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ORIGINAL RESEARCH ARTICLE

# Development and Testing of a Chronic-Disease Patient Experience Mapping Toolbox

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## Abstract

**Background** Stakeholders increasingly expect research and care delivery to be guided by and to optimize patient experiences. However, standardized tools to engage patients to gather high-quality data about their experiences, priorities, and desired outcomes are not publicly available. The objective of this study was to develop and test a Toolbox with a disease-agnostic interview guide template and accompanying resources to assist researchers in engaging patients living with chronic disease in a dialogue about their experiences.

**Methods** Guided by a multidisciplinary workgroup, a targeted literature review (PubMed) was conducted, followed by group discussions to identify/thematically organize patient experience concepts, development of a conceptual model, and drafting of an interview guide template and patient-facing visual. Materials were tested/refined via cognitive ($n = 5$) and pilot ($n = 30$) interviews conducted virtually with US patients diagnosed with chronic/potentially disabling conditions from December 2020 to April 2021. Patient-facing tools were reviewed by health literacy experts for applicability/accessibility. English-speaking adults who self-reported receiving a chronic condition diagnosis at least 6 months prior participated in a 60–90 min interview.

**Results** Patient experience concepts were organized thematically under three domains: (1) life before a diagnosis, (2) experiences getting a diagnosis, and (3) experiences living with a diagnosis. A plain language consent sheet template, interview guide template, and patient experience conceptual model were developed and revised based on input from interviewees, interviewers, and the workgroup.

**Conclusions** A disease-agnostic patient-engagement Toolbox was developed and tested to capture patient experience data. These materials can be customized based on study objectives and leveraged by various stakeholders to identify opportunities to enhance the patient centricity of healthcare delivery and research.

## 1 Background

Engaging patients in a dialogue about their experiences inside and outside the healthcare system often reveals unmet needs, reasons for nonadherence to care plans, or identifies other barriers (or facilitators) to timely, patient-centered care [1]. Patients and other healthcare stakeholders, including regulators, health technology assessment bodies, and research funding bodies, increasingly expect research and care delivery to be guided by and optimize patient experiences [2–4].

The US Food and Drug Administration (FDA) defines patient experience data (PED) broadly as the experiences, perspectives, needs, and priorities of patients related to signs and symptoms that affect day-to-day functioning and quality of life, course of disease over time, treatment experiences, and views on potential tradeoffs between disease outcomes and treatments [5]. PED can be collected using qualitative, quantitative, or mixed methods [6]. Qualitative research methods (e.g., interviews, focus groups), for example, are used to "obtain a deeper understanding of the patient experience" [6] to guide research and healthcare decision-making.

The members of the National Health Council's Patient Experience Mapping Workgroup are listed in Acknowledgements.

Extended author information available on the last page of the article

**Key Points for Decision Makers**

A "Patient Experience Mapping Toolbox," which includes a disease-agnostic interview guide template and accompanying resources has been developed and tested among people with chronic disease. The Toolbox can assist researchers in engaging patients living with chronic disease in a dialogue about their experiences.

Development of the Toolbox was led by the patient community using an iterative process, thus it is likely to account for some of the important, often overlooked, nonclinical aspects of the patient journey (e.g., social determinants of health, sources of information, challenges of misdiagnosis).

Applying these tools reduces the need to develop disease- or study-specific interview guides, increasing efficiency for researchers. In the future, the Toolbox will be updated to close gaps identified by researchers applying the Toolbox.

In 2013, the FDA began conducting disease-specific "Patient-Focused Drug Development" (PFDD) meetings and producing corresponding "Voice of the Patient" (VoP) summary reports. PFDD meetings capture patients' "perspectives on their condition and available therapies to treat their condition" through discussion questions that are standardized across diseases. PFDD meetings have clarified to many stakeholders, especially regulators, that "patients are experts in what is it like to live with their disease or condition and use of available treatments." However, the purpose of PFDD meetings is not to capture comprehensive PED in a scientifically rigorous manner. Data collection is limited to polls, public testimony, and occasionally premeeting surveys [7]. As a result, while PED collected through PFDD meetings is compelling and informative for hypothesis generation, decision-makers are likely to question the extent to which data are representative of target patient populations' experiences and perspectives.

There is broad agreement that patient engagement (i.e., qualitative research among patients) should be transparent, include patients that are representative of target patient populations, and be conducted in a timely manner so PED are available to guide decisions [5, 8, 9]. Numerous academic resources about developing and reporting scientifically rigorous qualitative research are available [10–12]. Tools to evaluate and communicate patient engagement approaches have also been published online and in the peer-reviewed literature [8, 9, 13]. Most are disease specific and thus more limited for use and purpose.

To encourage the collection of patient-reported outcomes data on pain, fatigue, physical functioning, emotional distress, and social role participation, the National Institutes of Health invested in the development of a publicly available resource, the Patient-Reported Outcomes Measurement Information System (PROMIS) [14]. However, no similar initiative to encourage the collection of qualitative data has been funded to date. For example, while the Patient-Centered Outcomes Research Institute (PCORI) requires researchers to engage patients in funded projects and provides an engagement rubric, and researcher training, PCORI does not provide researchers with resources to engage and document patient experiences [9].

Nonproprietary, disease-agnostics tools, such as an inventory of interview questions, to conduct scientifically rigorous qualitative research with patients about their experiences living with a chronic disease(s) are not readily available. In the absence of standardized interview guide templates, researchers develop interview guides de novo, leading to inefficient and inconsistent data collection, and impeding comparisons across studies [15]. Thus, the objective of this study was to develop a user-friendly Patient Experience Mapping Toolbox (Toolbox, from here on) with a disease-agnostic interview guide template and accompanying resources to assist researchers in engaging chronic-disease patients in a dialogue about their experiences in and outside the healthcare system. This manuscript describes the approach to Toolbox development and initial testing to ensure relevance and applicability to a wide range of chronic conditions and demographic characteristics.

## 2 Methods

### 2.1 Study Organization and Oversight

This study received an exempt determination from Advarra's Institutional Review Board (#00045816). An 18-member multidisciplinary workgroup, including patients, patient advocates, and patient engagement experts (employed by nonprofits, life science companies, and patient groups), guided all phases. Members of the workgroup are listed in the acknowledgements. The primary study outcome was developing a publicly available Toolbox for engaging individuals with chronic disease. The workgroup informed that the Toolbox should include a comprehensive interview guide that could be tailored based on the depth needed and study objective, a patient experience conceptual model ("visual") to be used in

tandem with the interview guide, a plain language consent form, and Toolbox-user training materials. Figure 1 shows an overview of development of the Toolbox. It included a targeted literature review to identify patient experience concepts, development of draft materials, cognitive interviews, and pilot interviews. Study methods and results are reported in alignment with the Consolidated Criteria for Reporting Qualitative research (COREQ) checklist for qualitative research.[10].

## 2.2 Development of the Draft Patient Experience Mapping Toolbox

### 2.2.1 Identifying and Organizing Patient Experience Concepts

Patient experience concepts were identified and described in published patient journey maps, frameworks, or conceptual models through a targeted literature search (PubMed), searching websites of patient group members of the National Health Council and workgroup discussion. The targeted literature search included peer-reviewed and gray literature, as well as patient group websites to identify existing patient experience conceptual models and patient journey maps. All searches were conducted in May–June 2019. Since this was not a systematic literature review, only one researcher initially reviewed titles and full-text articles. The eligible articles were saved in a shared folder and extraction of concepts was conducted as a group. We extracted existing journey maps or patient-centered conceptual models (illustrative examples to guide the development of the Toolbox conceptual model), terminology used to describe patients' journeys, and headers/subheaders used in journey maps or conceptual models to identify topics.

Patient experience concepts were extracted and discussed during a workshop among workgroup members in September 2019 (see Supplementary Materials 1 and 2). During the workshop, workgroup members considered a variety of questions, including the following: What concepts must be included? How do we expect the patient journeys to change within the next few years? What ideas can we take from prior maps? What important pieces are missing from current maps? The workgroup added to and organized the concepts through group discussions and originally classified the concepts into two categories: journey to diagnosis and journey with illness after diagnosis (see Supplementary Material 3).

Following further workgroup discussion in October 2019, the categories were refined to (1) life before a diagnosis, (2) experiences getting a diagnosis, and (3) experiences living with a diagnosis. These categories served as the basis for the conceptual model and the draft interview guide. Of note, during one of the workshops, patient workgroup members questioned the use of the term "patient journey," which is a term commonly used in market research and might imply a linear journey from point A to point B. To reflect complexity of diagnostic and healthcare "odyssey's" patient workgroup members preferred "patient experience." Thus, the project was renamed the "Patient Experience Mapping Toolbox" instead of the original title "Patient Journey Mapping Toolbox."

An interview guide template and consent sheet template were drafted based on an earlier qualitative study about atrial fibrillation patient experiences, Patient-Focused Drug Development (PFDD) questions, and de novo [16, 17]. All

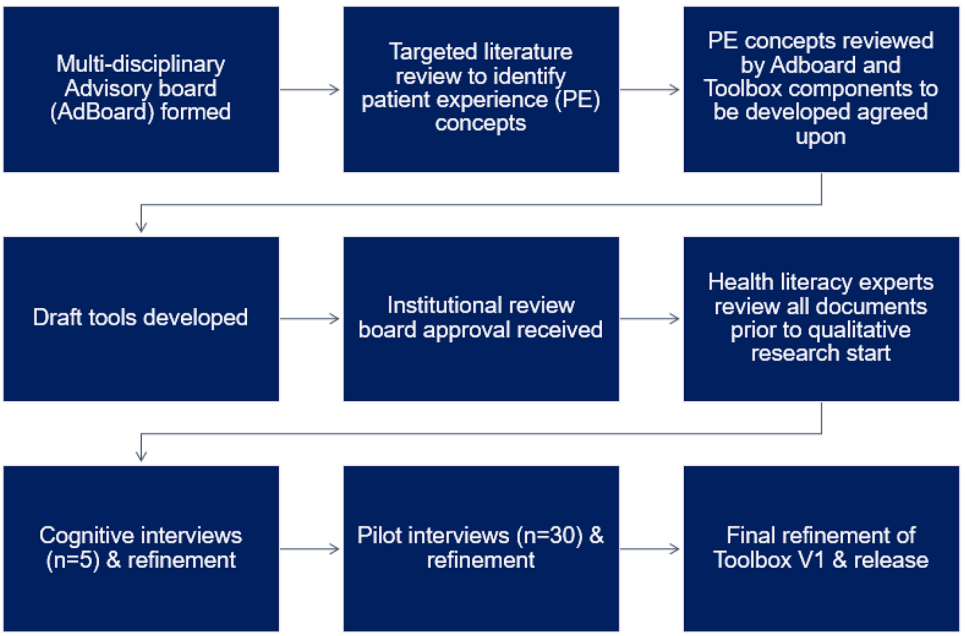


**Fig. 1** Patient experience mapping toolbox development methods

draft materials were first reviewed by workgroup members. Next, an external health literacy consultancy was contracted to review all patient-facing tools (conceptual model, consent sheet, interview guide) to align with health literacy principles [18]. The health literacy consultancy also designed a patient-friendly version of the conceptual model.

### 2.3 Testing and Refining the Patient Experience Mapping Toolbox

The research team conducted 90 min cognitive interviews ($n = 5$) to improve the conceptual model and 75 min pilot interviews ($n = 30$) to expand upon the interview guide template iteratively between December 2020 and April 2021. Interview participants were recruited by a market research vendor and included adults (age of majority in their state), with a self-reported chronic-condition diagnosis at least 6 months prior, could participate in a 60–90 min interview, and could read and communicate in English (see Supplementary Information 4 for complete eligibility criteria). We used the Centers for Medicare and Medicaid Services (CMS) list of chronic diseases to determine whether a chronic condition was "eligible to participate" [19]. Participants were purposefully sampled to ensure diversity and recruited from physician (40%) and patient (60%) panels.

Participants received an information/consent sheet before the interview (Supplementary Information 5). Researchers with qualitative interview experience [Cognitive interviews (TRL, MPH, female), pilot interviewers (EO/Ph.D.; LG/Ph.D.; KM/PharmD; and SS/B.A.; all females; RC/PharmD/male)] conducted the interviews. Interviews were audio recorded, anonymized, and transcribed.

We solicited feedback from participants to refine the tools using two different approaches. We conducted cognitive debriefing interviews for the "Map My Experience" visual aid (see Supplementary Materials for the Interview Guide). To refine the interview guide and consent documents, we asked participants for feedback as part of the interviews. These interview questions are listed in the "Feedback on Tools" section of the interview guide template (see Supplementary Materials). The project team met regularly to discuss additions or modifications needed to improve usability, breadth, and depth of the data collection tools. Specifically, before starting interviews, we determined to modify the interview guide during the cognitive interviews and following each interview. Edits were discussed with the workgroup after cognitive interviews, after the first 10, 20, and 30 pilot interviews.

Transcripts were not returned to participants for comment or correction. Interviewers provided suggestions for enhancing (i.e., adding new interview questions or sections) the interview guide based on their notes following each interview. All participants were compensated in alignment with the patient engagement fair-market value calculator [20].

## 3 Results

The targeted literature search intended to identify patient experience concepts to discuss with the workgroup and ultimately form the basis of an interview guide and conceptual model. The PubMed search initially identified 3178 articles. After deduplicating, titles and abstracts were screened by a single reviewer and 68 articles were determined to be eligible and were included in the qualitative synthesis. The identified literature primarily focused on patient journeys within specific conditions including prostate cancer, diabetes, rosacea, hearing impairments, and rheumatoid arthritis. Our search yielded 40 patient experience concepts, such as seeking care for symptoms, misdiagnosis, and finding a support system (see Supplementary Information 1). The concepts included many concepts related to disease or symptom onset (e.g., no noticeable symptoms, start experiencing symptoms), health system experiences and pathways (e.g., referral to/finding specialists, switching doctor to find "right fit"), and treatment-related experiences (e.g., treatment side effects, unnecessary treatment due to misdiagnosis). Several maps also described impacts on day-to-day life (e.g., effects on activities of daily life, effects on social life).

The concepts were organized into three categories during group discussions: (1) life before getting a diagnosis, (2) getting a diagnosis, and 83) living with a diagnosis. The conceptual model and interview guide template align with these categories.

### 3.1 Participants

Forty-one participants were screened to identify the final sample of 35 participants. No invitees refused; however, some were nonresponsive ($n = 4$) to follow-up or did not appear for the interview ($n = 2$). All participants completed the interview virtually at home. Interviewee demographic characteristics are summarized in Table 1. Supplementary Information 6 lists the complete distribution of chronic diseases across interviewed participants. Since the objective was to test the draft tools among a broad range of individuals with very different patient experiences, we sought to recruit individuals with different diagnoses, ages, ethnicities, and lifestyle factors. Examples of chronic disease diagnoses among interviewed individuals include sickle cell disease, multiple sclerosis, and hereditary amyloidosis.

Changes to the model included additional symbols for clarity (e.g., add pharmacy, clinic, and hospital). Most

modifications occurred during the cognitive interviews or the first 20 pilot interviews. Modifications included defining and expanding upon life-impacting factors and adding personal health goals, diagnosis at birth, systemic bias, and care coordination/multiple chronic conditions.

### 3.2 "Map My Experience" Conceptual Model

The "map my experience" conceptual model of patients' experiences with a chronic disease was developed to engage patients, rather than visually depict a summary of patient experiences with a specific disease. The "map my experience" conceptual model is a visual to guide patient participants through the interview (see Fig. 2). It is organized as winding roads and bridges connecting three islands, one for each domain. It includes cues and text related to the healthcare system, social determinants of health, and healthcare costs. It is not intended and was not tested as a standalone solution, but rather as a tool used in tandem with the interview guide (see Fig. 3). The pathways begin the starting points to account for asymptomatic diseases and symptomatic diseases: "I or someone close to me noticed something was different or I didn't feel right" or "A healthcare provider found a problem."

To ensure the map is a clear and useful tool for participants, we conducted (1) cognitive debrief interviews of the map and (2) asked participants for their feedback of the map during patient interviews. Table 2 provides sample feedback received during both stages of interviews.

Island 1 "life before getting a diagnosis" provides visual cues related to symptom onset, lifestyle changes, information gathering, and other experiences before entering the health system to seek a formal diagnosis. Island 2 explores patient experiences getting a diagnosis, including clinic visits and testing. The third island explores patient experiences living with and treating a chronic disease or disability, including different treatments that were tried, side effects, misdiagnoses, and desired outcomes. The straight pathway represents clear trajectories through each of the islands, whereas the winding pathway represents potential setbacks, misdiagnosis, trying different treatments, and other potential patient experiences. In addition, the conceptual model includes an illustrated list of "life factors" intended to capture any social, economic, and health-related burden that may impact or modify patient experiences across the care continuum. Life factors include the presence or absence of a family and support system, work or student life, housing and access to transportation, healthcare, insurance and access to care, mental health and other health conditions, finances, and other costs.

**Table 1** Demographic characteristics

| Variable | Cognitive debrief interview ($n = 5$) | | Pilot interviews ($N = 30$) | |
|---|---|---|---|---|
| | Frequency ($n$) | % | Frequency ($n$) | % |
| Sex | | | | |
| Female | 4 | 80.0 | 18 | 60.0 |
| Male | 1 | 20.0 | 12 | 40.0 |
| Age (years) | | | | |
| 18–30 | 2 | 40.0 | 6 | 20.0 |
| 31–45 | 1 | 20.0 | 15 | 50.0 |
| 46–64 | 1 | 20.0 | 7 | 23.0 |
| 65+ | 1 | 20.0 | 2 | 6.7 |
| Race and ethnicity | | | | |
| White | 4 | 80.0 | 13 | 43.3 |
| African American | 0 | 0.0 | 8 | 26.7 |
| Hispanic | 0 | 0.0 | 3 | 10.0 |
| Asian | 0 | 0.0 | 1 | 3.3 |
| Multiple races | 1 | 20.0 | 5 | 16.7 |
| Education level | | | | |
| No high school diploma | 1 | 20.0 | 0 | 0.0 |
| High school graduate | 0 | 0.0 | 3 | 10.0 |
| Vocational school | 0 | 0.0 | 2 | 6.7 |
| Associate degree | 0 | 0.0 | 2 | 6.7 |
| Some college | 0 | 0.0 | 5 | 16.7 |
| Bachelors degree | 3 | 60.0 | 12 | 40.0 |
| Graduate degree or higher | 1 | 20.0 | 6 | 20.0 |
| Neighborhood location | | | | |
| Rural | 2 | 40.0 | 3 | 10.0 |
| Suburban | 2 | 40.0 | 18 | 60.0 |
| Urban | 1 | 20.0 | 9 | 30.0 |
| US geographic region | | | | |
| South | 2 | 40.0 | 9 | 30.0 |
| Midwest | 1 | 20.0 | 6 | 20.0 |
| West | 1 | 20.0 | 5 | 16.7 |
| Northeast | 1 | 20.0 | 10 | 33.3 |
| Health insurance coverage | | | | |
| Public | 1 | 20.0 | 16 | 53.3 |
| Private | 3 | 60.0 | 11 | 36.7 |
| Private and public | 1 | 20.0 | 2 | 6.7 |
| Uninsured | 0 | 0.0 | 1 | 3.3 |
| Time since diagnosis | | | | |
| Less than 2 years | 2 | 40.0 | 3 | 10.0 |
| 2–5 years ago | 1 | 20.0 | 13 | 43.3 |
| 5–10 years ago | 2 | 40.0 | 6 | 20.0 |
| 10+ years ago | 0 | 0.0 | 8 | 26.7 |


**Fig. 2** National Health Council's "Map My Experience" patient-facing conceptual model

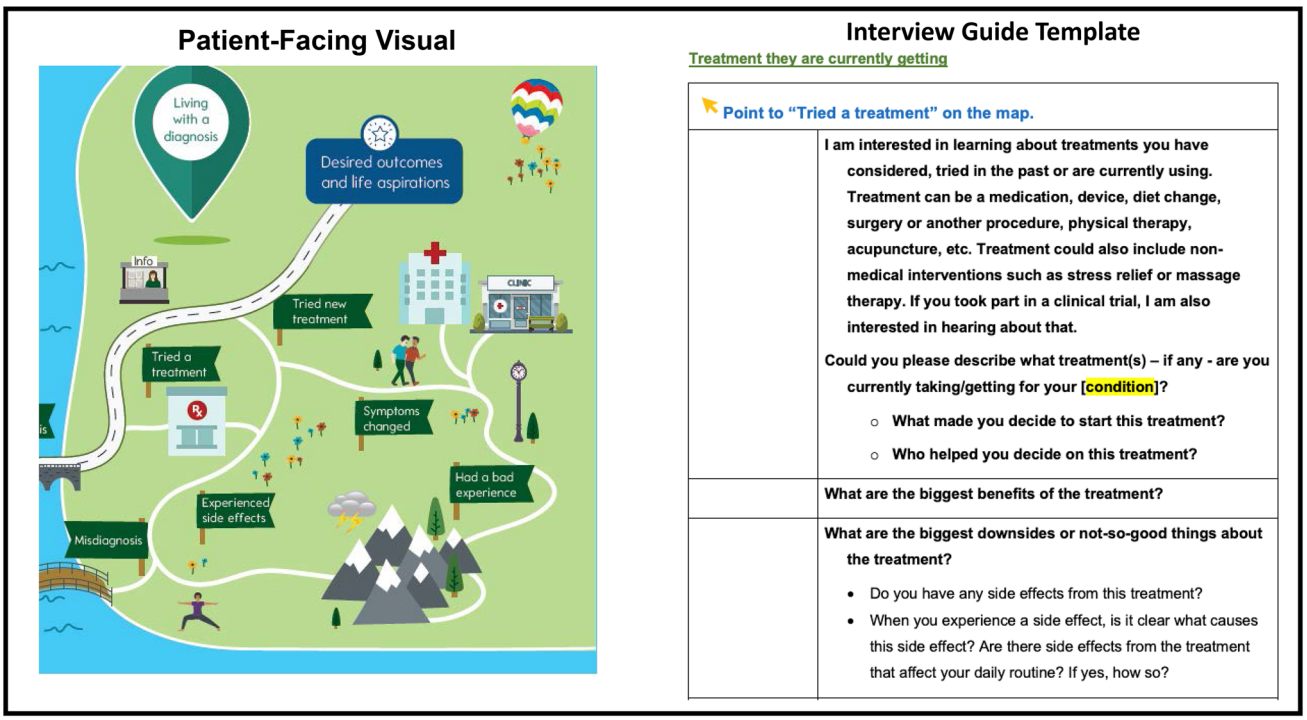


**Fig. 3** Illustrative example of the "Map My Experience" conceptual model used in tandem with the interview guide

## 3.3 Interview Guide Template

In addition to upfront language introducing the study objective, seeking verbal consent, and introducing the conceptual model, the interview guide template is organized around the following headers: "Ask about their experiences before getting a diagnosis," "Ask about their experiences getting a diagnosis," and "Ask about their experiences living with a

**Table 2** Example participant feedback on tools

| | |
|---|---|
| Feedback on map from cognitive interviews | Examples of overall feedback<br>"I like how it kind of wanders off into the weeds in the mountain, sometimes, because I think that's what tends to happen a lot of the time."<br>"Well, sometimes when you're stuck dealing with a bunch of symptoms you just lose focus. And when you're looking at a map like this, you can kind of see that you don't have to be stuck. You don't have to be just going around in a loop … you got to go down different paths. Try new treatments and stuff. [The map] gives you a chance to look what you've been through and see how far you've already gotten and that there are more paths ahead so you don't have to just be stuck in this one area forever"<br>Examples of participant feedback when asked to explain their interpretation of sections of the map<br>"Mountains and storms, like say if you went to a doctor. They brushed you off or your insurance company was like, we're not going to cover all this, it's not it's going to cost you a lot of money and you couldn't afford it or you couldn't find a doctor that would treat that kind of condition"<br>Examples of feedback on specific sections and changes made following cognitive interviews<br>[Misdiagnosis bridge] "I think it's good that even though it didn't apply to me. I think it's good that that misdiagnosis is on that map because unfortunately, that happens to quite a few people"<br>[Living with a diagnosis; the original map only had a hospital not a hospital and clinic] "Well, the way it's pictured it looks more like a hospital, but there are health care providers in buildings like that… To me it's just going to a doctor" |
| Feedback on map from pilot interviews | "I like it how you can kind of just go along. I've done other surveys and it hasn't been anything like this. I like being able. I'm a visual person. I like to be able to see something"<br>"I love this map I was looking at it beforehand and it helped me really prepare… makes it easier to talk and discuss with the visual.<br>"I liked how it went through when I was the 30 different islands on and I like how you could go back to one island, because a lot of times getting the diagnosis and things you go back and forth a lot on" |
| Feedback on interview guide questions | No, I just like how you went through the life before the getting a diagnosis and living with it… And I liked how you put the desired outcomes in life, because you'll always have more outcomes, especially with chronic illness … just because you get a treatment your symptoms don't just go away |

diagnosis." Example topics include symptoms/change over time, emotional health and personal goals, and treatment and health system experiences. To understand the interplay between people's experience with a disease or disability and the "life factors," consideration for how life factors (e.g., family, finances) are impacted by the disease/disability and how disease/disability impacts life factors, they are probed throughout the interview guide template. The sample introductory language can be modified based on the researcher's study objective, funding source, and disclosure requirements. To encourage standardization across studies, the interview guide includes bolded introductory text and questions, with unbolded "probe" questions. All bolded questions were tested across interviews (depending on relevance to chronic disease or disability), while unbolded "probe" questions were tested in multiple interviews.

Researchers can download a Microsoft Word version of the interview guide template and select which questions, probes, etc., to include based on their research objective and patient population (see Supplementary Materials). The breadth of sample interview questions is intended to support researchers with a wide range of study objectives. For example, questions about ideal treatment and clinical trial experiences could be used as part of patient-focused drug development efforts, while researchers interested in exploring healthcare inequities could include questions such as "Did you feel you were treated differently because of your race, age, or gender?" or "Did you have any positive or negative experiences you would like healthcare providers and researchers to know about? This could be anything to do with your condition such as an experience with symptoms, medication, healthcare providers, stigma or bias, etc."

### 3.4 Consent Sheet Template and Other Resources

The Toolbox includes a plain language consent sheet template for researchers seeking verbal consent. The template can be downloaded as an editable document in Microsoft Word and tailored based on study characteristics and objectives. To assist researchers in applying the tools, the NHC team developed an introductory video, a project-coordinator guide, and an interviewer training guide, which are available on a Toolbox website (see Table 3) [21]. The guides cover practical topics, including compensating participants, interview mode, and ethics review. Additionally, while the Toolbox is available to the public, to encourage consistency across studies and continual improvement, individuals accessing the Toolbox must make a free account, "Describe

how you will use the Patient Experience Mapping Toolbox" and "agree to provide feedback on the toolbox within 90 days of study/project completion, including modification to the interview guide questions and/or additions."

## 4 Discussion

To assist researchers in applying a systematic, consistent approach to engage patients living with chronic diseases holistically about their experiences, a Toolbox comprising a plain language consent sheet template, interview guide template, and patient experience conceptual model, was developed and pilot tested. The Toolbox facilitates an understanding of patient experience (1) before a diagnosis, (2) getting a diagnosis and (3) living with a diagnosis. All data collection tools were developed iteratively based on feedback from individuals living with chronic diseases, health literacy experts, and a multidisciplinary workgroup.

The Toolbox version 1.0 is an important step in helping researchers to develop conceptual models or "patient journey" maps reflecting multidimensional patient and family experiences. This is an important advance over traditional approaches that often depict linear, healthcare experiences and may not have been developed by engaging patients.

The Toolbox is intended to complement other initiatives and resources. For example, one mechanism that many patient groups have used to collect patient experience data is hosting externally led patient-focused drug development meetings. Data for PFDD meetings are often collected through online polling and in-person discussions. While Voice of the Patient reports summarizing PFDD meetings contains extremely useful insights, the way data are collected may not be rigorous enough for certain decisions (e.g., regulatory decisions). Specifically, since the meetings are not "research" per se, key information is often missing (e.g., participant demographic or clinical information, representativeness of emerging themes). To overcome this challenge, we have included the PFDD questions in the interview guide template. For patient groups who have already completed a PFDD meeting, these questions could be included in interviews to confirm findings from PFDD meetings. For patient groups that have not conducted a PFDD meeting, including the PFDD meeting questions makes it easy to collect patient experience data on topics FDA has denoted as important (e.g., characteristics of an ideal treatment). In parallel, interview questions about disease burden, financial impacts of disease, and treatment experience can help patient groups be responsive to questions that health technology assessment (HTA) bodies have about patients' lived experiences [22, 23].

**Table 3.** Overview of topics covered in accompanying tools

| | | |
|---|---|---|
| Project Coordinator Guide | This Project Coordinator Guide is intended for patient organization staff interested in using the PEMT. It will help guide you through several early steps of using the Toolbox, but is not a substitute for partnering with an experienced researcher | Getting started<br>Research question and aims<br>Participant eligibility criteria<br>Informed consent<br>Avoiding a data breach<br>Compensating interview participants<br>Interview preparation<br>Interview guide<br>Recall period mode<br>Inviting your interview participants<br>Considerations<br>Prepping the participant for the interview<br>Interviews and next steps<br>Disseminating findings |
| Interviewer Training Guide | This Guide can assist in familiarizing the individual(s) who will be conducting PEMT interviews with the Interview Guide and "Map My Experience" visual. It is not a substitute for partnering with an experienced interviewer. | Introduction<br>Interview guide<br>How do I use the interview guide?<br>Getting to know the participant and help them feel comfortable talking<br>Experiences before getting a diagnosis<br>Experiences getting a diagnosis<br>Note on the misdiagnosis loop<br>Experiences living with a diagnosis<br>Note on interactions with health system<br>Note on the desired outcomes and life aspirations<br>Note on special considerations/topics<br>"Map My Experience" Visual<br>Life factors<br>General Interviewing Tips |

Expected uses include as a data source to augment clinical trial and compliance data (e.g., explaining reasons for nonadherence) for treatment development strategy and approval, and to inform future research. Unlike proprietary patient experience/journey mapping tools, the Toolbox is publicly available, allowing researchers at different institutions to collect comparable data, facilitating comparisons across studies [21]. Academic researchers can apply the tools to engage patients meaningfully as PCORI requires for all funded projects [24]. The biopharmaceutical industry can leverage the Toolbox to collect high-quality PED to inform medical product development per the FDA's recommendations [25]. For example, the Toolbox has been cited as a useful tool to collect patient experience data as part of patient-focused drug development efforts [26]. A recent publication highlights how information on patient experiences and priorities gathered using the Toolbox can guide real-world study designs [27].

Applying the Toolbox may enhance the quality and efficiency of patient engagement research. The data collection tools were developed to capture the multidimensionality of patients' experiences, including the impact of lived support systems, beliefs, and social determinants of health that may influence access to care, treatment preferences, and ultimately outcomes [28–31]. The Toolbox is intended to capture data on the interplay between comorbidities, including interactions between treatments, coordination of care, and the impact on mental health [32, 33]. The objective of conducting pilot interviews among individuals diverse in terms of disease or disability, demographic, and clinical characteristics was to ensure applicability to a wide range of circumstances. For example, the interview guide includes a specific starting point for individuals diagnosed at birth or in vitro. The probes are intended for a wide range of ages and include prompts appropriate for individuals currently in school, individuals who work, and those who do not work.

Additionally, the Toolbox includes a range of questions about where patients seek information and evaluate the trustworthiness of information about health. A better understanding of patients' information-seeking behaviors can inform dissemination efforts, promoting the spread of trustworthy information, and enabling partnering with patient support and advocacy groups.

Resources in the Toolbox may also support a range of uses outside patient engagement research. For example, pilot interview participants stated that they were interested in using the model for nonresearch purposes, including for patient support groups and in clinical care for providers to help set patients' expectations upon diagnosis. Since releasing the Toolbox publicly, stakeholders have sought guidance concerning adapting the consent form for other research projects, utilizing specific questions from the interview guide for patient testimonials, and using the conceptual model to educate elementary school students about the health system.

The Toolbox will be updated in the future based on feedback from research teams using it. An immediate next step is to help researchers collect data that is more representative of patient experiences in the USA, the Toolbox should be culturally and linguistically adapted to allow implementation among diverse populations. Best practices published by the ISOQOL Translation and Cultural Adaptation Special Interest Group and the ISPOR Task Force for Translation and Cultural Adaptation could be informative to translating and culturally adapting all patient-facing materials [34, 35].

### 4.1 Limitations

Our approach to developing the Toolbox has several strengths: development was led by an umbrella patient advocacy organization and guided by multidisciplinary input, and the questions have all been pilot tested and refined based on input from individuals with a range of different chronic conditions and life experiences. All patient-facing tools were externally reviewed by health literacy experts.

There may be chronic diseases for which the data collection tools are not entirely applicable, and modifications may be required. For example, applicability to acute conditions has not been tested. Information reported by patients may be prone to recall bias. However, there is no expectation this would impact the tools' quality. Additionally, the Toolbox has only been tested in a research context, and its' use in clinical settings is currently unknown. Finally, the Toolbox was pilot tested among English speakers with internet access. Future research could include adaptation for acute diagnoses, and language or cultural adaptation. Additionally, the targeted literature review provided a starting point in identifying patient experience concepts; however, it was not a systematic review and only one reviewer screened articles for relevance. It is possible concepts were not identified; however, the iterative approach to improving the interview guide combined with discussions with workgroup members likely filled many gaps.

## 5 Conclusions

A toolkit was developed and tested to assist researchers in systematically gathering data about patient experiences. The Toolbox can be easily customized based on the study objective. These publicly available resources can be used to gather informative data on the experiences of individuals diagnosed with a chronic/potentially disabling condition. Since these tools were created with patients using an iterative process, they are likely to account for some of the important, often overlooked, nonclinical aspects of

the patient experience (e.g., social determinants of health, sources of information, challenges of misdiagnosis). Applying these tools reduces the need to develop disease- or study-specific interview guides, increasing efficiency for researchers. Various stakeholders can leverage these resources to identify opportunities to enhance patient centricity in healthcare delivery, patient-centered outcomes research, and patient-focused drug development. The Toolbox should help to standardize the capture of patient experience data in a user-friendly, relevant way. In the future, the Toolbox will be updated to close gaps identified by researchers applying the Toolbox.

**Supplementary Information** The online version contains supplementary material available at https://doi.org/10.1007/s40271-023-00658-3.

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## Declarations

**Author contributions** EMO conceived the study. EMO, SS, KM, EP, and Workgroup Members designed the study. EMO, SS, KM, LEG, RCC, and TRL collected and analyzed data, all authors and Workgroup Members interpreted the data. EMO, LEG, and RCC drafted the manuscript. SS, KM, TRL, EP, and Workgroup Members provided substantive edits to the manuscript. All authors read and approved the final version of the manuscript.

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**Conflict of interest** This work was supported by the National Health Council. EO is a former employee of the National Health Council (NHC) and employed by Applied Patient Experience LLC, which has contracts with a variety of nonprofit organizations, pharmaceutical companies, and academic institutions, including the NHC. SS is an employee of the National Health Council, a membership organization that receives dues and sponsorships from a variety of funders, both members and sponsors. Please see the NHC website for lists of members and sponsors (http://www.nationalhealthcouncil.org/). EP is a former employee of the NHC and also has a faculty appointment at the University of Maryland Baltimore School of Pharmacy and has received funding from the NHC, Merck, PhRMA, and the Innovation in Value Initiative. KM has no conflicts of interest to disclose. LEG has no conflicts of interest to disclose. RC is an employee of the Department of Defense. RC also has a faculty appointment the University of Maryland Baltimore Graduate School and Uniformed Services University. TRL completed an internship at the National Health Council and received consulting fees for conducting the cognitive interviews. TRL has received remuneration for completion of Voice of the Patient activities with Nephcure as a patient living with IgA Nephropathy. https://nephcure.org/getinvolved/become-a-voice-of-patient-volunteer/. SB was an employee of the National Psoriasis Foundation, a nonprofit organization representing individuals living with psoriatic disease, at the time the work was completed. MD has nothing to disclose. LSD is an employee of the pharmaceutical company Pfizer Inc. which provides funding to the NHC. RD has nothing to disclose. JF has nothing to disclose. LF was an employee of the RAND Corporation at the time the work was completed and serves on the Board of the Personalized Medicine Foundation, the International Society for Quality of Life Research, and the Medical, Scientific, and Medical Screening Advisory Board of the Alzheimer's Foundation of America. BG is a former employee of the Association for Vascular Access, the current President of the Board of Trustees for The Oley Foundation without compensation, and she represents the patient voice in various healthcare projects without compensation. She is periodically hired by various groups to give keynote speeches on the subject of patient harm. NH and EH, employed by the PKD Foundation, have no disclosures. NM was an employee of Boehringer–Ingelheim at the time the work was completed. Boehringer-Ingelheim provides funding for NHC. NM owns stock in Merck and Pfizer (former employers). CM is employed at Sangamo Therapeutics headquartered in Brisbane, CA. CLP has received research funding from Genesis Research. RFS has received consulting fees from GSK, Merck, and BreathResearch, salary and stocks from Pfizer, Theravance Biopharma US, and currently at BioMarin Pharmaceuticals Inc. JS is an employee of AbbVie Inc. which provides funding to the NHC and he owns AbbVie stock. JZ is an employee of and owns common stock in Gilead Sciences.

**Data availability** Interview transcripts analyzed in this study contain potentially identifiable information. Individual transcripts will not be shared. The corresponding author can be contacted with any specific questions.

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