NATIONAL HEALTH COUNCIL

Patient Experience Mapping Toolkit
Project Coordinator Guide

Welcome to the National Health Council's (NHC's) Patient Experience Mapping Toolbox (PEMT). 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. For background information and an overview of the PEMT, please visit our website and click on About the Toolbox.

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Getting Started

If you intend to use the PEMT as part of a research study, you will need to identify a Principal Investigator (PI). A PI is a researcher who is responsible for ensuring the study is conducted in an ethical and rigorous manner. The PI should be experienced in qualitative research and data analysis. The PI and project team will need to carefully plan all aspects of your study. Reviewing the Standards for Reporting Qualitative Research early on can be helpful in developing your approach and ensuring you capture all details needed to publish your study findings in a peer-reviewed journal.[1]

Once you have outlined your general approach and identified a PI, the PI will need to develop a study protocol and receive approval from an Institutional Review Board (IRB). An IRB is a "group of individuals responsible for reviewing research studies to assess safety, privacy, and confidentiality concerns as they relate to the research that is being considered. The main purpose of the IRB is to protect the rights and welfare of research participants who participate in research studies. The IRB also determines what information should be provided to the potential research participant and approves the informed consent form that is to be used before the study is started."[1] IRB's typically have sample protocol templates for you to use when describing your proposed study. We will guide you through several key components of an IRB protocol below.

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Research Question & Aims

A study objective explains what a research study is expected to achieve. It should summarize the purpose and methods, including the research question and hypothesis for the study. If you are a patient group centered on a specific disease or condition, you likely already have background expertise, connections to patients, and information about what matters to them, which will further help you identify the potential research topics and patient participants.

Participant Eligibility Criteria

Carefully consider the target patient population or profile of patients you would like to enroll in your study. Variables such as age, diagnosis status, and geographic location may be important. You will need to write out a formal list of inclusion and exclusion criteria.

Inclusion criteria: A list of requirements a person must meet to take part in a study.[2]

- Sample: Participants were diagnosed with [chronic condition] at least six months ago

Exclusion criteria: A list of reasons a person cannot be included in a study.[2]

- Sample: Participants are under 18 years of age

[1] O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

When developing your inclusion and exclusion criteria, consider how representative the results of your study will be to the population living with the chronic disease. Keep in mind, patients can be at different points of disease progression, different stages of treatment, and can have different manifestations of the same disease. All of this can change their perception of their disease and treatment, ultimately affecting the interview responses.

Informed Consent

Participants will share personal details about their life and their experiences with a disease. To ensure all participants are comfortable with the way you intend to use the information they provide, you will need to seek their consent (or assent) prior to conducting an interview. Table 1 describes pertinent terminology related to informed consent. For your convenience, the PEMT includes a sample participant consent form that can be modified based on your needs. Ask your IRB if the consent form paired with verbal consent is sufficient. The consent sheet should always describe:

- Purpose of the research;
- Whether the interview will be recorded and what will happen to that recording e.g., transcribed, anonymized, recording destroyed after x amount of time;
- How the participant's information will be de-identified;
- The risk involved to the participant;
- What the participant's personal information will be used for and who will have access to it; and
- Research funder (if applicable).

Keep in mind that it is crucial to:

1. Provide participants with ample time to review all consent documents. Answer any immediate questions the participant may have to the best of your ability. For additional questions, be sure to include a contact name, email, and telephone number so participants know who to contact with any questions or concerns.
2. Double check that the text includes patient-friendly terminology and language. For example, instead of referring to a nephrologist, try to use simpler language such as a kidney doctor. A general rule of thumb is consent forms "should be written" at or below an 8th-grade level. However, we recommend trying to simplify language to a lower grade level if possible.

Table 1. Informed Consent Terminology[2]

Consent	An adult (18 years of age or older), capable of giving permission to participate in a research study, can provide consent.
Parental Permission	When children/minors are included in research (<18 years of age), the parent/guardian must sign a parental permission consent document. Some

[2] Adapted from: "Informed Consent in Human Subjects Research." University of Southern California Office for the Protection of Research Subjects. Available from: https://oprs.usc.edu/files/2017/04/Informed-Consent-Booklet-4.4.13.pdf

	situations require permission from at least one parent, while other situations require permission from both parents.
Assent	Assent is a child's affirmative agreement to participate in research. If the participant is between 7 and 17 years of age, assent must be obtained. The assent form must be written at the appropriate reading level of the youngest participant.
Verbal consent	Verbal consent still contains all elements of written consent; however, the participant is verbally read the elements and verbally agrees to participate.
Information/ Fact Sheet	An information sheet may be used as a form of consent in certain circumstances where a signature could compromise the participant (e.g., identify them) or in studies where signed consent is not required by regulation (research procedures involving minimal/no risk).
Waiver of Documentation of Informed Consent	A waiver of documentation of informed consent can be obtained when the written consent is the only link to the study and record of the participants name could compromise the participant. In this case a verbal or information sheet can be used, or the consent may be read to the participant.

Avoiding a Data Breach

Patient interviews are generally considered to involve minimal risk to the participant. Often, the primary risk is a data breach, so it is critical that you deidentify all transcripts and delete audio recordings as soon as possible. Additional steps that can be taken to minimize the chance of a data breach include:

- Keeping your software up-to-date
- Encrypting sensitive data
- Educating study personnel about data security

Additional best practices can be found here.

Compensating Interview Participants

As you are planning your study budget, keep in mind participants should be compensated for their time spent providing expertise on their disease experience. The NHC has developed a Patient Engagement Fair-Market Value Calculator, which can guide you in determining appropriate compensation. We recommend each participant should be compensated at the same rate. Consider in advance how you will compensate participants who stop the interview early or if travel and/or parking needs to be covered.

Interview Preparation

The Interviewer Training Guide provides information to help the researcher conducting interviews familiarize themselves with the Interview Guide. This section of the Coordinator Guide is to help research staff think through some of the considerations in planning interviews and preparing an interview guide aligned with your study objectives.

Interview Guide

You can access a word version of the PEMT Interview Guide by following instructions listed on the PEMT homepage.

The interview guide is a semi-structured set of questions intended to facilitate a meaningful conversation with a patient about his or her experiences with a chronic health condition. The questions are designed to elicit information regarding a patient's experiences prior to receiving a diagnosis, while receiving the diagnosis, and subsequently living with the diagnosis. This guide is meant to facilitate conversations or assist the researcher in formulating questions, but is not intended to be followed verbatim. Many questions refer back to the corresponding "Map My Experience" visual; therefore, it is crucial that the two resources are used together. Depending on the specific study objective and the available time with the patient, you may decide that the Patient Experience Mapping interview guide goes into greater detail than is needed. If this is the case, please tailor the interview guide to your specific needs by removing and/or adapting questions. To ensure you are capturing sufficient information about a patient's experience, we recommend including, at a minimum, all of the bolded questions in the interview guide. Be mindful of the number of questions you choose to ask to avoid overwhelming the patient or running out of time.

The interview guide is divided into the following sections:

- Introduction
    - Start the interview: Introduce yourself and explain the interview's purpose
    - Privacy Disclosures and Consent
- Get to know the participant and help them feel comfortable talking
- Introduction to "Map my Experience" tool
- Ask about their experiences before getting a diagnosis
- Ask about their experiences getting a diagnosis
- Ask about their experiences living with a diagnosis
- Wrap-Up
- Feedback on Tools
- Conclusion

In addition to reading through the final interview guide, the interviewer should also comprehensively research the individuals condition(s), common signs and symptoms, its effects, and typical treatments prior to beginning interviews.

Recall Period

A significant challenge of patient experience mapping is understanding the accuracy of information patients recall from the past. Appropriate recall periods depend on several factors (i.e. recency, attributes, complexity) and the context or meaning of the recalled phenomenon, including salience, patient experience, and mood. Careful consideration of the recall period is needed if a patient is asked to remember and describe events that happened 10 or more years ago. They may inadvertently misremember a detail or describe something that happened at a different time. The following resources may be helpful in determining an appropriate recall period:

- Hermanowicz J.C. (2016) Longitudinal Qualitative Research. In: Shanahan M., Mortimer J., Kirkpatrick Johnson M. (eds) Handbook of the Life Course. Handbooks of Sociology and Social Research. Springer, Cham

- Saldana, J. (2003). *Longitudinal qualitative research: Analyzing change through time*. Walnut Creek: AltaMira.
- Stull DE, Leidy NK, Parasuraman B, Chassany O. Optimal recall periods for patient-reported outcomes: challenges and potential solutions. *Curr Med Res Opin*. 2009;25(4):929-942. doi:10.1185/03007990902774765

Interview Mode

Interviews can be conducted by telephone, in-person, or via web conferencing. Consider the comfort level of the participant as you design your approach. For example, if you are interviewing elderly participants who may be less familiar with web conferencing, it may be easier to facilitate an interview over the telephone or in-person. Plan ahead regarding how the interviews will be recorded.

If you are conducting interviews by telephone or web conferencing, be sure to email the "Map My Experience" visual as part of the participants confirmation email. If you are conducting the interview by web conference, ideally you will be able to share your screen during the interview, but it is important to anticipate technological challenges. If you anticipate that participants would prefer a printed version, you could consider mailing a copy in advance of your interview. You may also need to provide a printed copy for participants who may not have a computer (especially for interviews conducted by phone).

If you are using web conferencing software, keep in mind that by using a camera during the interview you are collecting personally identifiable information. This should be disclosed to the participant during the consent process and described in your institutional review board application. Prior to recording the interview, you may consider asking the participant to turn off their video to protect their privacy. In addition, you may want to rename the participant to ensure that no identifiable information (i.e. last name) will be captured in the recording.

Inviting Your Interview Participants

Before inviting the participants in your study you should know how much you will be compensating the participants, how long you will be expecting them to participate, and the expectation of fluency in a specific language. Invitations to participate in the study should use health literate and approachable language. When composing your invitation be sure to enumerate; the length of the interview, compensation for their time, a brief description of the topic of the study, the medium with which you will be conducting the interview (i.e telephone, or in-person), details on informed consent, and information on how they can reach out to express interest.

Considerations

Patients have varying levels of health literacy. Some will have little to no difficulty understanding any questions you pose, while others might need clarification on most of the terms. Before the interviews, go over your questions and identify any jargon or health terms that might need to be defined. You can substitute the words to eliminate the jargon or prepare plain language definitions. Additionally, some patients might not

disclose that they are unfamiliar with terms during the interview, so check-in with the patient regularly thoughout the interview or if they seem confused.

Each patient will have their own narrative and unique understanding of their illness journey. This means that the patient might not always tell their story or answer questions in a chronological way or even stay on topic with your questions. Anticipate conversation tangents, which can provide unexpected information at times but also can take the interview off-track. Try to gently bring the back to the question without cutting off or interrupting the patient. Allow time for for them to expand on experiences but be mindful of time constraints.

There are a lot of questions that can arise during the course of your study. Below is a list of questions that arose during development of the PEMT. They are listed for informational purposes to help you run a smooth study.

Scheduling Interviews

- What is the maximum number of interviews that should be scheduled per interviewer in a single day?
- How much time between interviews will the interviewer need?
- When providing interviewer availability to the recruiter, are the times provided end by times?
- What will be included in

Preparing Interviewer

- What information will the interviewer be given prior to interview appointment (e.g., patient's first name, health condition?)
- Do participants need to complete a certain amount of the interview to be compensated? Will participants be compensated if they stop the interview early?
- How and when will patients be compensated?
- What is the procedure when a participant does not show up for their appointment?
- What is the procedure if the participant's internet connection is poor and the interview is unable to be completed at that time?
- If the participant has questions/comments/complaints that the interviewer cannot answer/assist with, who should be contacted to follow-up with the participant?

Prepping the Participant for the Interview

To prepare the participant for the interview and maximize the allotted time, it is important to send a pre-interview letter/email. The letter should include:

- Amount of time for the interview
- What information will be discussed
- How to prepare for the interview (e.g. what information or materials to have readily available such as a list of current medications)
- A reminder that participation is voluntary and will be recorded

- Name and contact information to reschedule the interview and/or opt-out from participating in the interview
- How information from the interviews will be used
- Instructions for dialing in/accessing the interview or meeting details for in-person interviews
- Description of attachments (see below)
- Other required language per IRB

Attachments

- Consent form
- “Map My Experience” visual

Interviews & Next Steps

Please see the PEMT Interview Guide and Interviewer Facilitator Guide for more information. Once you have completed an interview, the recording should be transcribed for analysis. There are many transcription services available. Ensure services have appropriate data security measures in place to handle personal health information. Analyzing qualitative data is beyond the scope of this guide. If your organization does not have a research team experienced in analyzing qualitative data, we recommend partnering with an experienced researcher.

Disseminating Findings

The Patient-Centered Outcomes Research Insitute (PCORI) published the PCORI Dissemination and Implementation Framework & Toolkit. We highly recommend reviewing these documents while developing your study protocol. It is important that sharing study results with interview participants is one component of your dissemination plan.

This section will be updated as publications stemming from use of the PEMT become available.