how end-users prioritize, group, sort, and label content;[55,56] however, they specifically help to segue from idea generation and grouping into actual prototype building by revealing end-users' mental models for how things do (or should) work in the real-world. Mental modeling activities can involve end-users in creating or reacting to service images or service storyboards. **Service images** are used to present a concept, product, or idea in a memorable and familiar way. End-users are asked to imagine what the final tool will do or look like, and how they envision using it in practice.[58] **Service storyboards** are paneled sketches, images, or other visuals depicting sequences of events related to end-users' theoretical journey of (1) experiencing the ecosystem where they encounter the problem at hand, or (2) interacting with the anticipated tool to address that problem.[59,60,61] Since end-users are unlikely to directly code or format a PC CDS interface, they might instead be asked to react to a prototype featuring service images representing aspects of that interface—or to imagine what the PC CDS would look like and how they might use it.[58]

Prototype Building. While the prior activities involve end-users in more theoretical aspects of design, prototype building includes creating a version or representation of the design. Prototypes can take many forms—including the images and storyboards mentioned above, as well as drawings, visualizations, written scenarios, or physical models. Once developed, prototypes undergo iterative rounds of usability testing (Section 2.2.6) and revision, based on feedback from those tests. Each cycle of prototyping and testing generates and integrates input from experts, end-users, and/or key stakeholders[59] to yield new, more fully developed iterations of the prototype until it is viable for use in real-world settings. While certain prototype building activities can be conducted virtually, some teams arrange in-person convenings in the form of participatory design sessions (e.g., co-production workshops, design conferences, working sessions, community studios).[17,19,24,55,60,62,63]

Developers can work with individuals or groups of end-users to refine prototype concepts. Often, researchers will generate several ideas for prototypes, group those ideas into distinct tools or solutions, and then consult users to evaluate the proposed prototypes.

Exhibit 7. Examples of Convening Stakeholders to Build a Prototype

Category	End-user	Description
Generative Design	**Patient- and Clinician-facing**	In one example, design researchers consulted subject matter experts to develop and evaluate three prototype ideas. The proposed concepts were assessed based on guidelines established earlier in the co-design process using a decision matrix. The final prototype was determined through consensus between the researchers and stakeholders.[57]
	Clinician-facing	Others have used a series of prototyping workshops to engage a group of end-user clinicians. In the prototyping workshops, care team members brainstormed potential tools and solutions, which were then used to inform the development of two model-of-care prototypes.[63]
	Patient-facing	More participatory forms of prototype building can involve end-users in creating low-tech prototypes to demonstrate how a tool would be used. For example, researchers have asked children to physically build a prototype using Legos, paper, crayons, colored pencils, and other materials to represent how they would use a tablet to explain their symptoms to a clinician that informed design elements of the eventual tool.[55]
Evaluative Design	**Clinician-facing**	Following Generative Design, end-users, like care team members, can be included as co-design partners in the development of experiments for piloting and testing these prototypes within clinics.[63]

Benefits

While prototyping and usability testing are often reinforcing parts of iterative design cycles, end-users are not always involved in both. Involving end-users specifically in prototyping offers the benefits of:

- Getting direct input on design, rather than retroactive reactions after PC CDS is developed.[24,36,52]
- Preventing teams from incurring the expenses of time and effort to make post-hoc adjustments after a design is finalized.

Soliciting rapid input on low-fidelity prototypes (intended to be quick, easy, inexpensive, and adaptable)[17] can prevent teams from reaching the end of a full design process only to learn the design fails to meet end-users' needs or align with their priorities (e.g., PC CDS that is misaligned with clinical workflows).

The accessibility of these activities makes it possible to quickly organize, classify, and analyze large amounts of information. It also facilitates visualizing similarities and differences between concepts and ideas to quickly highlight priorities for design.

Finally, involving key stakeholders directly in prototyping can demonstrate their input is respected and valued, which may reinforce trust.[17]

Considerations

Where involvement in prototype building itself is not feasible, involvement in Idea Generation and Grouping or Mental Modeling can provide alternative means to solicit direct design input. These activities can be done through simple, relatively inexpensive approaches (e.g., card sorts)[64] that can often be conducted in person or online. Further, the end-user learning curve for prototyping is limited; creative activities (e.g., using visual images or familiar media, inviting new ideas or artistic representations) can feel more relatable to end-users than interviews or focus groups in which professional jargon is used.[65,66]

Individual prototyping activities may be simple for developers to conduct, and easy for end-users to understand. However, they are subject to the time and resource constraints of:

- Planning, organizing, and hosting or attending prototyping sessions.
- Preparing end-users to understand the activities, objectives, and parameters for collaboration.

Given these constraints, it may not be possible to involve as many patients or clinicians in prototyping as can be reached through surveys or focus groups.

Further, there may be challenges in translating end-user prototypes into PC CDS due to cost, time, and feasibility.[62,67] While end-users may articulate their needs, it is not always possible to build suggested features or functionalities into PC CDS design, or to do so in a way that also aligns with clinician end-users' needs. When suggestions cannot be incorporated, developers may be expected to communicate why they were unable to incorporate end-user suggestions.

2.2.6 Usability Tests

Usability testing methods involve asking about, or directly observing, end-users' interactions with a prototype to assess its effectiveness in meeting their needs. Where user interviews leverage typical qualitative interview methods to solicit end-users' verbal feedback about a prototype (i.e., asking questions), other forms of usability testing involve direct observation and monitoring as end-users naturally interact with the prototype to assess how or whether a prototype is effective.[68]

Defining Features

Usability testing includes different activities for assessing end-users' interactions with a prototype.

Usability Testing Approaches Include:

- ***User Interviews:*** Interviews designed to solicit qualitative feedback on the usability of a prototype.
- ***User Diaries:*** Activities that allow end-users to test prototypes on their own, documenting their experience and reactions to using a prototype.
- ***Direct Observation:*** Developer/researcher-observed simulated or real-world interactions between end-users and prototypes (e.g., behavior tracking, think-aloud methods, time-motion studies, in-situ studies).

User Interviews. During these interviews, end-users (1) use or interact with a prototype, and (2) provide qualitative information about the extent that it can address their identified need. Such tests can occur early in **Generative Design** (i.e., to identify and address problems) or in **Evaluative Design** once the product is nearly finished (i.e., to validate that it meets key requirements).[22]

User Diaries. This alternative to user interviews offers a remote, open-ended structure to solicit qualitative data on end-users' habits (e.g., when they interact with a prototype), motivations (e.g., why they interact with the prototype), and how they interact with the prototype over time or relative to other tools, systems, products, etc.[69] User diaries give end-users license to use prototypes in their natural setting, and to respond to questions or prompts immediately rather than saving feedback for an interview. It also invites feedback in open, creative, flexible formats; end-users can write about or record interactions with a prototype in real time (i.e., extensive journaling while using a product), or through short memos/videos captured in real time, supplemented with longer reflections at the end of each day.[69]

Direct Observation. Other forms of usability testing involve observing and monitoring end-users' interactions with a prototype. For these tests, data may be collected by tracking screen movements, monitoring behaviors and interactions, or asking people to "think aloud" and vocalize reactions.[59] Borrowing from ethnographic methods,[70] tests requiring direct observation can be conducted with support from a trained observer in controlled laboratory settings where the end-user gives consent to be observed while interacting with the prototype. They can also be conducted in natural settings, in which the observer evaluates how an end-user interacts with the prototype as part of their daily activities. In these instances, the observer records end-users' actions either quantitatively (e.g., numerical scale), or qualitatively (e.g., written comments).[71]

Activities involving direct observation include:

- **Time-motion studies,** where the observer specifically monitors and evaluates the time it takes an end-user to interact with the prototype to achieve a target goal (e.g., finding the right medication for a patient); and the end-user's efficiency in using the prototype (e.g., number of clicks to find the medication).[72]
- **In-situ simulations,** during which the observer evaluates use of a prototype in environments mimicking applicable settings.[16]

Exhibit 8. Examples of Usability Testing Approaches in the Evaluative Design Phase

Category	End-user	Description
User Interviews	**Patient-facing**	Interviews conducted with patients during usability testing allow patients to share their experiences using the PC CDS tool with developers. For example, patients testing the usability of a self-management app described what worked well for them and where they perceived areas for improvement to app developers.
	Clinician-facing	Researchers have also used usability interviews with clinicians to understand their experiences with a PC CDS tool.[73] Interview topics may include end-users' perceptions of their interaction with the tool, their suggested improvements, the feasibility of use in practice, and their overall acceptance of it.
Direct Observation	**Clinician-facing**	Direct observation of end-users has been used in the iterative design of PC CDS tools. Direct observation can often be paired with user interviews, where end-users are asked about their perspectives and then participate in a near real-life simulation of a CDS tool, which is observed by developers. During and following observation, end-users can provide feedback.[74]
	Clinician-facing	Researchers often use direct observation to compare the usability of a PC CDS tool with the standard of care, using outcomes from a simulated event against the normal workflow. For example, in one design of CDS for the management of fluids, electrolytes, and nutrition for critically ill pediatric patients, researchers documented clinicians' usual workflow while performing team rounds with an actual patient under observation. Then, clinicians performed simulated rounds using CDS on a mock patient. They were observed while asking clarifying questions and interacting with patient data, as they would while managing patient care.[15]
	Patient-facing	Several observation approaches can be combined throughout iterative usability testing to obtain feedback on various aspects and at several stages of refinement. For example, developers in one study employed the "think aloud" technique and eye-tracking software. Testing involved asking participants to examine and verbally describe their reactions to low-fidelity paper mockups and high-fidelity web-based prototypes of the CDS using the 'think aloud' technique. Then, end-users were

observed (and their eye movements were recorded) as they completed a series of structured tasks using the prototype. Information generated from these tests helped developers understand how end-users would interact with and navigate the interface.[75]

Benefits

The benefits of using iterative design cycles (e.g., prototyping, testing, revision) are well-established.[58,76] Thus, usability testing is among the more consistently defined and commonly used methods for involvement in co-design. Where summative testing (i.e., once the design is completed and deployed) requires a larger sample to establish validity, usability tests in rapid design cycles can involve smaller samples.[68] This allows for rapid solicitation of feedback that gets quickly incorporated into design and limits time spent preparing for interviews. Usability testing activities involving direct observation in controlled, simulated, or real-world settings can allow end-users to interact with a prototype as well as the design team.[67,70,77] This can provide developers with a complete picture of (1) how end-users will or do use PC CDS in practice, and (2) potential risks, harms, or other ethical considerations related to the design.[21]

Considerations

While interviewing methods are largely thought to be effective, developers' ability to make meaningful use of targeted interview responses (focused on a prototype) depends on their knowledge of end-users' broader needs. Thus, there are benefits to combining usability interviews with methods that involve end-users earlier and more actively in co-design (i.e., during Pre-design or Generative Design). This includes involving them in prototyping and other activities that elicit their direct input on design elements.[36,53,78,79,80]

While usability testing activities can provide rich information, people may intentionally or unintentionally modify usual behaviors when observed[81] or when asked to document personal feelings or experiences (i.e., in user diaries). In the case of PC CDS usability testing, it may be especially difficult for clinicians with busy schedules and public-facing jobs to undergo observation or accurately capture reflections in user diaries.

2.3 Choosing Co-design Methods: Reach versus Intensity of End-user Involvement

Referencing the table in **Exhibit 9,** as well as the benefits and considerations associated with each method (Section 2.2), developers can make informed decisions about which co-design methods to use. **Exhibit 9,** below, illustrates how the various co-design methods differ relative to parameters such as:

- **Intensity,** the nature of involvement (e.g., commitment of time, depth of input), and
- **Reach,** the relative number of people that can be involved using a co-design method.

The left column includes low-intensity forms of involvement, requiring limited commitment of time, resources, or information sharing. They can have the broadest reach, in part because they pose few barriers to involvement (e.g., one-touch activities, can be done remotely). The right column includes high-intensity forms of involvement, requiring deeper, repeat, or sustained forms of involvement. They may have narrower reach (in terms of the number of people involved), as they require greater investments of time, effort, or resources from co-design partners.

Exhibit 9. Summary Table of Co-design Methods by Phase of Co-design

Intensity →

Phases of Co-design				
Pre-design		**Surveys** (Section 2.2.2)	**Empathy Interviews** (Section 2.2.3) **Focus Groups** (Section 2.2.4)	**Consultative Groups** (Section 2.2.1) • Steering Committees, Advisory Groups, etc.
Design	Generative Design	**Surveys** (Section 2.2.2)	**Empathy Interviews** (Section 2.2.3) • Jobs to be Done (JTBD) Interviews **Focus Groups** (Section 2.2.4) **Prototyping** (Section 2.2.5) • Idea Generation & Grouping • Mental Modeling (e.g., service images, storyboards) • Prototype Building	**Consultative Groups** (Section 2.2.1) • Steering Committees, Advisory Groups, etc.
Design	Evaluative Design	**Surveys** (Section 2.2.2)	**Consultative Groups** (Section 2.2.1) • Shark Tanks, Reactor Panels, etc. **Focus Groups** (Section 2.2.4) **Usability Testing** (Section 2.2.6) • User Interviews • User Diaries • Direct Observation (e.g., time-motion studies, in-situ simulations)	**Consultative Groups** (Section 2.2.1) • Steering Committees, Advisory Groups, etc.

← Reach

Methods in the left column—with high reach and low intensity—can support quick, efficient data collection from large and potentially more representative groups. These methods generate insights that inform developers' understanding of (1) the ecosystem PC CDS is designed for, (2) the problem or need PC CDS can address, (3) similarities and points of variance across end-users, and (4) people or perspectives most likely representative of the broader target audience. Reaching large numbers of end-users via these methods, however, requires limiting barriers (e.g., frequency, intensity) to involvement. If developers want to pinpoint the PC CDS features of highest priority across diverse end-users, they might disseminate a survey en masse. This “one-touch” form of involvement would present end-users with an easy format and time-limited process for ranking, prioritizing, or selecting preferred features.

Methods in the center column (i.e., with moderate reach and intensity) can be used by developers to solicit more in-depth, directive input during co-design while requiring only one- or low-touch involvement. Where methods in the left column can solicit many diverse perspectives to identify general problems or priorities, methods in the center column involve smaller numbers of individuals to generate more specific or directive input on PC CDS design. For example, rather than provide information to indirectly inform developers’ design choices, end-users may be invited to attend co-production workshops during which they directly partner with developers to brainstorm ideas and create mockups.

The right column includes methods by which end-users are consulting in a more sustained or ongoing way, to provide input not only on the design itself, but also on the planning and execution of co-design. For example, at the onset of co-design, a steering committee or advisory board may decide that all major design changes must be made with the approval of this group. Once a series of revisions for a prototype is proposed, members of this group would then be invited to comment or vote on these to select and confirm improvements to be incorporated in the prototype.

3. Discussion

Developers may use the methods detailed above in combination as needed, affording both navigation of existing constraints as well as flexibility to offer multiple and diverse mechanisms for involving partners in PC CDS co-design. This section provides prompts to guide thinking about how to combine methods, as well as practices to set them up for success in implementing co-design. Recognizing that there is still a need for increased partnership in co-design, we identify opportunities for future research that might help to further advance the study and use of co-design methods for PC CDS.

3.1 Combining Co-design Methods

Just as patient and clinician PC CDS end-users are not homogenous, the range of co-design methods demonstrates that there is no “one size fits all” approach. The ways that patients and clinicians can and choose to be involved may be determined by individual characteristics (e.g., attitudes, experiences with the healthcare system) and organizational factors (e.g., policies that enable patient engagement).[82] Further, the success of involvement activities depends on whether the final PC CDS can be effectively integrated in healthcare ecosystems and patients’ lives, which are complex and dynamic.[21]

To account for this complexity, developers can combine co-design methods for different purposes. In making these choices, you can optimize co-design by balancing your own priorities with those of involved end-users and other co-design partners.[82] This requires understanding the aims of involvement, which can be explored through the following questions.

1. What information or outputs do you need from end-users' involvement?

> For example, do you need input that reflects the average or is representative of a given end-user group? Or do you need more intensive involvement or investment from those willing to delve deeper into key questions, even if only a self-selecting few are able to be that involved? Thinking through this prompt can help you select methods requiring the needed levels of involvement.

2. Where are you in your design process? Where in the process will it be most beneficial and appropriate to involve end-users?

> For example, are you still in pre-design activities during which it helps to gather more information about your end-users' background? Or are you ready to move into generative design, whereby you specifically get input regarding the key features and functionalities to be included in PC CDS? Thinking through this prompt can help you select methods best fit for the objective in each co-design phase.

3. What existing or anticipated constraints (e.g., time, capacity, financial and/or human resources) must be considered as you select your methods?

> For example, are end-users able to access the location where a focus group is being held, if in person, or face challenges navigating virtual environments? To what extent are you able to accommodate constraints associated with each method?

Using these questions, developers can select co-design methods that seem most natural and efficacious for those being involved. By combining methods, developers can also create options so that co-design partners can choose modes of involvement best aligned with their skills, strengths, communication, and contribution styles. Since this can change for individuals over time (i.e., someone who prefers being deeply involved may not always be able to do so), offering alternative mechanisms for involvement can encourage ongoing partnership in co-design, even when constraints emerge.

3.2 Setting Yourself Up for Successful Co-Design

Taking the following steps can help set design team members and end-user partners up to successfully engage in co-design activities.

1. Communicate clearly about expectations and roles/responsibilities of designers and end-users.[83] This may be accomplished by providing end-users with clear role descriptions, responsibilities, and expectations for involvement prior to the onset of involvement[27] and is important for setting end-users' expectations about their roles and responsibilities in different co-design phases. Consistent communication is also important for the sense-making process among designers.

2. Demonstrate empathy and inclusivity. Relative to co-design for other tools or products, PC CDS design requires that developers are sensitive to the deeply personal nature of health challenges. In conducting activities to involve diverse end-users in co-design, it is important that developers are mindful about honoring end-users' trust, privacy, and vulnerabilities.[21] This is critical to ensuring that team members and end-users can comfortably and meaningfully contribute to discussions.[84] For example, language differences can present barriers to collaborative design, as end-users may have limited familiarity with developer vocabulary or may speak English as a second language.[27] Developers may be unfamiliar with, or insensitive to, end-users' concerns about being judged or about using visuals or narratives that assume familiarity with specific social and cultural contexts.[27,84,85] Alternative approaches can include the use of visuals, narrative summaries, and/or oral and written communication approaches.[27] These alternatives help create a shared common language among end-users and designers that avoids jargon, promotes egalitarian partnership, and increases accessibility of content and involvement activities regardless of profession or literacy.[17] Such activities that promote a shared common language can improve the usefulness and real-world usability or acceptance of co-designed solutions.[65,86,87] By developing an understanding of partners to be involved, developers can determine if and how to tailor information or engagement channels to optimize end-user involvement.

3. Develop methods for bidirectional communication between designers and end-users.[27] Bidirectional communication ensures end-users who provide input also receive, in return, information and updates throughout the design process.[27] For example, it can be important to document key design changes that have been made based on end-user input, and then communicate back about (1) how feedback influenced design, (2) where and why feedback could not be incorporated, or (3) how revised designs look.[27] Bidirectional communication can allow for end-user access to information regarding how their input or feedback is integrated, as well as updates on progress of tool development. This feedback could be open-ended (e.g., through open discussion) or targeted (i.e., focused on certain parts of the process).[27] Conveying information related to the co-design process itself, as well as the final product, to end-users in accessible language and formats may improve the effectiveness of co-design, as well as tool uptake and use.[88] According to a key informant, having bidirectional pathways for gathering information from end-users (once PC CDS has been deployed) helps collect data or insights that can enhance ongoing or future development of PC CDS.

4. Invite and integrate different types of end-user contributions.[31] An individual end-user cannot represent all end-users; in the same ways that each end-user might interact differently with a PC CDS tool, each end-user might also interact differently with the co-design process. Offering different mechanisms by which end-users can participate in co-design helps to guarantee that input from diverse individuals is adequately elicited, captured, and considered. Developers can benefit from more robust and representative end-user input if they offer several channels for involvement.[89] For example, developers used a creative prototype building approach to solicit contributions of children and their parents in co-design by fostering a flexible environment for children to freely express themselves with guidance from the study team and parents.[55] Other end-user factors should be considered when deciding the group of stakeholders to engage. Vocal or extroverted end-users might contribute most readily during focus groups, whereas others may prefer to give written feedback or to submit input via surveys and online platforms. End-users steeped in the content area or research methods may prefer to be involved in a sustained way, to watch the design progression. Others facing time or health constraints, for example, may not have the interest or bandwidth to participate beyond a "one touch" activity such as a user test or interview.

5. Negotiate and resolve conflicts proactively and collaboratively to build trust and confidence in solutions. With the inclusion of several co-design partners who represent various perspectives, conflicting suggestions or differences in opinion may arise. Given the principles of democratization and equality that underly co-design, it is important to give all opinions and suggestions from partners equal consideration.[90] Developers should determine methods for resolving conflict early in the intervention process,[91] before conflict arises. Approaches to resolving conflicts that surface in co-design include: "selecting (satisfy one need but not the other), combining (keeping multiple options in the design), integrating (designing a new and coherent functionality that serves both needs) and reframing (redefine perspectives in a way that dissolves the conflict)."[92] Some co-design engagement approaches may also enable conflict resolution better than others. Compared to interviews or surveys, workshop and focus group formats involve a higher degree of partner engagement and allow for discussion and resolution among partners and for researchers/developers to directly respond to partner input.[90,93] Soliciting feedback on tangible prototypes can also be used to mediate collaboration and overcome conflicts in opinion by exposing underlying assumptions and seeking resolution.[94]

6. Establish an infrastructure for end-users to easily, equitably access co-design platforms and supportive resources.[17] Identified barriers to involvement in co-design include, but are not limited to,[17] time commitment, geographic location (for in-person involvement activities) and/or other issues related to inequitable access, levels of health and/or ability of involved partners, and differentials in knowledge and decision making authority between different types of co-design partners (i.e., developers vs. patients or clinicians). The establishment of formal policies for stakeholder engagement can support equitable access to co-design platforms and resources for end-users with diverse backgrounds and experience.[27] At the same time, policies should be flexible enough to ensure that engagement processes can be realistically completed.[91]

7. Provide compensation to recognize end-users' commitment and contribution.[31,95] Providing compensation removes barriers to participation, enabling a more diverse group of end-users to participate in co-design.[96] Several resources are available to guide researchers in planning for and developing equitable financial compensation rates for co-design partners, including the Person-Center Outcomes Research Institutes' (PCORI) Compensation Framework[97] and Budgeting for Engagement guide.[98]

3.3 Opportunities for Future Research

While the practices outlined above show promise for successful use of co-design methods to improve PC CDS, confidently identifying and recommending best practices will require being able to assess the effectiveness of interventions developed through co-design as well as the co-design process itself. Aside from occasional qualitative assessments, which are usually based on collaborators' self-reporting regarding their experience or satisfaction with the process, such evaluations are limited. Hence, it may be worth exploring if Design Science Research (DSR) methods (used to evaluate collaborative product design in other fields) may be adapted for PC CDS.[99]

In the future, embedding evaluation throughout the design process may inform future decisions about how best to involve end-users and integrate their input throughout Pre-design, Design, and Post-design phases.[100] Ultimately, further study on the effectiveness of these co-design methods can provide insight on the overall impact of co-design on PC CDS effectiveness, as well as the benefits for patients and clinicians using PC CDS to inform their clinical decision making.

4. Conclusion

This report presents a range of methods for involving end-users and other key stakeholders in PC CDS co-design. Findings from a semi-systematic literature scan, validated by KIIs, highlighted six co-design methods: consultative groups, surveys, focus groups, empathy interviews, prototypes, and usability testing. Developers can use these methods, independently or in combination, to optimize efforts for soliciting important input and involvement from patient and clinician PC CDS end-users, as well as other key stakeholders in health delivery ecosystems (e.g., caregivers, delivery system leaders). Some methods are particularly useful in Pre-design, as developers seek to identify and understand the end-user needs, context, and priorities that will dictate key PC CDS design decisions. Other methods may be well-suited to involving end-users in Generative Design (i.e., formulating ideas for what PC CDS should look like) or Evaluative Design (i.e., assessing functions, features, and usability of PC CDS) phases.

While these approaches each yield distinct benefits, they are also subject to distinct constraints (e.g., time and resource costs) that require developers' consideration. Developers can navigate these constraints by selecting and combining methods that are best fit-for-purpose to generate information needed in each phase of co-design; to do this, developers may consider the relative reach (i.e., number of stakeholders involved, range of stakeholders represented) and intensity (i.e., frequency of convening, duration, or depth of commitment) of involvement.

This resource provides several best practices for co-designing with end-users who are diverse in terms of their background, experiences, expertise, and uses of PC CDS. Communication (e.g., through bi-directional feedback), empathy (e.g., comfortable spaces for open communication and idea-generation), and accessibility (e.g., language, inclusion of children) are fundamental to ensuring understanding and alignment of expectations and roles within the co-design process. Future opportunities for developing, improving, and evaluating methods for PC CDS co-design may emerge as end-users' role in this process continues to grow.

5. Appendix

Scan Methods: Overview. We conducted a semi-systematic literature review, on co-design in PC CDS and broader patient-centered healthcare contexts to address two research questions:

- **RQ1:** What methods currently exist for involving patients throughout the PC CDS co-design process?
    - What are the defining features and benefits of, or considerations for using, each method?
    - How do these influence which methods are best suited to generate needed input at each point in co-design?
- **RQ2:** What promising and emerging practices can be used by PC CDS designers and developers to ensure robust end-user involvement in co-design?

Our initial searches (**Table A1**) yielded 88 peer-reviewed articles in PubMed. After removing two duplicate articles and screening articles according to our eligibility criteria, a total of 68 articles from our initial PubMed searches were included in our full-text review. We sourced 18 additional articles from members of the Trust and Patient-Centeredness Workgroup, key informants, and additional targeted searches.

Table A1. Key PubMed Search Terms

PubMed Search Terms	
Search 1	***Search 2***
(Decision Support Systems, Clinical [MeSH] OR Decision Support Techniques [MeSH] OR “Clinical Decision Support”[tw] NOT “decision aid”[tw]	(Decision Support Systems, Clinical [MeSH] OR “Decision Support System*”[tw] 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])	(“Co-design*”[tw] OR “Codesign*”[tw] OR “Collaborative* design*”[tw] OR “Participatory design”[tw] OR “Partnered design”[tw])
AND	
2017 - present	

Results from the scan were validated through key informant interviews (KIIs), focused on reviewing the identified co-design methods and strategies for success. Four KIIs were conducted during May 2023, with informants who identified as both leaders and participants in co-design. Two of these informants were members of the Trust and Patient-Centeredness Workgroup. Interviews were guided by a semi-structured discussion guide and reference materials that had been iteratively refined through Workgroup feedback. These materials included the Summary Table of Co-design Methods (**Exhibit 9**) and a simplified table outlining steps presented in Section 3.2.

References

[1] Institute of Medicine. *Crossing The Quality Chasm: A New Health System for the 21st Century.* Washington DC: National Academy Press; 2001.

[2] Tzelepis F, Sanson-Fisher RW, Zucca AC, Fradgley EA. Measuring the quality of patient-centered care: why patient-reported measures are critical to reliable assessment. *Patient Prefer Adherence.* 2015;9:831-835. Published 2015 Jun 24. doi:10.2147/PPA.S81975

[3] NEJM Catalyst. What Is Patient-Centered Care? Retrieved from: https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0559

[4] Agency for Healthcare Research and Quality. Clinical Decision Support. Retrieved from: https://www.ahrq.gov/cpi/about/otherwebsites/clinical-decision-support/index.html

[5] Dullabh P, Sandberg SF, Heaney-Huls K, et al. Challenges and opportunities for advancing patient-centered clinical decision support: findings from a horizon scan. *J Am Med Inform Assoc*. 2022;29(7):1233-1243. doi:10.1093/jamia/ocac059

[6] Marcial LH, Richardson JE, Lasater B, et al. The imperative for patient-centered clinical decision support. *EGEMS (Wash DC)*. 2018;6(1):12. Published 2018 May 30. doi:10.5334/egems.259

[7] Sunjaya AP, Martin A, Jenkins C. A design thinking approach to developing a clinical decision support system for breathlessness in primary care. *Stud Health Technol Inform*. 2022;290:839-843. doi:10.3233/SHTI220197

[8] Brunner MC, Sheehan SE, Yanke EM, et al. Joint design with providers of clinical decision support for value-based advanced shoulder imaging. *Appl Clin Inform*. 2020;11(1):142-152. doi:10.1055/s-0040-1701256

[9] Tendedez H, Ferrario MA, McNaney R, Gradinar A. Exploring human-data interaction in clinical decision-making using scenarios: Co-design study. *JMIR Hum Factors*. 2022;9(2):e32456. Published 2022 May 6. doi:10.2196/32456

[10] Organization IS*. ISO 9241-210:2010 Ergonomics of human-system interaction – Part 210: Human-centred design for interactive systems.* 2015. Geneva, Swiss: Organization IS.

[11] Middleton B, Sittig DF, Wright A. Clinical decision support: A 25 year retrospective and a 25 year vision. *Yearb Med Inform*. 2016;Suppl 1(Suppl 1):S103-S116. Published 2016 Aug 2. doi:10.15265/IYS-2016-s034

[12] 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;13(3):641-646. doi:10.1055/s-0042-1750355

[13] Ash JS, Sittig DF, Campbell EM, Guappone KP, Dykstra RH. Some unintended consequences of clinical decision support systems. *AMIA Annu Symp Proc*. 2007;2007:26-30. Published 2007 Oct 11.

[14] Stagg B, Stein JD, Medeiros FA, Cummins M, Kawamoto K, Hess R. Interests and needs of eye care providers in clinical decision support for glaucoma. *BMJ Open Ophthalmol*. 2021;6(1):e000639. Published 2021 Jan 15. doi:10.1136/bmjophth-2020-000639

[15] Zhang M, Ehrmann D, Mazwi M, et al. Get to the point! Problem-based curated data views to augment care for critically ill patients. In *CHI Conference on Human Factors in Computing Systems (CHI '22), April 29-May 5, 2022, New Orleans, LA, USA.* ACM, New York, NY, USA. doi: 10.1145/3491102.3501887

[16] Kunstler BE, Furler J, Holmes-Truscott E, McLachlan H, et al. Guiding glucose management discussions among adults with type 2 diabetes in general practice: Development and pretesting of a clinical decision support tool prototype embedded in an electronic medical record. *JMIR Form Res*. 2020;4(9):e17785. doi:10.2196/17785

[17] Grindell C, Tod A, Bec R, et al. Using creative co-design to develop a decision support tool for people with malignant pleural effusion. *BMC medical informatics and decision making*. 2020;20(1):179. Published 2020 Aug 5. doi:10.1186/s12911-020-01200-3

[18] Donia J, Shaw JA. Co-design and ethical artifical intelligence for health: an agenda for critical research and practice. *Big Data & Society.* 2021 Jul;8(2):1-12. doi:10.1177/20539517211065248

[19] Davies N, Sampson EL, West E, et al. A decision aid to support family carers of people living with dementia towards the end-of-life: Coproduction process, outcome and reflections. *Health Expect*. 2021;24(5):1677-1691. doi:10.1111/hex.13307

[20] Bird M, McGillion M, Chambers EM, et al. A generative co-design framework for healthcare innovation: development and application of an end-user engagement framework. *Res Involv Engagem*. 2021;7(1):12. Published 2021 Mar 1. doi:10.1186/s40900-021-00252-7

[21] Sanders EB, Stappers PJ. Probes, toolkits and prototypes: three approaches to making in codesigning. *CoDesign.* 2014;10(1):5–14. doi: 10.1080/15710882.2014.888183

[22] Noorbergen TJ, Adam MTP, Teubner T, Collins CE. Using co-design in mobile health system development: A qualitative study with experts in co-design and mobile health system development. *JMIR Mhealth Uhealth*. 2021;9(11):e27896. Published 2021 Nov 10. doi:10.2196/27896

[23] Genes N, Kim MS, Thum FL, et al. Usability evaluation of a clinical decision support system for geriatric ED pain treatment. *Appl Clin Inform*. 2016;7(1):128-142. Published 2016 Mar 9. doi:10.4338/ACI-2015-08-RA-0108

[24] Paskins Z, Bullock L, Crawford-Manning F, et al. Improving uptake of fracture prevention drug treatments: a protocol for development of a consultation intervention (iFraP-D). *BMJ open.* 2021:11(8), e048811. Published 2021 Aug 18. doi:10.1136/bmjopen-2021-048811

[25] Rousseau N, Turner KM, Duncan E, et al. Attending to design when developing complex health interventions: A qualitative interview study with intervention developers and associated stakeholders. *PLoS One*. 2019;14(10):e0223615. Published 2019 Oct 15. doi:10.1371/journal.pone.0223615

[26] O'Cathain A, Croot L, Duncan E, et al. Guidance on how to develop complex interventions to improve health and healthcare. *BMJ Open*. 2019;9(8):e029954. Published 2019 Aug 15. doi:10.1136/bmjopen-2019-029954

[27] Cope E, Dungan R, Isaacson A, PDRC LN Improving Representativeness Workgroup. Strategies for Improving Patient Representativeness in Research Governance. Retrieved from: https://www.pcori.org/sites/default/files/Strategies-Improving-Representativeness-February-2021.pdf

[28] Manville C, Hackett P, Gunashekar S, Jones MM. Regulatory cultures and research governance. *Rand Health Q*. 2013;3(1):5. Published 2013 Mar 1.

[29] Health Collaboratory. Patient Shark Tank. Retrieved from: https://www.healthcollaboratory.com/patientsharktank.html

[30] Mahadevaiah G, Rv P, Bermejo I, Jaffray D, Dekker A, Wee L. Artificial intelligence-based clinical decision support in modern medical physics: Selection, acceptance, commissioning, and quality assurance. *Med Phys*. 2020;47(5):e228-e235. doi:10.1002/mp.13562

[31] Cope E, Angove R, Millender S, PCORnet Engagement Coordinating Center. Partnerships & Infrastructure to Support Patient & Stakeholder Engagement: A Scan of PCORnet Practices. Retrieved from: https://www.pcori.org/sites/default/files/PCORnet-ECC-Engagement-Practice-Scan.pdf

[32] McCoy AB, Russo EM, Johnson KB, et al. Clinical collaboration to improve clinical decision support: the Clickbusters initiative. *Journal of the American Medical Informatics Association.* 2022;29(6):1050-1059. doi:10.1093/jamia/ocac027

[33] MRID Codesignkit. Questionnaires & Surveys. Accessed on April, 26, 2023. Retrieved from: http://codesignkit.org.au/the-toolbox/questionnaires-surveys/

[34] Moura J, Almeida A, Roque F, Figueiras A, Herdeiro MT. A mobile app to support clinical diagnosis of upper respiratory problems (eHealthResp): Co-design approach. *Journal of medical Internet research.* 2021;23(1):e19194. Published 2021 Jan 28. doi:10.2196/19194

[35] Peiffer-Smadja N, Poda A, Ouedraogo AS, et al. Paving the way for the implementation of a decision support system for antibiotic prescribing in primary care in West Africa: Preimplementation and co-design workshop with physicians. *J Med Internet Res*. 2020;22(7):e17940. Published 2020 Jul 20. doi:10.2196/17940

[36] Fleisher L, Bass SB, Shwarz M, et al. Using theory and user-centered design in digital health: The development of the mychoice communication tool to prepare patients and improve informed decision making regarding clinical trial participation. *Psychooncology.* 2020;29(1):114-122. doi:10.1002/pon.5254.

[37] van Gils AM, Visser LNC, Hendriksen HMA, Georges J, van der Flier WM, Rhodius-Meester HFM. Development and design of a diagnostic report to support communication in dementia: Co-creation with patients and care partners. *Alzheimers Dement (Amst)*. 2022;14(1):e12333. Published 2022 Sep 6. doi:10.1002/dad2.12333

[38] Lewis JR. The system usability scale: Past, present, and future. *International Journal of Human-Computer Interaction.* 2018, 34(7)577-590. doi:10.1080/10447318.2018.1455307

[39] Bangor A, Kortum PT, Miller JT. An empirical evaluation of the system usability scale. *International Journal of Human-Computer Interaction.* 2008;24(6):574-594. doi:10.1080/10447310802205776

[40] Grainger R, Townsley H, Langlotz T, Taylor W. Patient-Clinician co-design co-participation in design of an app for rheumatoid arthritis management via telehealth yields an app with high usability and acceptance. *Stud Health Technol Inform*. 2017;245:1223.

[41] Krueger RA. *Focus Groups: A Practical Guide for Applied Research.* Sage Publications, Inc;1988.

[42] Bright TJ. Transforming user needs into functional requirements for an antibiotic clinical decision support system: explicating content analysis for system design. *Appl Clin Inform*. 2013;4(4):618-635. Published 2013 Dec 25. doi:10.4338/ACI-2013-08-RA-0058

[43] Coteur K, Matheï C, Schoenmakers B, Van Nuland M. Co-design to increase implementation of insomnia guidelines in primary care. *Patient Educ Couns*. 2022;105(12):3558-3565. doi:10.1016/j.pec.2022.08.018

[44] Kastner M, Li J, Lottridge D, et al. Development of a prototype clinical decision support tool for osteoporosis disease management: a qualitative study of focus groups. *BMC Med Inform Decis Mak.* 2010;10(40). doi:10.1186/1472-6947-10-40

[45] Kildea J, Battista J, Cabral B, et al. Design and development of a person-centered patient portal using participatory stakeholder co-design. *J Med Internet Res*. 2019;21(2):e11371. Published 2019 Feb 11. doi:10.2196/11371

[46] Pryce H, Durand MA, Hall A, et al. The development of a decision aid for tinnitus. *Int J Audiol.* 2018;57(9):714-719. doi:10.1080/14992027.2018.1468093.

[47] Nelsestuen K, Smith J. Empathy Interviews. Accessed April 26, 2023. Retrieved from: Comm-Des-Ptners-Article-01202022-Prpfessional_Vol.41-No.-5_Empathy-Interview-Tool_Handout-2.pdf (learningforward.org)

[48] Gonzales MJ, Riek LD. Co-designing patient-centered health communication tools for cancer care. *2013 7th International Conference on Pervasive Computing Technologies for Healthcare and Workshops*. 2013;208-215. doi: 10.4108/icst.pervasivehealth.2013.252109.

[49] Wunker S, Wattman J, Farber D. *Jobs to be done: a roadmap for customer-centered innovation.* Amacom; 2016.

[50] Christensen CM, Hall T, Dillon K, Duncan DS. Know your customers' jobs to be done. *Harvard business review.* 2016 Sep 1;94(9):54-62.

[51] Stobierski T. Innovation in a Disrupted World: How to Discover New and Emerging Jobs to be Done. Harvard Business School Online. Accessed April 26, 2023. Retrieved from: https://online.hbs.edu/blog/post/jobs-to-be-done-framework

[52] Luna D, Otero C, Almerares A, Stanziola E, Risk M, González Bernaldo de Quirós F. Participatory design for drug-drug interaction alerts. *Stud Health Technol Inform*. 2015;210:45-49.

[53] Gennari JH, Reddy M. Participatory design and an eligibility screening tool. *Proc AMIA Symp*. 2000;290-294.

[54] Better Services by Design. Introduction. Accessed May 8, 2023. Retrieved from: http://www.bsbd.org.uk/

[55] Ruland CM, Slaughter L, Starren J, Vatne TM. Children as design partners in the development of a support system for children with cancer. *Stud Health Technol Inform*. 2006;122:80-85.

[56] IDEO.org. The Field Guide to Human-Centered Design. Accessed April 26, 2023. Retrieved from: https://design-kit-production.s3.us-west-1.amazonaws.com/Field_Guides/Field+Guide+to+Human-Centered+Design_IDEOorg_English.pdf?utf8=%E2%9C%93&_method=patch&authenticity_token=QZRbnzBBPY3M%2FCd3xeDx424iAXgVkgcTAi74f6cW4pU%3D&resource%5Btitle%5D=&resource%5Bsubtitle%5D=&resource%5Bauthor%5D=&resource%5Babout%5D=

[57] Singer I, Klatte IS, de Vries R, van der Lugt R, Gerrits E. Using co-design to develop a tool for shared goal-setting with parents in speech and language therapy. *Int J Lang Commun Disord*. 2022;57(6):1281-1303. doi:10.1111/1460-6984.12753

[58] Service Design Tools. Service Image: Capture the Essence of a Service Experience in a Single Frame. Accessed April 26, 2023. Retrieved from: https://servicedesigntools.org/tools/service-image#:~:text=The%20service%20image%20is%20aimed,immerse%20into%20the%20envisioned%20experience.

[59] Manski-Nankervis JA, Alexander K, Biezen R, et al. Towards optimising chronic kidney disease detection and management in primary care: Underlying theory and protocol for technology development using an Integrated Knowledge Translation approach. *Health informatics journal.* 2021;27(2):14604582211008227. doi:10.1177/14604582211008227

[60] Reponen S, Treasure-Jones T, Leinonen T, Pejoska J, Bauters M. Co-design Framework. Retrieved from: http://results.learning-layers.eu/methods/co-design/

[61] Young R, Sage K, Broom D, Hext A, Smith C. Effective use of storyboarding as a co-design method to enhance power assisted exercise equipment for people with stroke. *Design for Health*. 2022;6:2, 244-275. doi:10.1080/24735132.2022.2101257

[62] Jeffery AD, Novak LL, Kennedy B, Dietrich MS, Mion LC. Participatory design of probability-based decision support tools for in-hospital nurses. *Journal of the American Medical Informatics Association: JAMIA.* 2017;24(6), 1102–1110. https://doi.org/10.1093/jamia/ocx060

[63] Partogi M, Gaviria-Valencia S, Alzate Aguirre M, et al. Sociotechnical intervention for improved delivery of preventive cardiovascular care to rural communities: Participatory design approach. *Journal of medical Internet research.* 2022;24(8): e27333. https://doi.org/10.2196/27333

[64] Interaction Design Foundation. The Pros and Cons of Card Sorting in UX Research. Accessed May 8, 2023. Retrieved from: https://www.interaction-design.org/literature/article/the-pros-and-cons-of-card-sorting-in-ux-research

[65] Langley J, Wolstenholme D, Cooke J. 'Collective making' as knowledge mobilisation: the contribution of participatory design in the co-creation of knowledge in healthcare. *BMC Health Serv Res.* 2018;18:585.

[66] Simons H, Mccormack B. Qualitative inquiry integrating arts-based inquiry in evaluation opportunities and challenges. *Qual Inq.* 2007;13(2):292–311.

[67] Romero-Lopez-Alberca C, Alonso-Trujillo F, Almenara-Abellan JL, et al. A semiautomated classification system for producing service directories in social and health care (DESDE-AND): Maturity assessment study. *J Med Internet Res*. 2021;23(3):e24930. Published 2021 Mar 15. doi:10.2196/24930

[68] Barnum CM. *Usability Testing Essentials: Ready, Set… Test!* Elsevier Inc. 2011.

[69] Salazar K. Diary Studies: Understanding Long-Term User Behavior and Experiences. 2016. Accessed April 26, 2023. Retrieved from: https://www.nngroup.com/articles/diary-studies/

[70] Kushniruk A, Nøhr C. Participatory design, user involvement and health IT evaluation. *Stud Health Technol Inform.* 2016;222:139-51.

[71] Interaction Design Foundation. How to Conduct User Observations. Accessed April 26, 2023. Retrieved from: https://www.interaction-design.org/literature/article/how-to-conduct-user-observations

[72] Kalne PS, Mehendale AM. The purpose of time-motion studies (TMSs) in healthcare: A literature review. *Cureus*. 2022;14(10), e29869. doi:10.7759/cureus.29869

[73] Farr M, Pithara C, Sullivan S, et al. Pilot implementation of co-designed software for co-production in mental health care planning: a qualitative evaluation of staff perspectives. *J Ment Health*. 2019;28(5):495-504. doi:10.1080/09638237.2019.1608925

[74] Li AC, Kannry JL, Kushniruk A, et al. Integrating usability testing and think-aloud protocol analysis with "near-live" clinical simulations in evaluating clinical decision support. *Int J Med Inform*. 2012;81(11):761-772. doi:10.1016/j.ijmedinf.2012.02.009

[75] Wolpin SE, Halpenny B, Whitman G, et al. Development and usability testing of a web-based cancer symptom and quality-of-life support intervention. *Health Informatics J*. 2015;21(1):10-23. doi:10.1177/1460458213495744

[76] Walden A, Garvin L, Smerek M, Johnson C. User-centered design principles in the development of clinical research tools. *Clinical Trials.* 2020;17(6):703-11.

[77] Saperstein Y, Ong SY, Al-Bermani T, et al. COVID-19 guidelines changing faster than the virus: Implications of a clinical decision support app. *International Journal of Clinical Research & Trials.* 2020;5(2), 148. doi:10.15344/2456-8007/2020/148

[78] Hunter B, Biezen R, Alexander K, et al. Future health today: Codesign of an electronic chronic disease quality improvement tool for use in general practice using a service design approach. *BMJ open.* 2020;10(12), e040228. doi:10.1136/bmjopen-2020-040228

[79] Lee MH, Siewiorek DP, Smailagic A, Bernardina A, Badia SBI. Co-design and evaluation of an intelligent decision support system for stroke rehabilitation assessment. *Proc. ACM Hum.-Comput. Interact.* 2020;4(CSCW2):156. doi:10.1145/3415227

[80] Kurtovich E, Guendelman S, Neuhauser L, Edelman D, Georges M, Mason-Marti P. Development and first phase evaluation of a maternity leave educational tool for pregnant, working women in California. *PLoS One*. 2015;10(6):e0129472. Published 2015 Jun 24. doi:10.1371/journal.pone.0129472

[81] Schnelle JF, Osterweil D, Simmons SF. Improving the quality of nursing home care and medical-record accuracy with direct observational technologies. *The Gerontologist.* 2005;45(5):576-82.

[82] Carman KL, Dardess P, Maurer M, et al. Patient and family engagement: A framework for understanding the elements and developing interventions and policies. *Health Affairs.* 2013;32(2). doi:10.1377/hlthaff.2012.1133

[83] Agency for Clinical Innovation. Co-design Toolkit: Ways of Working Together in Co-design. Accessed on May 8, 2023. Retrieved from https://aci.health.nsw.gov.au/projects/co-design/working-together

[84] Bridgeable. Inclusive Co-design Toolkit: Best Practices for Making Co-design Inclusive of People with Language Barriers. Accessed on May 8, 2023. Retrieved from: https://cdn2.hubspot.net/hubfs/3421112/Inclusive%20Co-design%20Toolkit%20%7C%20Bridgeable-1.pdf

[85] Goodyear-Smith F. Use of codesign in primary care research: real-life examples. *Family Medicine and Community Health.* 2021;9(Suppl 1). doi:10.1136/fmch-2021-001181

[86] Robert G, Macdonald AS. Co-design, organisational creativity and quality improvement in the healthcare sector: 'designerly' or 'design-like'? Design for Service: Key Issues and New Directions. *Bloomsbury Academic.* 2017.

[87] Clarke J, Waring J, Timmons S. The challenge of inclusive coproduction: the importance of situated rituals and emotional inclusivity in the coproduction of health research projects. *Soc Policy Adm.* 2018;53:233–248.

[88] Farrington CJ. Co-designing healthcare systems: between transformation and tokenism. *J R Soc Med*. 2016;109(10):368-371. doi:10.1177/0141076816658789

[89] Beyond Sticky Notes. What is Co-design? A Brief Overview. Accessed May 8, 2023. Retrieved from: https://www.beyondstickynotes.com/what-is-codesign

[90] Kirk J, Bandholm T, Andersen O, et al. Challenges in co-designing an intervention to increase mobility in older patients: a qualitative study. *J Health Organ Manag*. 2021;35(9):140-162. doi:10.1108/JHOM-02-2020-0049

[91] Boaz A, Hanney S, Borst R, O'Shea A, Kok M. How to engage stakeholders in research: design principles to support improvement. *Health Res Policy Syst.* 2018;16(1):60. Published 2018 Jul 11. doi:10.1186/s12961-018-0337-6

[92] Austin J, Van Dijk J, Drossaert C. When theory meets users in co-design: four strategies towards synergy between bottom-up and top-down input. In: Boess S, Cheung M, Cain R, eds. *Synergy - DRS International Conference 2020*. 2020. doi:10.21606/drs.2020.152

[93] Carman KL, Dardess P, Maurer M, et al. Patient and family engagement: a framework for understanding the elements and developing interventions and policies. *Health Aff (Millwood)*. 2013;32(2):223-231. doi:10.1377/hlthaff.2012.1133

[94] Andersen PVK, Mosleh WS. Conflicts in co-design: engaging with tangible artefacts in multi-stakeholder collaboration. *CoDesign.* 2021;17(4):473-492. doi:10.1080/15710882.2020.1740279

[95] Slattery P, Saeri AK, Bragge P. Research co-design in health: a rapid overview of reviews. *Health Res Policy Syst*. 2020;18(1):17. Published 2020 Feb 11. doi:10.1186/s12961-020-0528-9

[96] Ní Shé É, Harrison R. Mitigating unintended consequences of co-design in health care. *Health Expect*. 2021;24(5):1551-1556. doi:10.1111/hex.13308

[97] Patient-Centered Outcomes Research Institute (PCORI). Compensation Framework, Version 1.0. Published June 10, 2015. Accessed July 18, 2023. Retrieved from: https://www.pcori.org/sites/default/files/PCORI-Compensation-Framework-for-Engaged-Research-Partners.pdf

[98] Patient-Centered Outcomes Research Institute (PCORI). Budgeting for Engagement Activities. Published October 2020. Accessed July 18, 2023. Retrieved from: https://www.pcori.org/sites/default/files/PCORI-Budgeting-for-Engagement-Activities.pdf

[99] Simões AS, Maia MR, Gregório J, et al. Participatory implementation of an antibiotic stewardship programme supported by an innovative surveillance and clinical decision-support system. *J Hosp Infect.* 2018;100(3):257-264. doi:10.1016/j.jhin.2018.07.034

[100] Carroll C, Marsden P, Soden P, et al. Involving users in the design and usability evaluation of a clinical decision support system. *Computer Methods and Programs in Biomedicine.* 2002;69(2):123-135.