Title: Theory-based and Person-centered Approach to Design a Digital Tool for Improving Lifelong Congenital Heart Disease Care

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Abstract

There is a critical need to support patients with congenital heart disease (CHD), especially during their young adulthood, to help maintain lifelong care with adult CHD specialists. The near ubiquitous use of digital tools, especially among the young adults, offers potential solutions to develop effective, scalable, accessible, and sustainable strategies to support these patients. This study describes the development of a digital tool using the combination of theory-based behavioral analysis, semi-structured interviews with 54 patients and clinicians, and community-based participatory research approaches. Four hopes for the digital tool emerged: easy access to credible resources, uplifting of patient voices, customizing to patient needs, and centering positivity and joy. The digital tool, named by community partners as Empower My Congenital Heart (EmpowerMyCH), is web- and mobile-based, Apple- and Android-compatible. Key intervention components include a digital medical passport, expert and peer advice, and peer support. EmpowerMyCH redefines how we support patients to be actively involved in their care and could potentially reduce some care gaps.

Keywords: digital health, behavior change, congenital heart disease, person-centered

Introduction

It is recommended that individuals with congenital heart disease (CHD) receive ongoing lifelong care with clinicians specialized in managing CHD.[1] Yet, up to 85% experience care gaps. These gaps are most pronounced when transitioning from pediatric to adult care but can present throughout their adult life.[2–6] Those with care gaps are at risk of poor outcomes, including higher emergent admissions, costs of care, and mortality.[7–10] While various health system-, provider- and patient-level factors have been described for these care gaps,[2,11–14] there is lack of accessible, scalable, and sustainable strategies to reduce the care gaps and improve the quality of life (QoL) for CHD patients.

According to the Chronic Care Model, supporting patient activation skills—defined as the knowledge, ability, willingness, and confidence to manage one's health and care—can result in an engaged patient and, thus, reduced care gaps, better outcomes, and cost savings.[15,16] Studies among adolescents and young adults have demonstrated that clinic-based processes (nurses, transition clinics) can support patient activation skills resulting in timely CHD clinic visits and better QoL.[17–19] While these findings are promising, these processes remain poorly adopted in many US and non-US centers.[20] One possible explanation is that interventions that rely solely on clinic-based processes are challenging to deliver reliably due to missed clinic visits, variability inherent to delivery (e.g., by nurse vs. physician), available resources (e.g., patient navigators), and limited clinic time.[11,20–22] Furthermore, interventions delivered during clinic visits can sometimes overwhelm patients and may not effectively reach members of the patient's support network. Hence, it is important to identify tools that may help foster skills in patient activation but that can be implemented outside of the clinic. Such tools can augment individualized patient-clinician care, allowing for more efficient use of valuable clinic resources, and they can scale up to meet demand.

Digital healthcare interventions can reach a broad patient population while providing a unique opportunity to support patient activation skills.[23–26] More than 95% of patients rely on smartphones for online access, especially racial/ethnic minorities, lower-income patients, and young adults.[27] Patients with CHD have reported positive perceptions of mobile health interventions.[28,29] However, there are lack of digital interventions to promote patient engagement skills for the diverse CHD patients. We, therefore, developed a browser and mobile app-based tool called "Empower My Congenital Heart (EmpowerMyCH)" to enhance the uptake of a patient activation intervention.

Developing an effective digital healthcare intervention requires a strong theoretical foundation to understand the critical factors leading to an intervention's failure or success in producing the desired outcomes.[30] Furthermore, using the Community-Based Participatory Research (CBPR) approach in designing interventions allows scientific researchers to partner with the impacted communities and obtain direct input from the target users, thus addressing social determinants of health.[31] This paper provides a detailed report of the iterative development process of the EmpowerMyCH digital tool components, which were designed using theory-based and person-centered approaches to intervention design, evaluation, and implementation. The methods and findings can inform others developing interventions to improve care for CHD and other chronic conditions.

Methods

Overview of the intervention development process. The fundamental aim of a person-centered approach is to ground the development of behavior change interventions in understanding the perspective and psychosocial context of the people who will use them, gained through iterative, in-depth qualitative research. This is a vital part of the intervention development to ensure (at a minimum) that interventions are usable, acceptable, and engaging.[32,33] Initially, we created a set of philosophic principles for EmpowerMyCH (**Table 1**) that served as a guide for patients and health professionals to identify and incorporate intervention components. An overview of the patient activation intervention development is shown in **Figure 1** and described in detail below.

Behavioral frameworks:

Theory-based interventions are recommended when designing complex approaches to behavior change. The Behavior Change Wheel (BCW) theoretical model was primarily used to design the patient activation intervention within the EmpowerMyCH digital tool. To make the interventions equitable and relevant to diverse CHD patients, we incorporated the principles of digital health equity, diffusion of innovation, and behavioral economics in its design and adoption (**Table 2**).[34–36]

The BCW framework is based on multiple models of health behavior and is designed to enable the systematic development of interventions for supporting behavior change. The BCW has been identified as most effective at changing individual health behavior in various cardiac and noncardiac chronic conditions but hasn't yet been explored in use to improve care for CHD.[37–42] At its core (or hub of the wheel) is the COM-B model, which consists of three necessary conditions for a given '**B**ehavior' to occur: (1) '**C**apability' (psychological/physical); (2) '**O**pportunity' (physical/social); and (3) '**M**otivation' (reflective/automatic). Capability, Opportunity, and Motivation can be subdivided into 14 further constructs (domains) within the Theoretical Domains Framework (TDF).[38] Exploration of a given behavior in relation to the COM-B and/or TDF components helps identify which psychological determinants need to be addressed to achieve behavior change. The BCW framework then supports the selection of intervention functions and policy categories. Intervention function refers to broad categories of ways an intervention can change a behavior. As applicable, one or more of these intervention functions can be chosen and applied depending on the COM-B component targeted for change. The nine intervention functions described in BCW include education, persuasion, incentivization, coercion, training, restrictions, environmental restructuring, modeling, and enablement. Policy categories comprise the final outer layer, or the wheel's rim, and help identify the types of policy categories one may wish to consider to further influence the drivers of behaviors (COM-B).

We collaborated with communities to adapt the BCW components to support CHD patient activation skills.

Qualitative Semi-structured Interviews:

A trained research assistant recruited CHD patients (≥18 years) and clinicians. Patients were identified from UCSF using chart review and contacted. Patients from outside UCSF were recruited through our community partners. All patients underwent an informed consent process and completed a demographic questionnaire at the end of their interview. We purposefully sampled patients to achieve demographic, geographic, and socioeconomic diversity, including patients with and without at least a 3 year gap in care throughout their adult life.[1] Patients with intellectual disabilities who could not provide informed consent were excluded. Clinicians included adult congenital or pediatric cardiology nurses, doctors, coordinators, board-certified patient advocates, and program leaders from UCSF and outside UCSF. The final sample size was determined based on theoretical saturation.[43] Interviews were conducted using a semi-structured guide comprising of open-ended questions to explore barriers and enablers to patient engagement in care and attitudes and opinions toward the use of a digital tool for overcoming challenges related to patient engagement. We explored content domains within the COM-B framework. Interviews were conducted over video conference calls, and the audio was recorded. Each interview lasted between 45-60 minutes and was professionally transcribed. A combination of inductive and deductive coding was completed by at least two independent coders per transcript. We created a structured data matrix using Rapid Qualitative Analysis[44] to identify various themes and subthemes for patient activation and digital health perspectives.

Community-Based Participatory Research:

The goal of the research team in recruiting community partners (https://empowermych.eurekaplatform.org) was to represent diverse perspectives in CHD care. They included 21 members comprising 11 patients or family members who are racially and geographically diverse, six pediatric or ACHD physicians, a social worker, an ACHD nurse, two nurse practitioners, and six advocacy representatives, some of whom represented more than one role. Our community partnering organizations included the Adult Congenital Heart Association (ACHA), Conquering CHD, The Mended Hearts, and Team Uncle Joe.[45–48] The community partners have been involved in all aspects of the EmpowerMyCH planning, design, execution, implementation, and dissemination. This involves, but is not limited to, reviewing the existing literature; drafting and finalizing the EmpowerMyCH design and features philosophies and branding; reviewing and sharing personal experiences related to intervention content and design; and partnering throughout the iterative prototype testing process. They have also helped with the recruitment of participants for qualitative interviews and in the implementation, evaluation, and dissemination of the EmpowerMyCH tool. One of our patient partners (JV) leads the creation of a design guide to ensure consistency and uniformity in our intervention materials, building of the EmpowerMyCH website (empowermych.org), and develops strategies to elevate participant experience. Our community members have shared their stories as part of the intervention content and partnered as co-authors in scientific and community writing and dissemination. These activities are planned through hourly monthly meetings with all the community members and weekly meetings with community research partners (two patients and two clinicians).

Results:

COM-B determinants of behaviors: We interviewed 54 participants (37 patients and 17 clinicians) to understand the various determinants for barriers and enablers to ACHD patient engagement. The median age of the patient participants was 32 years; 57% were women, 3% Alaska Native or Native American/White, 21% Asian, 15% Black or African American, 18% Hispanic or Latino, 3% Native Hawaiian or Pacific Islander, 35% White, 3% Other, 3% Declined, 41% had some college or less education, and 35% had three or more years of gaps in cardiology care. Using the COM-B domains allowed us to develop an ACHD patient activation framework to guide our intervention development (**eTable 1**). We also identified four emerging hopes that the participants described from the digital tool. These included i) Easy access to credible resources; ii) Uplifting of patient voices; iii) Customization to patient needs; and iv) Centering positivity and joy (**eTable 2**).

CHD-related Unique Challenges to Inform Intervention Design and Features:
The findings from the literature review, qualitative methods, and CBPR approach informed our intervention design objectives and key features to address challenges uniquely faced by CHD patients. These challenges centered around users' perspectives, loneliness, feasibility, accessibly, credibility, and scalability (**Table 3)**. The design objectives and intervention features were developed during the design phase to ensure that the intervention within EmpowerMyCH addresses the diverse and co-occurring needs of the users. While the BCW model is available and used in other disease states, the aspects/challenges unique to CHD were prioritized in our theory-based intervention framework.

Digital Research Platform: The EmpowerMyCH digital tool is hosted on the Eureka Research Platform, a digital research infrastructure implemented by personnel at the University of California, San Francisco (UCSF). The UCSF Institutional Review Board (IRB#22-36667) reviewed and approved the Eureka platform and the EmpowerMyCH study. Studies on the Eureka Research Platform follow a user-centered approach, with the study design and content undergoing iterative revisions in response to participant feedback, research collaborations, new scientific or public health findings, and newly developed research questions arising during the research.[49] The electronic consent process allows easy recruitment and engagement of patients from anywhere using QR codes or web links without the active involvement of a research coordinator. Third-party vendors of cloud services have been vetted for their security practices and meet or exceed privacy and security standards for UCSF electronic research health records management. UCSF established a Business Associate Agreement with Amazon Web Services to host the Eureka Platform. Eureka is built for web and smartphones, including Apple iPhones and Android-based phones, and can be translated into any language to facilitate the recruitment of non-English speakers. Established Eureka "messaging queue," successfully applied in other trials, involves combinations of app-based notifications, text messages, and emails to nudge participants and facilitate behavior changes.[50,51]

Registration in EmpowerMyCH involves entering basic information (name, email, and date of birth) on the Eureka platform to avoid duplicate participants and ensure they meet study eligibility, followed by creating a new study profile. Persons are then logged into the study and can provide electronic informed consent. The Eureka platform facilitated enrollment of CHD patients in other Eureka studies, such as the Health eHeart and Congenital Heart Initiative.[52,53] Once an account is created within Eureka, the participant uses the same Eureka account irrespective of the study they are participating in but signs the study-specific electronic informed consent.

The community members developed the EmpowerMyCH logo and branding for use within and outside the digital platform. The EmpowerMyCH name with an arrow in the logo was chosen to reflect the primary goal of uplifting and empowering patients. Red, blue, and purple colors were chosen to reflect the diversity within CHD lesions and their uniqueness from other heart diseases.

Patient Activation Intervention: The primary behavioral target of the intervention within the EmpowerMyCH tool includes enhancing CHD patients' activation and engagement skills, which is expected to enhance patient experience and improve health outcomes (**Figure 2).** The BCW was used to identify six intervention functions (Education, Training, Environmental Restructuring, Modeling, Persuasion, and Enablement) and mapped them to the intervention components within each of the Capability, Opportunity, Motivation, and TDF domains (**Table 4**).[54] For example, modeling the benefits of timely ACHD specialist visits through patient experiences to highlight things such as better quality of life and reduced complications, target **O**pportunity (social influences), and **M**otivation (community connections, knowledge-sharing, and self-efficacy) domains.

EmpowerMyCH Participant Journey: The participants can engage in EmpowerMyCH activities on the mobile app on their smartphone or a web browser on their preferred device. Participants receive EmpowerMyCH activities every 2 months (**Figure 3)**. Each activity includes surveys, exhibits and linkages to the wearables or patient portal. Surveys are meant to gather self-reported data about the participants, their feedback for exhibits, and allows them an opportunity to share their stories or ask any questions (**eTable 3**). Exhibits are concise insights from CHD experts and patients to help boost participant's confidence and knowledge in navigating their CHD. Community partners identified seven priority themes based on user needs that determined the exhibit content (**eTable 4**). Exhibit content in the first month includes standards of care and key considerations when finding an ACHD team. Through an iterative process, the community members develop a structure (three takeaways) for each exhibit content and then curate the existing credible resources to carefully craft the exhibits to have actionable items and references (links or resources) for in-depth information. All the materials are designed using a design guide (**eTable 5**) to ensure uniformity and consistency and enhance readability for the participants. All exhibits (https://empowermych.org/resources) include a combination of knowledge-based information, 'Empowerment' and 'Peer Empowerment' quotes, and sometimes trivia questions to test knowledge on a topic (**Figure 4)**. "Empowerment" quotes are motivational, confidence-building messages from healthcare providers and experts designed to reinforce the patient's role as an active participant in their care. "Peer Empowerment" quotes are similar messages and stories shared by other CHD patients designed to persuade the participants using emotion, optimism, and social influences. All the content can be modified or newly designed if needed on an on-going basis, depending on user needs and preferences or as new information or resources become available. Finally, participants can connect their patient portal, smartphone data (Apple Health or other health data), or wearable device (FitBit) accounts to their EmpowerMyCH account. This information helps us gain insights into the experiences and behaviors of CHD patients, supporting research and understanding of CHD.

Each set of activities are available for 2 months for the participants to complete. The participant can go back and change draft responses within a survey, but they cannot change responses within the app after submitting the survey. The surveys completed by the participants in the third and fourth months after joining allow them to automatically build their personal digital medical passport, a hub for their vital health information. Once built, the medical passport is always accessible inside the mobile app (**Figure 5**).

Engagement in EmpowerMyCH: Enhancing engagement in digital clinical studies is a challenge, and we have employed several engagement approaches. We send a push notification to participants at the time the activities become available. In order to address various time zones as well as work schedules, we send 3 reminders at three different times of the day before the next set of activities are available for the participants. Reminders are sent via emails followed by a delayed push notification in the app and a delayed SMS text message (push and SMS are only sent if the activities are not completed before the delay) with a link to the Eureka app. The SMS text message is deliberately utilized less frequently than the mobile app-based notification to be less intrusive.

A unique engagement strategy in this study is the "Poke", which is incorporated into the participant flow approximately every other month. The day when the Poke is sent is intentionally variable to avoid predictability and to invoke intermittent reinforcement. The content of the Poke is highly variable, ranging from stories/experiences/questions shared by users, important study updates (e.g., new features), study results, new CHD research, CHD fun facts, and new CHD studies that participants might be eligible for. The Pokes are sent to all the participants at one point in time, irrespective of how long the participant has been in the study.

Reach and scalability: We aim to recruit and engage a representative CHD population, particularly those with a high risk for gaps in care (rural residence, men, lower socioeconomic status, those living far away from CHD centers, etc.) and those not previously engaged in research. Mobile phones are nearly ubiquitous - 96% of Americans (and 94% of ACHD patients) in their twenties and thirties own a mobile phone, and reliance on them for online access is especially common among young adults, non-Whites, and lower-income

Americans.[27,28,55] This provides us with a huge opportunity to enhance the reach and scalability of our digital health-based intervention to various subgroup of CHD patients. We are optimistic that with the use of digital health equity and diffusion of innovation frameworks, and the versatility of options for our digital intervention (cross-platform low bandwidth content delivery with opportunities for translation, etc.), our intervention will be relevant to the most representative CHD population. We are also working on releasing a Spanish version to target the 15-20% of ACHD patients who are primarily Spanish-speakers.

Discussion

We describe a theory-based and person-centered approach to developing a patient activation intervention for CHD patients to navigate their CHD and healthcare. To our knowledge, this is the first web- and mobile-based (Android and Apple compatible) digital intervention to enhance the confidence and skills of diverse CHD patients to engage in their care. Our approach drew on the evidence-base and large qualitative studies to map out targets for patient engagement, intervention success, and intervention design solutions, linking these to theory focusing on behavior change and implementation.[1,2,30,56] Our CBPR approach throughout intervention planning and development ensured that the views of CHD patients and the clinicians who will support them were incorporated into the design. The intervention enables CHD patients to access content at their convenience and passively, guided by user-friendly principles and the nudge concept. Also, we allow the participants to build connections with their peers and actively contribute to improving the health and well-being of the entire CHD community. Our experience provides insights into the process of developing a theory-based digital intervention for patients with other chronic conditions.

Adults with lifelong health conditions exhibit substantial challenges in engaging in their care. Currently, clinic-based processes (navigators, nurse educators, etc.) are proposed to enhance knowledge and provide support but these are not widely adopted, and patients continue to experience care gaps. We thus sought to develop a digital tool to enhance engagement skills outside clinic visits. The EmpowerMyCH tool aims to foster skills in patient engagement by augmenting rather than replacing individualized patient-provider focused care; and thus, allowing for more efficient use of the valuable clinic resources. While an increasing number of digital platforms are being utilized to address care gaps for specific populations, the major concern exists regarding sustainability. We have thus used the Eureka Digital Research Platform, developed at UCSF with support from the National Institutes of Health (NIH), for digitizing and mobilizing health research.[49] The technology is owned and operated by the UCSF, a not-for-profit public university, and led by the UCSF Division of Cardiology investigators (GMM being one of them). Furthermore, Eureka supports standardized digital recruitment methods, electronic consent (eConsent) and HIPAA authorization, eligibility assessment, baseline activities, randomization, and follow-up data collection while delivering intervention components within the same platform or through simple integration with another platform as needed. With hundreds of studies currently hosted on the Eureka platform, these features allow for a cost-efficient and sustainable platform for EmpowerMyCH.

We could have considered alternative theory-based approaches, such as Intervention mapping, used in a prior CHD transition intervention in Sweden.[56] However, we preferred BCW since this approach is less prescriptive for behavior change and has been used in prior digital interventions.[26,30,57] Another commonly used comprehensive determinant framework, the Consolidated Framework for Implementation Research (CFIR), is a reasonable alternative or complementary approach to BCW theory to plan, implement, and evaluate behavior change interventions.[58] Overall, the process of mapping the behavioral domains of the theoretical models to address important barriers or design intervention components enabled us to detail the content of our intervention in a transparent way using a shared language from taxonomy and theory and was also crucial for documenting the proposed theory of action of the intervention.[54] Complementing this approach, the person-centered approach ensured that target users' needs were understood and accommodated to maximize engagement and implementation.[33] This technique was crucial, as it allowed us to create person-centered materials to fulfill the CHD patients' healthcare and psychosocial needs—by incorporating both expert and peer guidance. It also prevented us from re-creating existing educational content or materials and enabled us to simultaneously address barriers to engagement and implementation and design the intervention components. The only difficulty of adopting a theory- and person-centered approach is that the entire process is time-consuming, and it may not be feasible to complete with limited resources. However, this approach is flexible and can be adapted depending on the available resources. For example, it may be reasonable to supplement qualitative studies with rapid stakeholder consultation.[59]

Many barriers to behavior change identified within our qualitative study were similar to those reported in the literature.[2] However, the qualitative and CBPR methodology allowed us to develop a deeper insight into the context of the barriers, determine which barriers to prioritize, identify appropriate enablers to patient engagement, and determine digital tool features acceptable to the users. For example, we knew that some CHD patients are unaware of or might not recognize the need to establish or maintain care with an ACHD specialist, especially when they are otherwise feeling well. We attempted to address this knowledge gap with evidence-based information in our intervention material. However, qualitative interviews and CBPR feedback indicated that we had to incorporate patient stories and real-life scenarios to underscore the importance of the message. This led to the “Empowerment” and “Peer Empowerment” quotes and patient stories being critical elements to use as modeling and to boost the participants' confidence. This highlights how valuable qualitative and CBPR approaches are in designing behavioral interventions, prototype testing, and refining, even when barriers are known, and teams are experienced.

We recognize that the digital tool is accessible only to people with a smart device or computer with internet access. However, since the tool is available on web and/or native iOS and Android applications, we can reach >90% of the Americans. Also, to allow people with limited bandwidth to still benefit, we focused on accessibility and readability of our materials on any device and provide access to all the exhibits on our webpage and via an email to the participants. Although we attempted to incorporate many diverse perspectives throughout the design, but it is possible that we did not account for the views held by members or organizations not included in this initial phase of intervention development. However, the EmpowerMyCH infrastructure is very responsive to participant feedback and research collaborations, thus allowing for us to continuously adapt. For example, any future intervention component (e.g., mental health, physical activity) or patient-educational materials can be implemented and tested within the existing infrastructure. The EmpowerMyCH tool began recruitment in September 2024 (with 400+ active participants) and is currently undergoing testing for its acceptability and feasibility outcomes. Currently, patients ≥ 18 years old who can speak English are eligible to participate. We are actively working to linguistically and culturally adapt EmpowerMyCH for Spanish-speaking patients. Individuals with intellectual disabilities are currently excluded due to the complexities involved in addressing their unique needs and our belief that the intervention may need to focus more on their caregivers.

This theory-based and person-centered digital tool aims to provide CHD patients with the necessary tools, resources, and support to become activated and involved while feeling confident as they navigate CHD and healthcare. The ongoing EmpowerMyCH process evaluation studies will help understand how each intervention component is relevant or less important for the intended outcomes, making it possible to refine and tailor the intervention further, allowing for future hybrid comparative effective trials. If proven effective, it can be implemented in other chronic conditions as the strategies and outcome of the intervention are relevant for other chronic conditions. Furthermore, the EmpowerMyCH digital infrastructure allows for rapidly recruiting diverse CHD patients in future research or health policy efforts.

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Abbreviations:
BCW: Behavior Change Wheel theoretical model
CBPR: Community-Based Participatory Research
CFIR: Consolidated Framework for Implementation Research
COM: Capability, Opportunity, and Motivation of the Behavior Change Wheel theoretical model
COM-B: Capability, Opportunity, Motivation for Behavior Change
CHD: Congenital Heart Disease
eConsent: electronic consent
EmpowerMyCH: Empower My Congenital Heart
HIPAA: Health Insurance Portability and Accountability Act
iOS: iPhone Operating System
NIH: National Institutes of Health
SMS: Short Message Service
TDF: Theoretical Domains Framework of the Behavior Change Wheel theoretical model
QoL: Quality of life
QR code: Quick response code
UCSF: University of California, San Francisco
US: United States

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Figure Legends:

Figure 1: Overview of Person-based Approach for EmpowerMyCH Planning and Development Process
Behavioral frameworks combined with semi-structured interviews and an iterative design process through a community-based participatory research approach, optimized the key objectives to build patient activation and empowerment skills to reduce gaps in congenital heart disease (CHD) care. This led to the creation of Empower My Congenital Heart (EmpowerMyCH) digital tool.

Figure 2: Congenital Heart Disease (CHD) Patient Activation Intervention within EmpowerMyCH
The intervention components within the mobile and web-app include expert and peer guidance, digital medical passport, and peer connections. These components function as tools for providing education, training, enablement, persuasion, modeling, or environmental restructuring to enhance the Capability, Opportunity, and Motivation domains of CHD patients. Our hypothesis is that this will support CHD patients' activation and engagement skills, ultimately improving patient experience, reduce gaps in care and improve health outcomes.

Figure 3: Participant Flow Through EmpowerMyCH
EmpowerMyCH is available on mobile app or on web. Participant creates a University of California San Francisco (UCSF) Eureka Research account as the first step. They are then prompted to read and sign the EmpowerMyCH consent form. Once they sign the consent form electronically, a participant receives study activities (surveys, Exhibits, and the opportunity to link their health data) and a 'Poke' every two months.

Figure 4: Exhibit Content in EmpowerMyCH
The exhibit content includes various materials such as educational information and referenced resources enhancing patient knowledge. Exhibit content also includes trivia questions to increase patient engagement, "Peer Empowerment" quotes (messages and stories shared by other CHD patients), and "Empowerment" quotes (CHD provider messages).

Figure 5: Digital Medical Passport
By answering a series of surveys in the third and fourth months after joining, participants within EmpowerMyCH automatically build their own personal hub for their vital health information, the digital medical passport. This is an example of the type of health information easily accessible to participants at any time when using the EmpowerMyCH mobile app.

Table 1. EmpowerMyCH Philosophy

Characteristics designed to foster credibility

- Explicitly evidence-based, using scientific rationale for behavioral theories
- Expert guidance for content creation (e.g., CHD follow-up guidelines)
- Person- and theory-informed approach at all stages of design and evaluation to meet individual needs of the target CHD population
- Non-commercial, developed by the named team of medical and behavior change experts

Characteristics designed to encourage uptake and long-term engagement

- Nimble, user-friendly interface with lay-person oriented messaging, leveraging existing tested capabilities and proven methods of the digital research platform
- Simplicity, with direct, concise, and actionable messaging designed to foster participants' capabilities, opportunities, and motivation
- Proactive, repetitive content delivery using nudge principles rather than relying on patients to seek out information, enhancing its reach and impact
- Mechanisms for modeling and sharing experiences within the user community, aimed at boosting self-efficacy and promoting positive affect among participants

Table 2. Theoretical Frameworks in the Design of EmpowerMyCH

Frameworks	**Summary of the Theoretical Frameworks for Improving ACHD Care**
Behavioral Change Wheel (BCW)	**1.** Define health problem in behavioral terms (e.g., patient engagement in navigating the health system, timely visits) **2.** Understand determinants of behavior (Capability, Opportunity, Motivation for Behavior Change- COM-B Model) **3.** Select intervention functions i.e. means by which an intervention changes behavior (e.g., education, enablement, persuasion, and training)
Digital Health Equity	Apply concepts of: **1.** Health literacy: **i)** use plain and clear language, **ii)** include relevant content: assume no background knowledge of participants, avoid cognitive burden from too much information and use simple numbers and percentages to develop content, **iii)** format conducive to comprehension, **iv)** content appeals to users of different identities and backgrounds **2.** Readability: sixth-grade reading level or lower **3.** Ease of Use
Diffusion of Innovation	Engaging all levels of adopters (highly engaged and less engaged CHD patients) and CHD champions in the design, adoption, and dissemination of the intervention
Behavioral Economics	Nudge and defaults in designing the digital tool to alter behavior and facilitate the decision-making process

Table 3. EmpowerMyCH Design Objectives and Intervention Features Unique to CHD

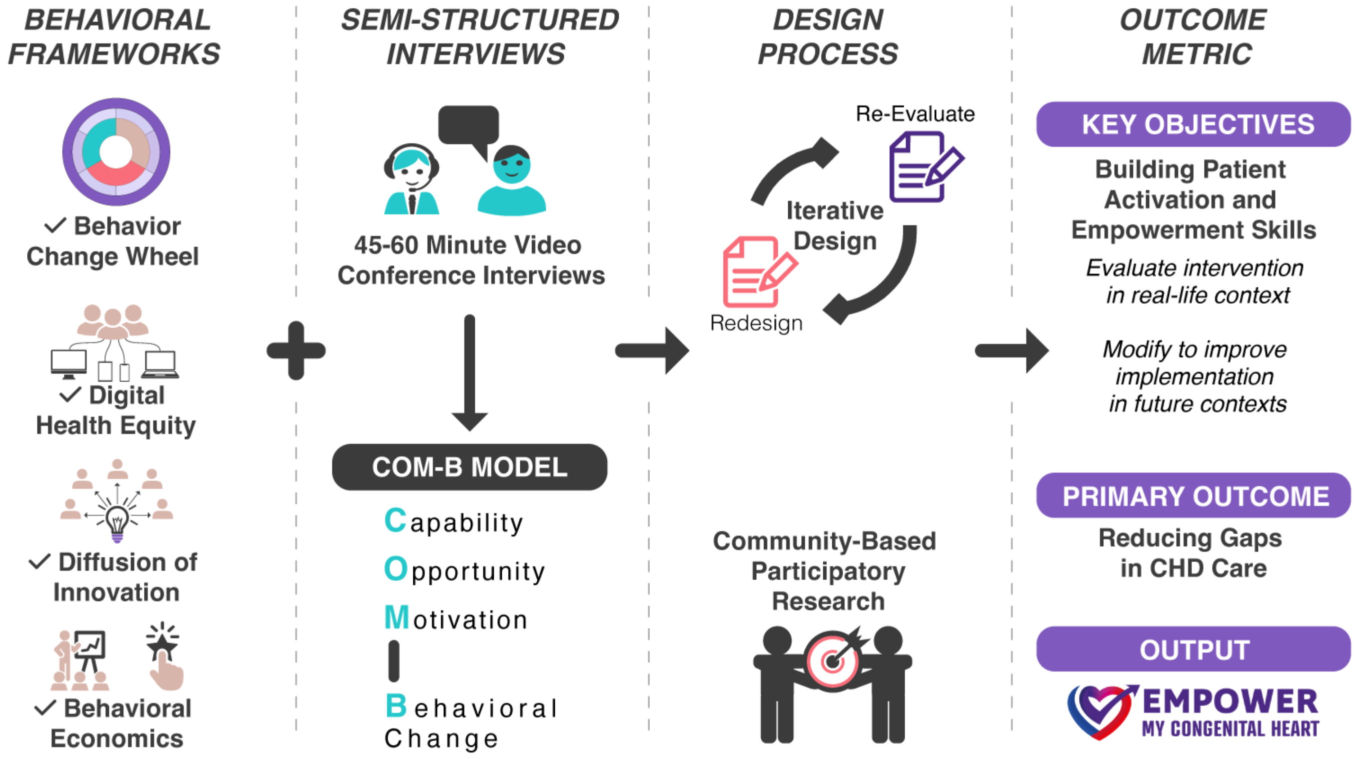
Key Findings	Design Objectives	Key Intervention Features
Perspectives: CHD patients might not understand the need to establish or maintain care with an ACHD specialist especially when they are otherwise feeling well. At times, they may prefer to avoid thinking about their heart to prevent their health condition from interfering with their life	An approach which promotes well-being, rather than illness management	• Empowering tone—Focus on the patient as the hero of their journey, avoiding language that centers on illness or portrays them as passive recipients of care • Building motivation for changes from first user contacts and in recruitment materials • Begin with simple, concise interventions, such as clarifying basic terms like the distinction between defect and disease, while offering the option for users to explore more detailed resources • Allowing users to engage with intervention elements and information which are most relevant to them
Loneliness: CHD patients often feel lonely in their health journey and don't know how their condition is similar or different compared to others	Build a community	• Patient's narratives shared as "Peer Empowerment" quotes to provide practical guidance • Engage the EmpowerMyCH users in sharing their experiences • Linking resources, including, community events, community building opportunities, or peer-to-peer connections
Feasibility: Given the intervention's goal to target multiple barriers to the behaviors, there was a risk for the intervention to be too large and complex for the project team to satisfactorily develop it for the many unique needs that CHD patients have, especially within the resources available	Efficient and multiphase design	• Phased-development of interventions with the initial phase targeting barriers determined by CBPR participants as key drivers for gaps in ACHD care (e.g., knowledge about CHD care, symptom management, etc.) • Targeting behaviors that can achieve multiple outcomes (e.g., patient activation and engagement which can improve timely ACHD visits, mood, and general illness perception) • Strike balance between making intervention broadly applicable to CHD patients, while ensuring it is relevant and has impactful information for users; while being cost-effective • Continuous Development—Regularly adapt and improve intervention components based on user needs and feedback with the opportunity to modify existing content or create new content or features
Accessibility: Most CHD patients are young and have other priorities	Enabling easy, timely, non-intrusive access to concise information, which can be read and acted on quickly when needed	• Short, succinct, actionable information that users can benefit from in just a few minutes • Mobile friendly—easy to read information that fits on a phone screen • Content delivered to patients using nudge approaches through email, SMS, or app notifications that act as gentle reminders • Contents delivered as small bursts of information over time • Automated delivery of the content, independent of whether users are seeking the information
Credibility: There is an abundance of information, but it isn't reaching the CHD patients, it often seems overwhelming, and it's unclear which one is reliable	Use credible sources for content creation rather than re-inventing content that already exist.	• Partnering with community organizations to curate exiting information • Formatting and delivering content in an easy to understand and readable way • Tailoring content based on repeated feedback from participants about their needs and priorities

Scalability: There could be variations in terms of age, health literacy, prior engagement in care and research, making it difficult to tailor interventions to meet these diverse needs	Design and content tailored to diverse needs	• Use web and mobile based tools, that are cross-platform including Android and iOS • Content formatted for readability irrespective of the quality of device used • Minimize use of formats (e.g., videos, complicated graphics) that have higher broadband needs • All material formatted for 5th grade reading level • Include questions to facilitate anonymous sharing of knowledge and personal stories and experience between the highly engaged and less engaged CHD patients • Build community that supports each other and future generations of patients

Table 4. Behavior Change Wheel (BCW) framework for EmpowerMyCH Tool

BCW Framework			**Intervention Components**
COM domains	**TDF sub-domains**	**COM + TDF based Intervention functions *(definition)***	**Examples of EmpowerMyCH Activities Associated with Interventions Functions**
Psychological **C**apability Reflective **M**otivation	Knowledge Beliefs about capabilities Beliefs about consequences Motivation and goals	Education *(Increase knowledge and understanding)*	Provide information on CHD care guidelines Raise awareness of the need to establish and maintain care with ACHD specialist
Psychological **C**apability Physical **O**pportunity	Memory, attention and decision processes Reinforcement Environmental context and resources	Training *(Imparting skills)*	Use expert and peer guidance to train CHD patients with confident decision making process as they navigate health care Train patients on using tools (e.g., patient portals) to enhance their care experience
Physical **O**pportunity	Memory, attention and decision Processes Environmental context and Resources Social influences	Environmental restructuring *(Changing the physical or social context)*	Provide CHD education components outside the clinic visits, at their own convenience through an app Provide opportunity to carry all their medical information in their pocket all the time through a Digital Medical Passport. Allow easy access to key resources such as ACHD provider directory, CHD community events, etc. on the app
Social **O**pportunity Automatic and Reflective **M**otivation	Social/professional role and Identity Beliefs about capabilities Beliefs about consequences Motivation and goals Optimism Emotion Behavioral regulation Reinforcement	Modeling *(Providing an example for people to aspire to or imitate)*	Use patient stories and experiences to demonstrate and inspire adoption of desired behavior Allow sharing of experiences among the users to develop a sense of belonging and community

Automatic and Reflective **M**otivation	Social/professional role and Identity Beliefs about capabilities Beliefs about consequences Motivation and goals Optimism Emotion	Persuasion *(Using communication to induce positive or negative feelings or simulate action)*	Using influential imagery and/or respected messengers to promote behavior change (e.g., “*Empowerment” and “Peer Empowerment”* quotes)
Psychological **C**apability Physical and Social **O**pportunity Automatic and Reflective **M**otivation	Beliefs about capabilities Beliefs about consequences Motivation and goals Memory, attention and decision Processes Environmental context and Resources Optimism Social influences Emotion Behavioral regulation Reinforcement	Enablement *(Increasing means/ reducing barriers to increase capability beyond education and training, or opportunity beyond environmental restructuring)*	Improve availability and accessibility to credible resources to manage CHD care Nudge or reminders to promote access and adherence to care guidelines Build self-esteem and self-advocacy skills to feel valued partners within the health system



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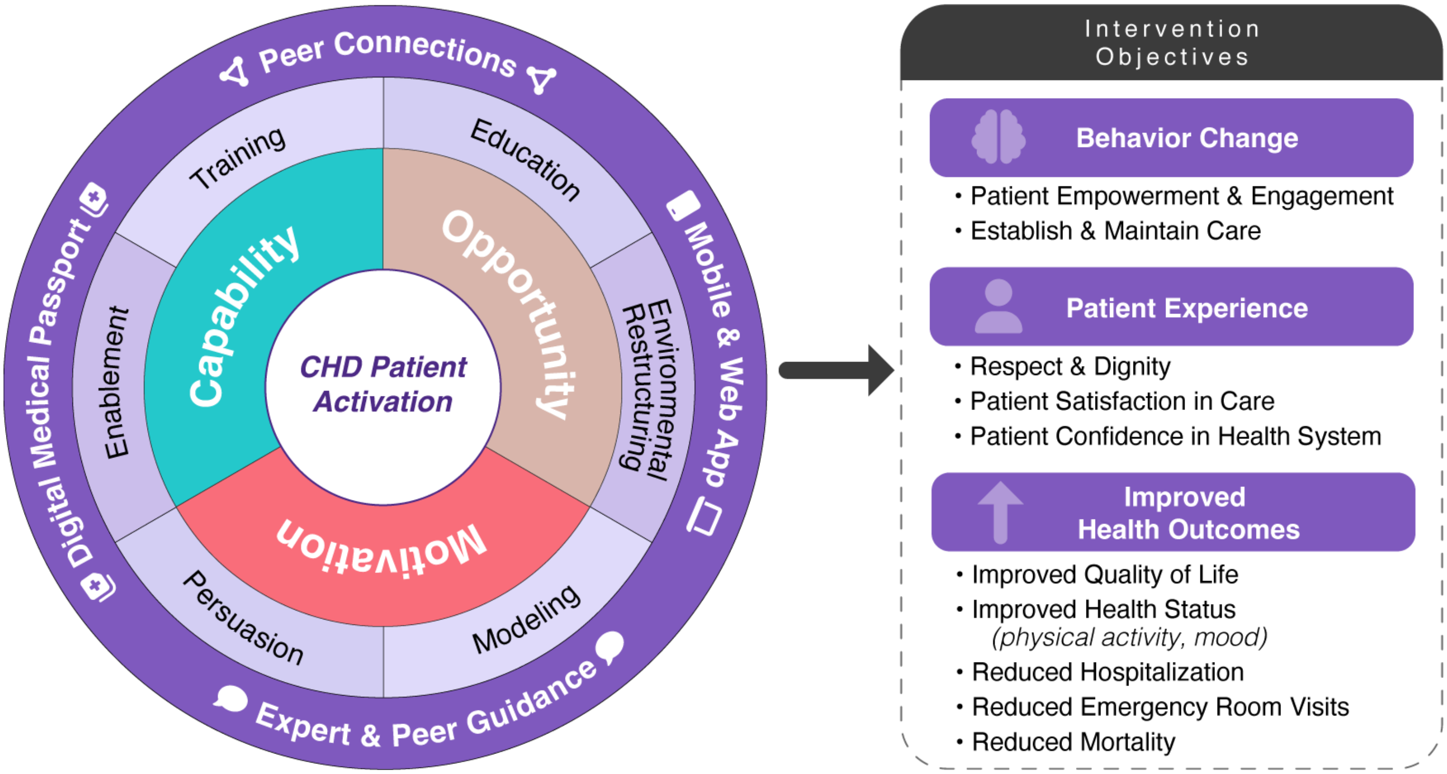

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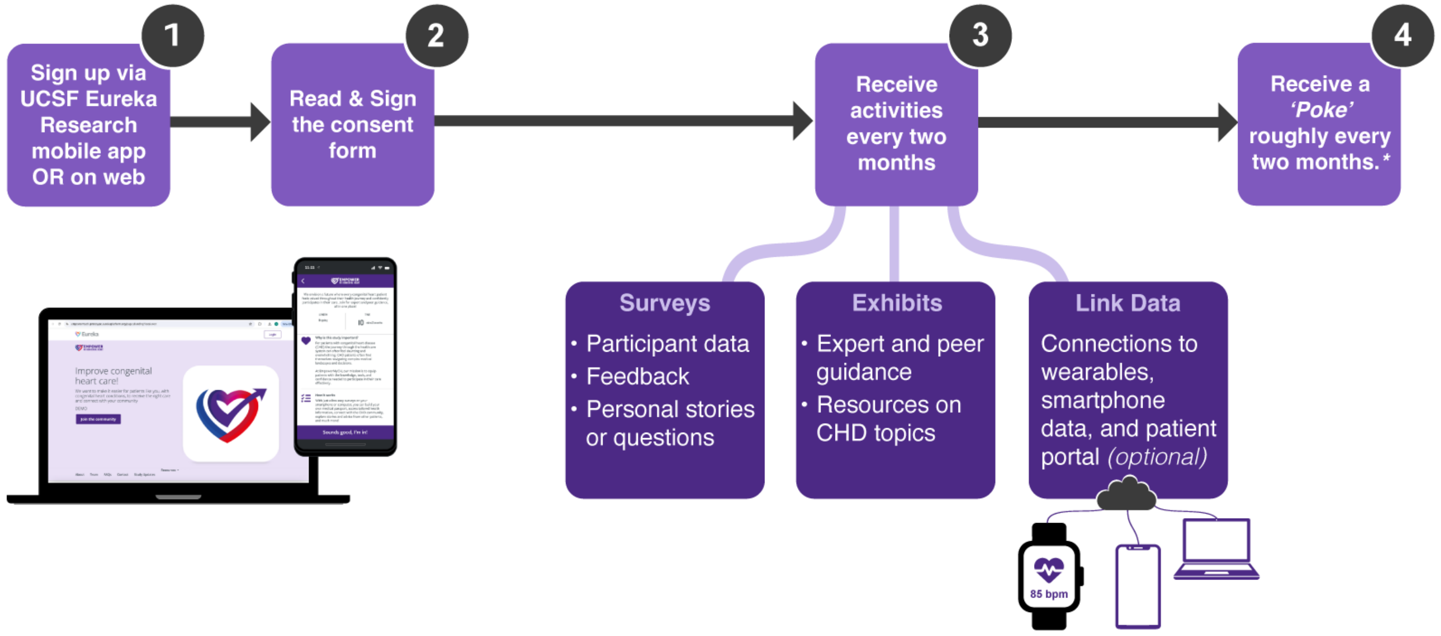

*The content and timing of the Poke are variable. They aim to facilitate the exchange of questions and stories between users while also providing important study updates, such as new features, study results, recent ACHD research, and information about ACHD studies that users might be eligible for.

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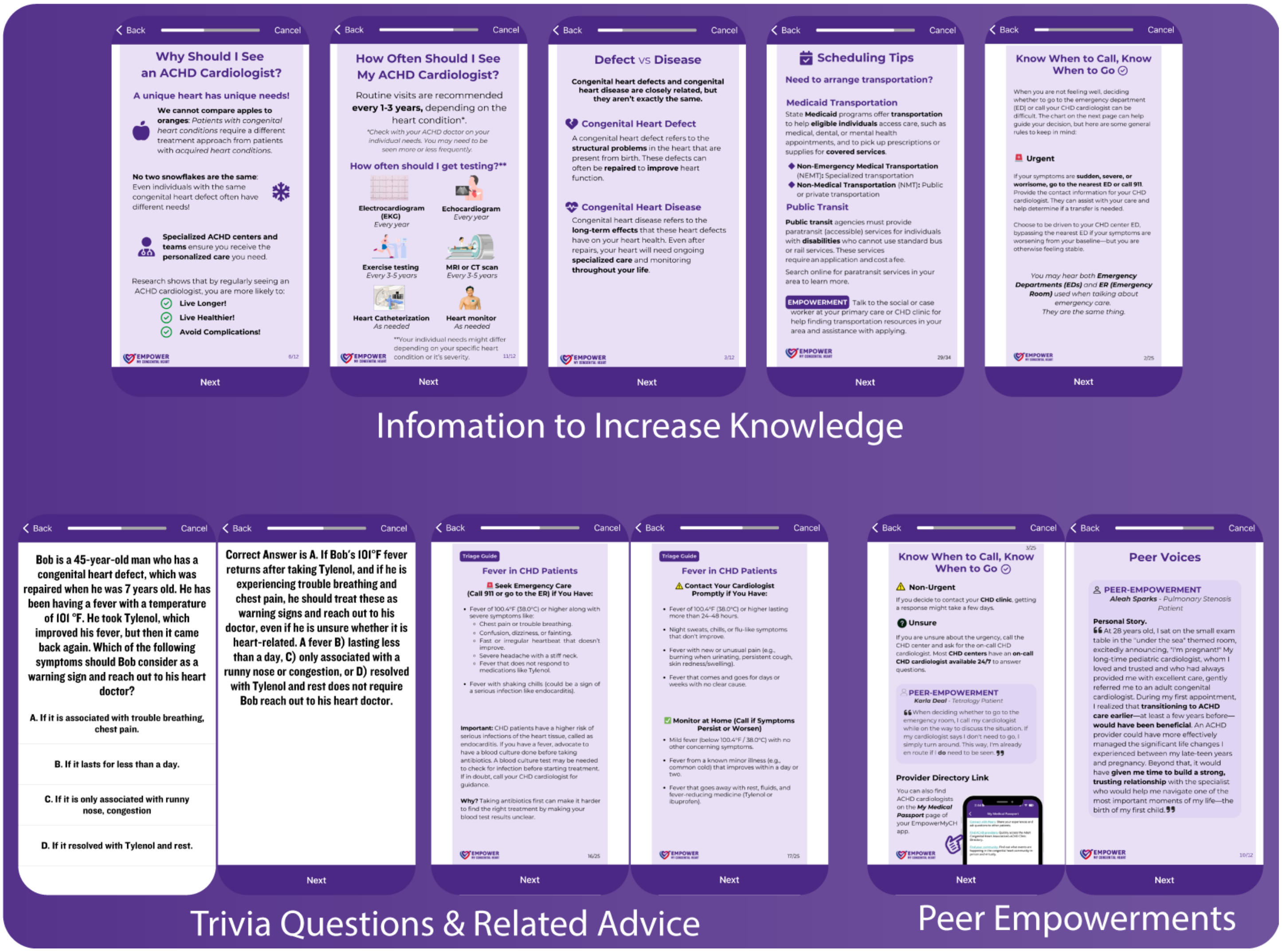

Why Should I See an ACHD Cardiologist?

A unique heart has unique needs!

We cannot compare apples to oranges: *Patients with congenital heart conditions* require a different treatment approach from patients with *acquired heart conditions*.

No two snowflakes are the same: Even individuals with the same congenital heart defect often have different needs!

Specialized ACHD centers and teams ensure you receive the **personalized care** you need.

Research shows that by regularly seeing an ACHD cardiologist, you are more likely to:

- ✓ **Live Longer!**
- ✓ **Live Healthier!**
- ✓ **Avoid Complications!**

6/12

How Often Should I See My ACHD Cardiologist?

Routine visits are recommended **every 1-3 years,** depending on the heart condition*.

**Check with your ACHD doctor on your individual needs. You may need to be seen more or less frequently.*

How often should I get testing?**

Electrocardiogram (EKG) *Every year*

Echocardiogram *Every year*

Exercise testing *Every 3-5 years*

MRI or CT scan *Every 3-5 years*

Heart Catheterization *As needed*

Heart monitor *As needed*

**Your individual needs might differ depending on your specific heart condition or it's severity.

11/12

Defect vs Disease

Congenital heart defects and congenital heart disease are closely related, but they aren't exactly the same.

Congenital Heart Defect

A congenital heart defect refers to the **structural problems** in the heart that are present from birth. These defects can often be **repaired** to **improve** heart function.

Congenital Heart Disease

Congenital heart disease refers to the **long-term effects** that these heart defects have on your heart health. Even after repairs, your heart will need ongoing **specialized care** and monitoring **throughout your life**.

3/12

Scheduling Tips

Need to arrange transportation?

Medicaid Transportation

State **Medicaid** programs offer **transportation** to help **eligible individuals** access care, such as medical, dental, or mental health appointments, and to pick up prescriptions or supplies for **covered services**.

- ◆ **Non-Emergency Medical Transportation** (NEMT): Specialized transportation
- ◆ **Non-Medical Transportation** (NMT): Public or private transportation

Public Transit

Public transit agencies must provide paratransit (accessible) services for individuals with **disabilities** who cannot use standard bus or rail services. These services require an application and cost a fee.

Search online for paratransit services in your area to learn more.

EMPOWERMENT Talk to the social or case worker at your primary care or CHD clinic for help finding transportation resources in your area and assistance with applying.

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Know When to Call, Know When to Go

When you are not feeling well, deciding whether to go to the emergency department (ED) or call your CHD cardiologist can be difficult. The chart on the next page can help guide your decision, but here are some general rules to keep in mind:

Urgent

If your symptoms are **sudden, severe, or worrisome, go to the nearest ED or call 911**. Provide the contact information for your CHD cardiologist. They can assist with your care and help determine if a transfer is needed.

Choose to be driven to your CHD center ED, bypassing the nearest ED if your symptoms are worsening from your baseline—but you are otherwise feeling stable.

*You may hear both **Emergency Departments (EDs)** and **ER (Emergency Room)** used when talking about emergency care.
They are the same thing.*

2/25

Bob is a 45-year-old man who has a congenital heart defect, which was repaired when he was 7 years old. He has been having a fever with a temperature of 101 °F. He took Tylenol, which improved his fever, but then it came back again. Which of the following symptoms should Bob consider as a warning sign and reach out to his heart doctor?

A. If it is associated with trouble breathing, chest pain.

B. If it lasts for less than a day.

C. If it is only associated with runny nose, congestion

D. If it resolved with Tylenol and rest.

Correct Answer is A. If Bob's 101°F fever returns after taking Tylenol, and if he is experiencing trouble breathing and chest pain, he should treat these as warning signs and reach out to his doctor, even if he is unsure whether it is heart-related. A fever B) lasting less than a day, C) only associated with a runny nose or congestion, or D) resolved with Tylenol and rest does not require Bob reach out to his heart doctor.

Triage Guide

Fever in CHD Patients

Seek Emergency Care (Call 911 or go to the ER) if You Have:

- Fever of 100.4°F (38.0°C) or higher along with severe symptoms like:
  - Chest pain or trouble breathing.
  - Confusion, dizziness, or fainting.
  - Fast or irregular heartbeat that doesn't improve.
  - Severe headache with a stiff neck.
  - Fever that does not respond to medications like Tylenol.
- Fever with shaking chills (could be a sign of a serious infection like endocarditis).

Important: CHD patients have a higher risk of serious infections of the heart tissue, called as endocarditis. If you have a fever, advocate to have a blood culture done before taking antibiotics. A blood culture test may be needed to check for infection before starting treatment. If in doubt, call your CHD cardiologist for guidance.

Why? Taking antibiotics first can make it harder to find the right treatment by making your blood test results unclear.

16/25

Triage Guide

Fever in CHD Patients

⚠ Contact Your Cardiologist Promptly if You Have:

- Fever of 100.4°F (38.0°C) or higher lasting more than 24–48 hours.
- Night sweats, chills, or flu-like symptoms that don't improve.
- Fever with new or unusual pain (e.g., burning when urinating, persistent cough, skin redness/swelling).
- Fever that comes and goes for days or weeks with no clear cause.

✓ Monitor at Home (Call if Symptoms Persist or Worsen)

- Mild fever (below 100.4°F / 38.0°C) with no other concerning symptoms.
- Fever from a known minor illness (e.g., common cold) that improves within a day or two.
- Fever that goes away with rest, fluids, and fever-reducing medicine (Tylenol or ibuprofen).

17/25

3/25

Know When to Call, Know When to Go

⚠ Non-Urgent

If you decide to contact your **CHD clinic**, getting a response might take a few days.

Unsure

If you are unsure about the urgency, call the CHD center and ask for the on-call CHD cardiologist. Most **CHD centers** have an **on-call CHD cardiologist available 24/7** to answer questions.

PEER-EMPOWERMENT
Karla Deal *- Tetralogy Patient*

“When deciding whether to go to the emergency room, I call my cardiologist while on the way to discuss the situation. If my cardiologist says I don't need to go, I simply turn around. This way, I'm already en route if I **do** need to be seen.”

Provider Directory Link

You can also find ACHD cardiologists on the ***My Medical Passport*** page of your EmpowerMyCH app.

Peer Voices

PEER-EMPOWERMENT
Aleah Sparks *- Pulmonary Stenosis Patient*

Personal Story.
“At 28 years old, I sat on the small exam table in the "under the sea" themed room, excitedly announcing, "I'm pregnant!" My long-time pediatric cardiologist, whom I loved and trusted and who had always provided me with excellent care, gently referred me to an adult congenital cardiologist. During my first appointment, I realized that **transitioning to ACHD care earlier**—at least a few years before—**would have been beneficial**. An ACHD provider could have more effectively managed the significant life changes I experienced between my late-teen years and pregnancy. Beyond that, it would have **given me time to build a strong, trusting relationship** with the specialist who would help me navigate one of the most important moments of my life—the birth of my first child.”

10/12

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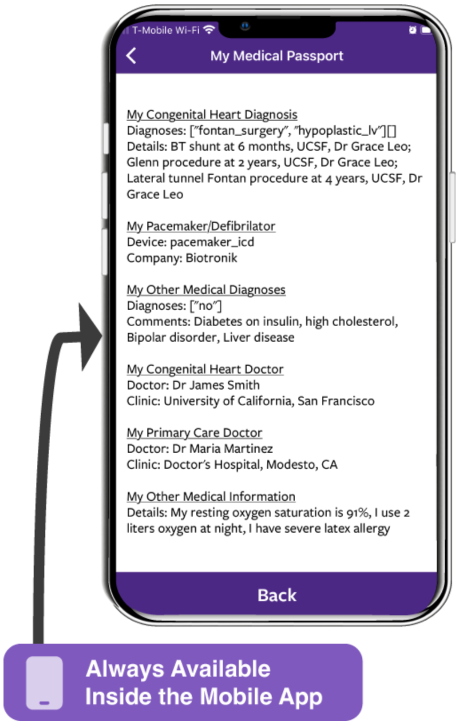

My Congenital Heart Diagnosis
Diagnoses: ["fontan_surgery", "hypoplastic_lv"][]
Details: BT shunt at 6 months, UCSF, Dr Grace Leo; Glenn procedure at 2 years, UCSF, Dr Grace Leo; Lateral tunnel Fontan procedure at 4 years, UCSF, Dr Grace Leo

My Pacemaker/Defibrilator
Device: pacemaker_icd
Company: Biotronik

My Other Medical Diagnoses
Diagnoses: ["no"]
Comments: Diabetes on insulin, high cholesterol, Bipolar disorder, Liver disease

My Congenital Heart Doctor
Doctor: Dr James Smith
Clinic: University of California, San Francisco

My Primary Care Doctor
Doctor: Dr Maria Martinez
Clinic: Doctor's Hospital, Modesto, CA

My Other Medical Information
Details: My resting oxygen saturation is 91%, I use 2 liters oxygen at night, I have severe latex allergy

Always Available
Inside the Mobile App

Figure 5: Digital Medical Passport
By answering a series of surveys in the third and fourth months after joining, participants within EmpowerMyCH automatically build their own personal hub for their vital health information, the digital medical passport. This is an example of the type of health information easily accessible to participants at any time when using the EmpowerMyCH mobile app.

Competing Interests

The authors declare the following competing interests:
Dr. Mark Norris is a Consultant for American College of Cardiology since 2024.

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The National Clinical Trial number is NCT06581484.