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Partnering With Stakeholders to Inform the Co-Design of a Psychosocial Intervention for Prenatally Diagnosed Congenital Heart Disease

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Abstract
Input from diverse stakeholders is critical to the process of designing healthcare interventions. This study applied a novel mixed-methods, stakeholder-engaged approach to co-design a psychosocial intervention for mothers expecting a baby with congenital heart disease (CHD) and their partners to promote family wellbeing. The research team included parents and clinicians from 8 health systems. Participants were 41 diverse parents of children with prenatally diagnosed CHD across the 8 health systems. Qualitative data were collected through online crowdsourcing and quantitative data were collected through electronic surveys to inform intervention co-design. Phases of intervention co-design were: (I) Engage stakeholders in selection of intervention goals/outcomes; (II) Engage stakeholders in selection of intervention elements; (III) Obtain stakeholder input to increase intervention uptake/utility; (IV) Obtain stakeholder input on aspects of intervention design; and (V) Obtain stakeholder input on selection of outcome measures. Parent participants anticipated the resulting intervention, HEARTPrep, would be acceptable, useful, and feasible for parents expecting a baby with CHD. This model of intervention co-design could be used for the development of healthcare interventions across chronic diseases.

Keywords
behavioral health, cardiovascular disease, caregiving, community engagement, patient engagement, qualitative methods

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Introduction

Diagnosis of a pediatric chronic disease affects the emotional wellbeing of parents, families, and children (1). Parents of children with chronic diseases report elevated rates of anxiety, depression, and traumatic stress (2,3), which can be stronger predictors of child developmental and behavioral outcomes than medical factors (4,5). For congenital conditions, such as congenital heart disease (CHD), diagnosis may occur prenatally and can lead to substantial stress and trauma for expectant mothers and their partners (6–11). Parent and clinician stakeholders across pediatric chronic diseases emphasize the need for family-based psychosocial interventions soon after the initial diagnosis to prevent long-term negative psychological effects (9,12–18). While psychosocial interventions have previously been evaluated with families of children with CHD during hospitalization and after hospital discharge (16,17), conceptually driven prenatal psychosocial interventions for mothers expecting a baby with CHD and their partners are currently being developed and tested to address the substantial stress and trauma experienced during this critical stage (N. Kaspian, personal communication, January 20, 2022) (19).

Input from patients and parents with lived experience is critical to the process of designing and testing healthcare interventions (20). Rigorous models of intervention development include stakeholder engagement as a core component (21,22). Patient and parent input, typically obtained through qualitative interviews or focus groups, is used to define and refine the basic elements of the intervention to support feasibility and acceptability (21). Consistent with core features of participatory action research (23), patients and parents should be active partners in the research process, including developing the research questions, identifying meaningful goals and outcomes, interpreting results, and deciding what actions should occur in response to the research findings. Including patients and parents as active partners in the process of intervention design is a departure from more traditional, investigator-led approaches and is increasingly gaining momentum in pediatric research (24–27). However, included stakeholders are often not culturally, socioeconomically, linguistically, or gender diverse (24,26–28). The resources required to engage in the research process (eg, time, transportation, childcare, language translation) may deter patients and parents from underserved or minority communities from volunteering and may inhibit research teams from engaging underrepresented groups. Additionally, mistrust of the healthcare system due to historical and ongoing discrimination likely serves as a barrier (29).

Models of intervention co-design that facilitate engagement of diverse groups at every phase are needed to ensure acceptability and feasibility for all stakeholders and could result in more effective intervention strategies. This paper describes a novel five-phase, mixed-methods, virtually-based approach to co-design healthcare interventions with parent stakeholders from diverse backgrounds and demonstrates how the results inform the co-design of HEARTPrep, a psychosocial intervention to promote family wellbeing following prenatal diagnosis of CHD.

Methods

Parent Participants

Participants were parents of children with CHD (ages 6 months to 5 years) who were diagnosed prenatally and underwent cardiac surgery during infancy at 1 of 8 health systems within PEDSnet (30). PEDSnet is a national network established to support the efficient conduct of pediatric research and quality improvement across institutions (30). Inclusion criteria included the ability to read and write in English or Spanish and access to the internet on a smartphone, tablet, or computer. Only one parent per family was eligible to participate to ensure independence of participant data. Parents/guardians not involved in the child’s prenatal care (eg, caregivers who assumed care after birth) were not included.

Research Partners

The research team included clinician research partners (CRPs) and parent research partners (PRPs). CRPs were 8 healthcare providers from each of the 8 health systems within PEDSnet. CRPs were selected based on their roles in the care of fetal or neonatal patients with CHD and their families within their respective health systems, while also intentionally including a range of disciplines (fetal and pediatric cardiology, neonatology, psychology, and nursing). Four parents (2 mothers and 2 fathers from 4 families) were identified by the CRPs and invited to serve as PRPs based on their relevant CHD experiences, with intentional inclusion of parents representing a range of racial and ethnic backgrounds. They were paid for their time on the project (31). CRPs assisted with participant recruitment, and both PRPs and CRPs contributed to study development, results interpretation, and intervention design through monthly phone/virtual meetings and frequent email correspondence.

Participant Recruitment

Participants were selected using maximum variation purposeful sampling to identify variation and shared patterns in perspectives across heterogeneous groups (32). Over 2 months (December 2019-February 2020), CRPs identified approximately 12 eligible parents within each health system who represented a range (ie, maximum variation) of racial and ethnic backgrounds, including both English- and Spanish-speaking mothers and fathers, with the goal of enrolling a diverse sample of 50 parents. Identified parents were provided with a flyer about the study in person or by email/text. The flyer was available in English/Spanish and included an electronic...
Participants were paid per question/survey response. They were posted within Yammer for quantitative data collection. The study received Institutional Review Board (IRB) approval, and the eConsent process and data collection, management, and analysis were conducted at Nemours Children’s Hospital, Delaware.

**Data Collection and Intervention Co-Design**

Data collection was a multiphasic, iterative process completed between February and December 2020 and including both qualitative (Phases I-III) and quantitative (Phases IV-V) data to inform the co-design of HEARTPrep (Table 1). Qualitative data were collected through Yammer using crowdsourcing (35), which engages an online community to generate ideas and produce results (see Sood et al (36) 2021 for a review of crowdsourcing methods for qualitative data collection). Study questions were translated into Spanish by a bilingual team member and then posted to the English- and Spanish-language private online Yammer groups. Online postings included 2 to 4 questions each, with 2 weeks between postings, for a total of 28 questions. The first set of posted questions was selected a priori by the research team to elicit a range of feelings and experiences related to prenatal diagnosis of CHD (How did you learn that your baby may have a heart condition? Who told you and how did they tell you? What do you remember most about the days and weeks after finding out that your baby may have a heart condition? What stands out to you?). The 26 subsequent questions were informed by participant responses to prior questions (Table 1). Participants received notifications through the Yammer app and email when questions were posted and provided responses of any length using their mobile device or computer. Participants could also view and comment on other participants’ responses (ie, interact as a “crowd” (36)). Links to 2 REDCap surveys were also posted within Yammer for quantitative data collection. Participants were paid per question/survey response.

**Data Analysis**

Qualitative data were analyzed using an inductive thematic approach, focused on subjective perceptions and experiences (37). Parent responses to open-ended questions were extracted from Yammer and uploaded into Dedoose Version 8 (SocioCultural Research Consultants, LLC, Los Angeles, CA). Data were coded through an iterative process led by a three-person coding team (ES, CG, APR), with input from all research team members. To establish inter-coder reliability, the coding team independently coded 4 participants’ complete responses in English (0.86-0.88 pooled Cohen’s kappa coefficient), after which coding disagreements were resolved through discussion. The remaining responses were then divided among the coders for independent coding. All Spanish-language responses were coded by one bilingual team member. Qualitative themes informed the design of HEARTPrep. Quantitative data were analyzed using descriptive statistics.

### Results

**Participant Characteristics**

Of the 50 parents who enrolled in the study, 41 (30 mothers, 11 fathers; 82%) set up an account on Yammer and responded to questions to inform the co-design of HEARTPrep (Phases I-III). All 8 health systems were represented within the final sample, and parents reflected a racially and socioeconomically diverse group, including 8 whose primary language was Spanish (6 provided Spanish-language responses) (Supplemental Material 1). All parents had a living child with CHD at the time of participation. Those who responded to questions on Yammer (n = 41) did not differ from the total enrolled sample on sociodemographic factors (sex, race, ethnicity, education level, annual household income). A total of 23 (19 mothers, 4 fathers) parents subsequently provided input on the preliminary design of HEARTPrep (Phase IV) and 28 (24 mothers, 4 fathers) provided input on the selection of outcome measures (Phase V). The sociodemographic composition of these subgroups did not differ significantly from the total sample.

**Phase I: Engage Stakeholders in Selection of Intervention Goals and Outcomes**

A total of 12 difficult feelings/experiences and 8 helpful feelings/experiences after prenatal diagnosis of CHD were identified from qualitative data (Supplemental Material 2). Based on participant input regarding which feelings/experiences should be targeted through intervention, 4 intervention goals were established: (1) reduce distress (eg, anxiety, depression, anger), (2) reduce social isolation, (3) increase parenting self-efficacy, and (4) increase hope for mothers expecting a baby with CHD and their partners (Table 2).

Many parents indicated that reducing distress and increasing parenting self-efficacy were the most urgent intervention goals, while noting the interrelated nature of all 4 goals and the likelihood that addressing one would improve the others. Several parents noted that reducing distress was a necessary first step in addressing other goals (eg, to be ready to connect with others which could reduce social isolation, to be able to process information that could increase parenting self-efficacy). Many parents noted that addressing these 4 goals through intervention would have likely improved their overall wellbeing (eg, less anxiety, depression, guilt), ability to enjoy and celebrate the pregnancy, relationship
Table 1. Phases of Data Collection and Intervention Co-Design with Parent and Clinician Stakeholders.

| Phase I: Engage Stakeholders in Selection of Intervention Goals and Outcomes | Method | Sample questions | Parent participant contributions | PRP/CRP contributions |
| --- | --- | --- | --- | --- |
| | Crowdsourcing: 7 open-ended questions over 8 weeks | What do you remember most about the days and weeks after finding out that your baby may have a heart condition? Which of these feelings and experiences were most challenging for you, and why? | • Described feelings/experiences following prenatal CHD diagnosis | • Drafted and refined open-ended questions |
| | | | • Reviewed 20 common feelings/experiences and provided input on which were most important to address (i.e., increase or reduce) through intervention | • Assisted with interpretation of results |
| | | | • Provided input regarding the potential impact of, and optimal timing for, achieving these goals | • Identified intervention goals from parent participant responses |

| Phase II: Engage Stakeholders in Selection of Intervention Elements | Crowdsourcing: 12 open-ended questions over 8 weeks | In the time before your baby was born, what helped you feel less distressed? What conversations, experiences, or actions made you feel more distressed? | For each of the 4 intervention goals: | |
| | | | • Described experiences or actions during the prenatal period that they perceived as helpful in achieving this goal | • Drafted and refined open-ended questions |
| | | | • Described experiences or actions during the prenatal period that they perceived as not helpful in achieving this goal | • Assisted with interpretation of results |
| | | | • Identified supports and resources they wish they had received to achieve this goal | • Identified intervention elements from parent participant responses |
| | | | • Provided input on how intervention elements should be delivered to increase uptake and utility | |
| | | | • Provided input on the utility of including partners and extended family members in the intervention | |
| | | | • Provided input on when intervention elements should be presented to expectant parents to increase uptake | |

| Phase III: Obtain Stakeholder Input to Increase Intervention Uptake/Utility | Crowdsourcing: 9 open-ended questions over 6 weeks | At what point during the pregnancy would you have liked to receive information on how to connect with other parents of a child with CHD? | • Provided input on how intervention elements should be delivered to increase uptake and utility | |
| | | | • Provided input on the utility of including partners and extended family members in the intervention | • Drafted and refined open-ended questions |
| | | | • Provided input on when intervention elements should be presented to expectant parents to increase uptake | • Assisted with interpretation of results |
| | | | • Reviewed preliminary description of HEARTPrep (summarized and presented through text and graphics in REDCap) | • Determined how and when intervention elements should be delivered based on parent participant responses |
| | | | • Rated the acceptability, | |

| Phase IV: Obtain Stakeholder Input on Aspects of Intervention Design | Online survey: 6 Likert scales, 11 open-ended questions | How helpful do you think HEARTPrep will be for parents who find out that their baby has a heart condition before birth? | | |
| | | | • Reviewed preliminary description of HEARTPrep (summarized and presented through text and graphics in REDCap) | • Drafted and refined survey questions |
| | | | • Rated the acceptability, | • Assisted with interpretation of results |
| | | | | • Determined necessary refinements based on (continued)
with their partner, understanding of their child’s medical condition, and ability to make decisions for their child.

**Phase II: Engage Stakeholders in Selection of Intervention Elements**

Six broad categories of intervention elements were identified from qualitative data regarding experiences/actions during the prenatal period that were perceived as helpful or not helpful for achieving each of the 4 intervention goals (Table 3). These categories included (1) normalization and processing of emotions, (2) development of coping skills, (3) strategies for engaging a supportive network, (4) peer-to-peer support, (5) CHD educational tools, and (6) exploring the role of cultural beliefs and faith. Parents who responded in Spanish tended to report a strong reliance on their faith and described fewer experiences with peer-to-peer support and educational tools compared with parents responding in English.

Results supported a modular intervention design, in which the intervention can be subdivided into meaningful units that are implemented in complement with one another (38). The research team determined that **HEARTPrep** will have 3 modules delivered during pregnancy following CHD diagnosis: the *Adjusting* module will focus on reducing distress, the *Connecting* module will focus on reducing social isolation, and the *Preparing* module will focus on increasing parenting self-efficacy (Figure 1). All 3 modules will focus secondarily on increasing hope. Each module will include intervention elements across the 6 broad categories listed above, aimed at achieving primary and secondary module goals (Supplemental Material 3).

**Phase III: Obtain Stakeholder Input to Increase Intervention Uptake and Utility**

In Phase III, participants provided input on how **HEARTPrep** should be delivered to increase intervention uptake and utility. Many participants emphasized that intervention elements should be introduced by their fetal cardiac providers and embedded within their fetal cardiac care, while also being accessible at any time from anywhere. Participants generally described online support (reputable websites, peer-to-peer social networking groups) as most accessible, but added that it was difficult and time-consuming to seek out material from multiple sources. Based on this feedback, the research team decided that the optimal format for **HEARTPrep** would be a comprehensive mobile app, incorporating educational tools and resources that could be accessed at any time as well as live telehealth sessions with a psychosocial provider (eg, psychologist or social worker embedded within the cardiac team).

Participants provided input on the utility of including partners and other family members. Most were in favor of incorporating partners by scheduling one or more telehealth sessions with both partners to allow emotional expression, help partners understand the other person’s coping styles and reactions, and address communication difficulties. Participants were less in...
favor of directly including other family members, noting that family members have varying levels of knowledge about CHD and sensitivity toward its emotional impact. Learning how to cope with and respond to unhelpful comments from family and friends was of interest to many parents. Examples included having access to educational tools that could be shared with family/friends with guidance on how to support expectant parents.

Participants also provided input on the optimal timing of intervention elements during pregnancy to increase uptake. Many parents wished they had received general information about intervention elements, such as professional mental health and peer-to-peer support, from the fetal cardiac team at the time of diagnosis with more detailed information provided over subsequent weeks. Several parents stated they would have been ready to access these intervention elements immediately, whereas others noted they would have appreciated the introduction at the time of diagnosis but needed time to process the diagnosis before engaging with the intervention.

Phase IV: Obtain Stakeholder Input on Aspects of Intervention Design

Twenty-three participants reviewed the preliminary description of HEARTPrep and provided input (Supplemental Material 4). Most respondents indicated that HEARTPrep would be very helpful (91%) and that the topics were very relevant (96%) for mothers and partners expecting a baby with CHD, though the importance of tailoring resources and supports as needed (eg, for single parents) was noted. Several parents emphasized the importance of facilitating peer-to-peer interaction (eg, providing information about peer-to-peer support options locally and through national organizations, such as Mended Little Hearts and Conquering CHD) in addition to reading about or listening to the experiences of other parents. The need for flexibility and an individualized approach to timing was a consistent theme that emerged from open-ended responses. Some parents felt the intervention could be condensed to ensure all elements have been completed in the case of preterm birth, whereas others felt that more time within a specific module would be helpful.

Most respondents (87%) reported favorable feedback regarding participation through a mobile app, with the vast majority (96%) noting that HEARTPrep would be very convenient. The need to access information and resources at any time was a consistent theme that emerged from open-ended responses. A few parents indicated that an app could allow them to participate in an intervention that they otherwise would have declined due to competing demands such as childcare responsibilities and medical appointments. While overall parents supported the use of telehealth within HEARTPrep, responses were mixed (78% liked telehealth “very much,” 17% “mostly,” and 4% “somewhat”). Many parents noted telehealth may be the most practical and accessible option for families who live far from the hospital; however, parents added that telehealth does not fully replace in-person interactions and that having an in-person option may be beneficial. The
**Table 2.** Intervention Goals and Representative Quotes Supporting the Need for Each Goal.

| Intervention goals          | Representative parent quotes                                                                                                                                                                                                 |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reduce distress             | • “I remember crying almost throughout the rest of my pregnancy and asking myself if I did anything wrong … I had already lost my first pregnancy so it was a lot to bear. My husband wasn’t around throughout the period and I just had to stay strong.” Parent 10  
• “Lots of fear, insecurity, worry … I didn’t have the slightest clue about such a severe heart problem and to know that my daughter had it was very distressing. On top of everything else, having just moved to a new country, for me to get this news, the language was the hardest thing. I didn’t know my way around the big hospital and to know that I had to be there for one to two months was very depressing.” Parent 110 (translated from Spanish) |
| Reduce social isolation     | • “My husband and I didn’t know anyone with a heart baby. Everyone we knew had healthy kids. They complained about things that we didn’t have the time or energy to even think about. Even the people we thought we could count on couldn’t understand. Some even pulled back completely.” Parent 15  
• “I went to almost all of my appointments alone. My doctor never asked me why I was alone. I would have liked for them to be more involved with my husband. For me it was really hard. I cried a lot because my husband wasn’t with me.” Parent 106 (translated from Spanish) |
| Increase parenting self-efficacy | • “I felt completely out of control. The next half of my pregnancy was completely in the doctors’ hands and I no more had a say … I felt like all my decisions were no longer mine and I was just going through the motions being told what to do and when to do it.” Parent 39  
• “I don’t think I fully felt prepared for the road ahead. I was not prepared for a feeding tube, giving daily shots to our baby and the possibility of surgery on day 2. This was all so new to us and we were also new parents as well. It was so challenging and very overwhelming … And in the first couple days after our son was born, my wife was at another hospital recovering from a C-section. So as a brand new dad who had never changed a diaper, to be there with my son in the hospital was hard.” Parent 14 |
| Increase hope               | • “For me, having faith was not praying that her heart would magically become whole … it was knowing that God is faithful even if I were to lose her. That her time on earth was not in vain. And that I would love her with all of my heart regardless of what may happen in the future.” Parent 31  
• “In my hours of internet research I came across the fact that [Olympic athlete] was born with [the same] defect … We still had so many challenging emotions, but knowing that someone could overcome that defect and be a great surfer, skater, and Olympic snowboarder was at least a ray of hope that she would not necessarily spend her whole life ‘packed in cotton.’” Parent 5 |

The importance of ensuring accessibility for diverse families was also emphasized (eg, content provided in multiple languages, captions for individuals with hearing impairment).

**Phase V: Obtain Stakeholder Input on Selection of Outcome Measures**

Twenty-eight participants reviewed items from the PROMIS item banks for Emotional Distress (Depression, Anxiety, and Anger) (39), Social Isolation (40), General Self-Efficacy (41), and Meaning and Purpose (42), which were designed using item response theory to allow custom short forms to be created that yield comparable, standardized scores. Participant input regarding which items were the best fit for mothers expecting a baby with CHD and their partners informed the creation of custom PROMIS short forms to measure intervention outcomes (distress, social isolation, parenting self-efficacy, hope) (Supplemental Material 5).

**Discussion**

This project engaged parent and clinician stakeholders across 8 health systems to inform the co-design of an intervention to improve family wellbeing following prenatal diagnosis of CHD. The 5 phases of co-design were achieved using a combination of online crowdsourcing and survey-based methods in under 12 months. This approach could be adopted for the development of stakeholder-informed interventions across a range of chronic diseases.

Results support the need for an individualized approach to psychosocial intervention. HEARTPrep intervention elements were perceived as relevant to almost all parent participants as they are intended to address common challenges among expectant parents following prenatal diagnosis of a congenital anomaly (eg, self-blame, interpersonal challenges, lack of emotional preparedness) (9). However, participants reported varying needs regarding intervention timing and duration and the involvement of partners. Modular approaches are flexible by design (38) and may be especially useful for facilitating flexible delivery of intervention elements to culturally diverse families due to their ability to balance research evidence with individualized family needs (43). Just-in-time adaptive intervention designs, which aim to provide the right type and amount of support at the right time by adapting to the individual (44), may be particularly well suited to address the individualized needs of families affected by chronic disease.
The need for accessibility was emphasized throughout all phases. For parents expecting or caring for a child with chronic disease, competing demands, distance from the care center, and limited resources are likely to prevent many from accessing psychosocial intervention (18). Disproportionate intervention delivery to those with greater resources can widen health disparities (45). As a result of the COVID-19 pandemic, the use of virtual healthcare (eg, telehealth) has increased substantially (46). Even for families who could travel to the care center for psychosocial intervention, the ability to access intervention elements via mobile app at the time they are needed most and from a place that is comfortable and convenient is likely to enhance utility. A universally accessible app can also facilitate psychosocial intervention for families in the context of limited psychosocial resources within a particular healthcare setting. While intervention via mobile app, including telehealth, seems to meet needs for accessibility, in-person delivery of certain intervention elements should be offered as an option to facilitate the therapeutic relationship.

Many parents emphasized the importance of incorporating a focus on faith and cultural beliefs into intervention. Mental health and behavioral interventions have traditionally not included a strong emphasis on faith or cultural beliefs; however, more recent efforts to tailor interventions to specific ethnic and cultural groups have resulted in an increased focus on the role of culture and faith (47,48). The effects of cultural tailoring for intervention uptake and effectiveness are not yet well understood (48). In this study, faith was frequently described as central to the process of adjusting to and coping with CHD, particularly among Spanish-speaking parents, who were less likely to report having accessed peer-to-peer support or educational tools. Despite an increase in informational resources and peer-to-peer support options for parents of children with CHD over recent years, many of these resources are not available in languages other than English. Translation of resources initially created by and for English-speaking families may result in materials that are not optimally culturally relevant or sensitive. Intervention development research should include non-English-speaking participants to ensure intervention elements are accessible, useful, and relevant for culturally and linguistically diverse groups.

**Limitations**

While the ability to contribute to intervention co-design using a mobile device likely reduced barriers to participation for many parents, this methodology excluded parents with low literacy or...
without reliable Internet access. Despite the use of a sampling strategy that prioritized racial and ethnic diversity, the resulting sample differed from the broader population of parents of children with CHD with regard to education level (59% with college or graduate degree) and family structure (90% living with a spouse/partner). It will be important to evaluate through future research whether HEARTPrep is feasible and beneficial for underserved populations, with adaptations made as needed. Incorporating components of implementation science into future research evaluating HEARTPrep may help to promote the systematic uptake of research findings into routine care for diverse families receiving a prenatal diagnosis of CHD (49). All Spanish-language responses were coded by one bilingual team member after achieving inter-rater reliability on English-language responses. While coding in the original language is generally recommended as meaning may be lost from the participant’s implicit expression when translated before coding (50), inter-rater reliability achieved with English-language responses may not fully generalize to Spanish-language responses. Lastly, while PROMIS item banks were designed to allow the creation of customized short forms with comparable standardized scores, PROMIS short forms have not previously been tested in this specific population. Future research will need to evaluate the psychometric properties of the custom short forms created to measure intervention outcomes.

Conclusion
This study demonstrated that engaging parent and clinician stakeholders to inform the co-design of a psychosocial intervention is feasible over a relatively short period of time using a five-phase approach that incorporated online crowdsourcing and survey-based methods. This study resulted in the preliminary design of HEARTPrep, which is currently being pilot tested at Nemours Children’s Hospital, Delaware with mothers expecting a baby with CHD and their partners. This approach to intervention co-design could be adopted for other disease groups, thereby incorporating diverse stakeholder perspectives into the design of much-needed psychosocial interventions for patients and families.

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Declaration of Conflicting Interests
The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval
Ethical approval to conduct this study and report the results was obtained from the Nemours Institutional Review Board (IRB# 1395313).

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Statement of Human and Animal Rights
All procedures in this study were conducted in accordance with the Nemours Institutional Review Board’s IRB# 1395313 approved protocol.

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Supplemental Material
Supplemental material for this article is available online.

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