Lived Experience in Healthcare and Health Systems Research

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Purpose of...

This Handbook

Health research is a process of systematically studying people or activities to increase knowledge about areas of health that are of interest or importance to a group of people. The research question is always of interest to the researcher, but may not be relevant to patients, funders of research studies, or policymakers. Patients and their families have a special interest in what research is done and how findings are distributed and shared because their lives may be affected by what is learned. Recently, engaging patients and their families as full partners in research studies has been recommended by funders and other professionals in the United States.

As partners, families and patients have a chance to help select the questions that are asked and help plan research studies that directly affect their health care, well-being, and quality of life. Patient and family partners have concerns and questions that are important to them, which may be different from those of academic researchers. Often, researchers, families, and patients share these concerns, but sometimes they do not. Therefore, partnering with patients and their families in designing and carrying out research is likely to increase the relevance of what is learned. Other stakeholders with lived experience may also have an interest in what research questions are asked and how research is conducted. Such stakeholders may include patient navigators, community leaders, nurses, and others.

This handbook has been written to help researchers and people with lived experience, including patients and families, work together on research studies in ways that respect the needs of patients and families while making research more meaningful. We also want to recognize the important work that researchers do, which includes not only conducting studies, but also thinking through research agendas, applying for funding, recruiting participants, working with institutional review boards (IRBs) to ensure that research is ethical, and managing the many details that contribute to excellent research.

This handbook is meant to provide a more advanced road map and "how-to" guide for researchers, people with lived experience, and research teams who want to work together as true partners. We intend to engage the reader in a conversation about the meaning of research partnerships and how to achieve equitable collaborations that have a transformative impact on the relevance and value of the research to the people it serves. Important to successful partnerships is developing relationships built on trust, equity, and mutual respect.

This handbook assumes a basic understanding of partnerships between researchers, patients, families, and others with lived experience. It digs deeper into the "why" and "how" of working as a collaborative team. If you are brand new to partnering, you might want to check the Resources chapter of this guide for toolkits and training that will help you learn about the basics of partnerships. There are some excellent materials for both researchers and partners to get you started. In particular, we recommend that you take the PORCCH training (www.PORCCH.ca), which is a free online program that can be completed on your schedule. Each module presents an aspect of the research process in clear, easy-to-understand language.

Many funders suggest or require that researchers partner with patients, families, or others with lived experience while failing to provide guidance about the scope and coordination of creating a partnership, what partnership means, or how to achieve it. This handbook builds on a thorough review of existing guides and frameworks from three countries and brings together what we consider to be the best current resources, plus recommendations for creating lasting and productive partnerships.

While we discuss various types of collaborative research relationships such as advisory boards and community partnerships, the handbook focuses on partnerships between individual people with lived experience and the research team.

We hope that you will find his handbook helpful in advancing those partnerships.

KEY POINTS

This handbook

Helps researchers, families, and patients work together on research studies in ways that respect the needs of patients, and families while making research more meaningful.

Provides a more advanced road map and "how-to" guide for working together as partners

Assumes a basic understanding of partnerships between researchers, patients, and families.

Focuses on partnerships between individual patients, family members, and the research team.

Contents of...

This Handbook

We are pleased to present a labor of love—the handbook that we have long wished we had, and finally took it upon ourselves to write. Lived Experience in Health Care and Health Systems Research presents the nuts and bolts of a topic that is known by many names, including "patient- and family-centered research," "patient-centered outcomes research," "participatory research," "patient engagement in research," and "public involvement." We have adopted the term "lived-experience partner" throughout this handbook to refer to research partners who might be called "family partners," "youth partners," "patient partners," or "community partners" in other contexts.

This handbook is meant to help both researchers and lived-experience partners understand the benefits of partnering together in research. Although the authors are experts in health systems r esearch, we believe you will find that the principles shared here are applicable to any research that is meant to benefit people. While it may be difficult to imagine how to involve families, patients, and the public in some types of research (for example, genetic sequencing of viruses or the life cycle of the platypus), they can play very important roles in helping scientists to think about what aspects of research might be most helpful to different groups of people.

In this handbook, we go deeply into how partnerships between professional researchers, their research teams, and lived-experience partners can be beneficial to both researchers and lived-experience partners. We outline many of the steps that both parties can take to ensure productive and meaningful collaborations. We offer guidance on involving lived-experience partners specifically as co-investigators on studies, rather than limiting them to advisory or consulting roles. We consider partnerships between researchers and individuals who represent youth, families, patients, and the public, whose job it is to provide the research project with expertise on their lived experiences. In these types of research partnerships, one or more individuals are hired to participate as co-investigators on a research team. These partners have similar status as other members of the research team, are paid, and share in the research process from start to finish, including often being co-authors of papers and other intellectual products from the study. A study with lived-experience partners may also have a community advisory board, but that board has a different role in the study than the lived-experience partners.

Each chapter of this handbook introduces a topic, provides definitions and background on the topic, and explains why the topic is important to successful research partnerships. At the end of each chapter are topics for group discussion. These are meant to provide opportunities for researchers and lived-experience partners to talk about partnerships, the projects they will be working on, and other aspects of the research, including any training needed or requested by lived-experience partners, the orientation of lived-experience partners and the research team, or other technical topics. In addition, these thought topics help team members discuss sensitive issues that can make positive collaborations difficult. These may include issues of trust, equity, historical mistreatment of certain populations, tokenism, or power dynamics. Finally, thought topics provide a way to discuss the important contributions of lived-experience partners through a deep understanding of their lived experiences, and provide a way to help researchers think about how their studies can be improved by collaboration with lived-experience partners.

This handbook provides important information on how to create and maintain effective research partnerships between professional researchers and lived-experience partners. If you want an expanded or more structured learning experience, see the list of resources in Chapter 9, including training modules, toolkits, frameworks, and literature to help both researchers and lived-experience partners improve their partnership skills. Resources are grouped into assessment tools, trainings, guides, and communication tools.

The editors hope that the information provided here will help research teams work together. We also invite funders, reviewers, and policymakers to become familiar with the information provided here to better understand how lived-experience partners may be involved in research projects they review.

The term "lived-experience partner" refers to research partners who might be called "family partners," "youth partners," "patient partners," or "community partners" in other contexts.

Helps the reader understand the benefits of partnering with youth, families, patients, and the public in research.

Outlines steps to ensure productive and meaningful collaborations.

Chapter 1

What are lived-experience partnerships in research and why do we need them?

Charlene Shelton | Clarissa Hoover

Introduction

Researchers have studied people and their health in one form or another for centuries. Scientists from Isaac Newton to Francis Collins have wondered about how the universe and the human body work and have taken steps to satisfy their curiosity. While research done without a focus on the well-being or interests of people being studied has sometimes produced irrelevant (or occasionally catastrophic) results, research done with a commitment to what people need and want has had a positive impact on societies. Partnerships between researchers, patients, families, community members, and interested stakeholders have often led to research questions that are important, meaningful, and relevant to the populations being served.[1–3] The value of involving lived experience partners in the research process cannot be overstated; however, involving them in meaningful ways is easier said than done.

Throughout this handbook, we use "lived-experience partners" to refer to patients, families, and community members whose personal experiences with health care and health-related factors in their communities can improve the relevance and trustworthiness of a study.

Background

Partnerships between researchers and lived-experience partners and communities have a rich history of contributing to the success and relevance of research studies.[4] Often known as community-based participatory research (CBPR), participatory action research (PAR), or community-engaged research (CER), these partnerships involve lived-experience partners in different advisory capacities. Depending on the research project, lived-experience partners have been asked to provide information on the needs of a community or population, recruit participants, act as cultural brokers in a community, design communication materials, weigh in on potential health interventions, and many other roles.[5] However, they have not always been employed as co-investigators on a research team, but rather as advisors with varying degrees of responsibility and power to shape the direction of a given project.

In the recent past, researchers and funders of studies have begun to recognize the value of lived experiences in crafting and shaping research studies, including improving the internal and external validity of projects.[5] Foundations and other organizations that fund research have started insisting that lived-experience partners be engaged in the research process, and some recommend the involvement of lived-experience partners in research studies as co-investigators. Unfortunately, there has been little specific guidance in this type of partnership, so researchers have often adapted the principles of community-based partnerships to fit traditional models of how studies are carried out or of the research process. These adjustments are not always appropriate for working with one or two individual co-investigators. Furthermore, some researchers have run into roadblocks that include a lack of understanding of the value of partnerships by institutions, researchers not knowing the role that they want the lived-experience partners to have in the study, not enough time to work out the logistics of partnerships, and/or a lack of funding to pay partners. This lack of understanding and guidance can result in partnerships that lack meaning or benefit for either the lived-experience partners or the study teams.[6,7]

BECAUSE . . .

Partnerships between researchers and people with lived experience can lead to important, meaningful, and relevant research,

WE NEED TO UNDERSTAND . . .

How lived-experience partners impact research projects,

AND PRACTICE . . .

Building strong collaborations between lived-experience partners and research partners.

Yet, research teams that have taken the time to engage lived-experience partners in meaningful partnerships have been rewarded. For example, in 2008, English and colleagues created a community coalition to increase mammography screening in Native women in New Mexico.[8] The result was a better understanding of tribal health systems by the researchers, increased trust between them and the tribe, accessible screening, and the development of local policy that helped tribes increase cancer control. Gagnon and colleagues worked with patients to see if a diabetes empowerment program would work in various health care settings. While the lived-experience partners came away with a better understanding of how the health care system functions, they recognized that there was little opportunity for patients to participate in shaping the system unless there was a deliberate effort to involve them in the decision making.[9]

Principles and practices to facilitate lived-experience partnerships have begun to emerge both in the literature and in practice. For example, when funders make lived-experience partners' involvement a condition of funding, researchers and institutions are forced to think about the value of partnerships and how they can best serve the goals of a study. External pressure from families and communities to pay attention to their needs has begun to resonate with researchers and funders. Assistance from family- and community-led organizations in recruiting and supporting lived-experience partners, and the knowledge of individuals who previously worked as lived-experience partners and can orient and support current partners and researchers who are new to a research partnership, has improved how partners are integrated into projects.

Concepts

Throughout this handbook, we discuss various concepts that contribute to meaningful partnerships. Each chapter focuses on an aspect of partnership that helps to ensure that the study is benefiting from the input of those who will be affected by its outcomes.

Meaningful partnership: Individuals learn from and honor each other as they contribute their expertise to the project. It means that the project is a co-production of the lived-experience partners, professional researchers, and contributing team members; everyone's input is valuable and necessary to produce a good study. Partnerships are based on ethical principles of patient-centered outcomes research (PCOR), trust, honesty, co-learning, transparency, and reciprocal relationships, as well as mutual respect.10,11 Each person on the research team derives a benefit from their participation, including the feeling that their time was well spent, that they contributed in a meaningful way, and that they learned something of value.

Lived-experience partnership: ". . . involving anyone not professionally interested or experienced in health and [health] care in research. Public involvement is another term often used that describes initiatives to give lay people an effective, active role in health and [health] care research. . . . Public involvement [and partnerships] have similar goals: to develop research that addresses patients' and the public's needs, and thereby improve the success, cost-effectiveness, and impact of research."[1]

Community partnerships: These overlap with lived-experience partners; different people might use this term in different ways. In this handbook, it is used to mean partnerships that occur at the community level, and involve working with community representatives who may or may not qualify as lived-experience partners. These partners are trusted advisors on a research team. A study might employ a group of community members or other advisors as well as lived-experience or community co-investigator partners. Community partnerships as we describe them here may involve individuals who have a sense of the needs of a community, but may not have lived experience that is specific to the topic of the research project.

Throughout this handbook, we discuss various concepts that contribute to meaningful partnerships. Each chapter focuses on an aspect of partnership that helps to ensure that the study is benefiting from the input of those who will be affected by its outcomes.

The person-on-the-street effect: Because lived-experience partners come from outside the research community, they may have different perspectives from researchers. To some extent, anyone from outside the research community could provide this. Lived-experience partners may be particularly motivated to learn about background issues and may see the implications of the research topic through their own lens.

Some examples of how lived-experience partners contribute to a study include an understanding of:

Lived experience (of course):

> ***"We don't go home at night."*** Lived-experience partners are experts in what happens to patients outside of the formal health care system, leading to an understanding of adherence (or lack of) to treatment plans, needs of the patient and family, and social determinants of health from the patient perspective.
>
> ***Carrying out interventions at home.*** Lived-experience partners do the work of nurses, doctors, and therapists at home—especially since the COVID-19 pandemic—leading to an understanding of how much families know about clinical, therapeutic, and behavioral interventions.
>
> ***Structural health literacy.*** Lived-experience partners have often found ways to navigate the complicated health care system's structures, resulting in the ability to get their needs met, even when they must use unconventional methods.
>
> ***Human engineering.*** Lived-experience partners find creative ways to meet patients' and families' needs such as hanging feeding pumps from clothes hangers in the car or making a small space accommodate a large wheelchair or using a bag of rice as a weight for physical therapy when equipment is not available.

"North star": Lived-experience partners help the research team stay focused on big goals—wellness, quality of life, equity, and relevance to the populations being studied.

> **Lived-experience partners can help teams think about the impacts on patients such as the underrepresentation of certain populations.**

I'm OK, you're OK: Lived-experience partners can help destigmatize the experience of illness and disability, leading to a normalization and humanization of the experiences of patients and families.

Innovation: Lived-experience partners can identify understudied topics with potential for a big impact on patients and families. They can talk about novel ways that they navigate the health care and other systems.

Translation from theory to practice: Lived-experience partners can describe how the system works, versus how it was intended to work.

Overview of the Chapters

Chapter 2 discusses power dynamics in research partnerships. The authors discuss power differentials and dynamics and how they either contribute to effective partnerships or create discord amongst research team members.

Chapter 3 discusses equity, diversity, and inclusion. Through the lens of children and youth with special health care needs and inclusion of children and families as research participants, the authors discuss the importance of ensuring that populations who are underrepresented in research (UiR) are included in every aspect of research and give concrete suggestions for including them.

Chapter 4 discusses family-centered design. Practical advice is offered for ensuring that studies are patient- and family-centric and that lived-experience partners have a hand in the design of the study from start to finish.

Chapter 5 is about co-production and collaboration: Co-production involves an effort by multiple parties to jointly determine the output of their collaboration; it encompasses different types of collaborations including:

- Co-authorship: writing together, sharing ideas, and mentoring lived-experience partners and other community partners to be full contributors to the public narrative of the project and its findings.
- Co-creation: when researchers and lived-experience partners design a research question and methodology together in such a way that it reflects the needs of both the research team (to answer the research question) and the patients (to address their lived experience and patient-centered needs).
- Co-learning: collaborators learn together and learn from each other.

Chapter 6 discusses project management. There are tools that are basic to every study. Managing study projects goes beyond creating a budget and meeting deadlines. Using the Project Management Body of Knowledge as a guide, this chapter goes through the many steps needed to effectively manage research studies, ensuring that all the pieces of the project are addressed in a timely and efficient manner.

Chapter 7 discusses evaluation. The reader is guided through an evaluation process, and tools that are available to assess the impact of having lived-experience partners on the study are suggested.

Chapter 8 discusses research ethics. Without a strong commitment to ethical research, studies like the Tuskegee Study of Untreated Syphilis in the Negro Male can harm patients and dissuade participation in research. The most important ethical principles required for good research are presented and discussed.

Chapter 9 discusses resources for further learning. A list of resources that are highlighted throughout the handbook—and many that are not—is provided as additional sources of information. The list is not exhaustive, as new resources are emerging all the time.

Recommendations

Each chapter of this handbook includes a section of specific recommendations relating to that chapter's topic. In this introductory chapter, our main recommendation is that you read the rest of the handbook!

Future Directions

As both researchers and funders continue to recognize the value of working with lived-experience partners, we are hopeful that including them in research projects is becoming the norm. While the impact of having lived-experience partners on studies is difficult to quantify, that itself is an important research question. Researchers are thinking about how to measure the impact and making a case for the meaningful involvement of stakeholders as research partners.

Group Discussion

1. What are some specific roles that lived-experience partners can play in a research project?
2. What are your top priorities for the research project that you are working on (or hope to work on)?
3. What are some doubts or fears you have about working together on a study?

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Chapter 2

Power Dynamics in Research Partnerships

Charlene Shelton | Jonah Stoller | Audre Greer | Lisa Maynes
Toni Hines | Megumi Okumura

Introduction

Power dynamics are one of the biggest barriers to making lived-experience partnerships successful. This chapter unpacks and examines common challenges that arise from the power dynamics and differentials inevitable in conducting equitable partnered research. We discuss these power dynamics in terms of how they can both facilitate and impede equitable partnerships. We want to acknowledge, however, that the field of equity, diversity, and inclusion is moving at a rapid pace and much of the thinking about how to equitably involve communities that have been underserved and marginalized is evolving. Power is at the heart of equity;[1] therefore, we approach this chapter with the understanding that there is much more to understand about power and how it impacts equity than is within the scope of this handbook.

Some readers of this handbook already understand, by drawing on their personal experiences or training, what makes power dynamics such a tricky subject. Others are still struggling to understand, unsure how to proceed, or even comfortable believing that power is a topic that can safely be ignored. While this handbook was in development, the public conversation in the U.S. made huge advances in handling this topic as part of a national conversation about racism driven by the Black Lives Matter movement. We have witnessed a corresponding shift in how willing and able researchers are to talk about issues of power, privilege, race, and racism in the health care system. We hope that this chapter, and the following chapter on equity, diversity, and inclusion, will allow readers in a wide range of starting positions to advance in how they think about power dynamics in the context of lived-experience partnerships.

A mother of a child with a health disability talks about power

It seems like a lot of health care providers feel like they're the ones in danger in this relationship. After all, they could actually get fired based on complaints by patients and families! Meanwhile, I'm thinking, they literally hold my daughter's life in their hands. And they're part of a huge cohesive unit of people who mostly stand by one another and have all kinds of insider knowledge that I don't have. Where do I even start trying to explain how scary my situation is? To people who think that losing a job is as bad as it gets—hah! I lost my job, I lost my whole career, and it was just a side issue at the time. That's how vulnerable my position is, that's how vulnerable my daughter is.

BECAUSE . . .

Lived-experience partners can't contribute effectively to research when they're afraid or cynical about research partners' intentions,

WE NEED TO UNDERSTAND . . .

How current behavior, larger social context, and past life experiences create power dynamics that shape relationships between partners,

AND PRACTICE . . .

Recognizing and responding to power imbalances in lived-experience partnerships.

Background

The priorities of researchers have not always matched the priorities of patients and their families. This may lead to mistrust of the values and motives for research, including beliefs that researchers are only interested in money, career advancement, power, and control, and that findings are inaccessible to the average person and have little connection to functional changes in services.[2] Over time, researchers have realized that involving patients, families, and other stakeholders in the research process has far-reaching, positive implications for the trust, value, and relevance of research to the communities the findings are meant to help.3 Thus, over the last four decades, the concept of community engagement has evolved to include diverse communities whose interest in research mirrors the needs of the communities they represent. "Community" does not always mean a geographic area. It can include groups of people with similar interests such as the community of children with special health care needs; immigrant groups; cultural groups; or people with specific medical conditions such as autism. Community engagement in research has typically meant that multiple representatives of a community of interest come together to advise a research team, hospital management, or other entity that is interested in the views and opinions of the community in question through community advisory boards (CABs) that can include a large number of members.

In the recent past, however, researchers and funders have recognized that CABs, while providing targeted advice, may not be involved in the minutia of project planning and execution because of the number of people on them. Thus, involving a small number of individuals (one to four) from those communities as full members of a research team allows a level of targeted representation and involves them in the day-to-day workings of the study such as setting priorities, writing and editing papers, study leadership and design, interviewing participants, analyzing data, dissemination of results, and other areas of a project that are often beyond the scope of a larger advisory board.3 Lived-experience partners who are employed as co-investigators rather than as advisors are thus empowered to share their knowledge and experience in a way that can increase the relevance and impact of a study to their community.

The power dynamics between lived-experience partners and professional researchers can have an important effect on if and how partners are able to assert their experience to benefit the community being studied. This is of particular significance as it relates to the principal investigator and other team members with advanced degrees or in positions of power. Power plays an important role in how teams function: It can move from individuals to groups within the team, can form across groups, and shift within a project. Understanding these power dynamics is important to ensuring representation of communities within the research team so that community representatives are given ample opportunity to contribute freely to the discussion and advocate for a study's relevance to their community.

Concepts

Equitable partnerships are defined by the UK Collaborative on Development Research as "Partnerships in which there is mutual participation, mutual trust and respect, mutual benefit, and equal value placed on each partner's contribution at all stages of the research process."[4] Creating equitable partnerships involves acknowledging the power hierarchy and ensuring that all parties have the ability to influence the course of a study based on the needs of the community being studied.[5]

Recruitment of families and patient participants with an equity lens involves bringing stakeholders to the team from the communities of interest. In doing this, it is essential that potential lived-experience partners have a level of trust in the researchers, the institutions, and the process. It is the job of the researchers to establish this trust within the communities in which they choose to

work. While a full discussion of establishing trust is beyond the scope of this handbook, the reader should be aware that trust is a key factor in effectively working with communities. Establishing trust takes time and effort. Connections with community leaders are also beneficial through community brokers or other community leaders.

Understanding power and hierarchy: Sociologists and philosophers have written about different types of power for centuries and have identified both negative and positive uses and implications of power. Power is not simply based on fear of retribution or harm. It is complex and multifaceted, not cut-and-dried. Power does not imply morality. For example, when someone has power over another, it does not mean that they will use that power in an adverse way. Power is not always fixed; it can be consolidated or transferred.[6] Power also has multiple sources. It can be structural, as in the case of institutional regulations, or it can arise from interpersonal dynamics, like that between a parent and child, or it can be based on one's position within a power structure. However, often power is derived from the norms of a society that inform how power is perceived and used.[7]

In this chapter, power is considered primarily as a result of external structures like whether or not someone has an advanced degree, their employment status at a given institution, or their level of lived-experience knowledge. In these settings, power differences are often perceived or are present regardless of assurances from those holding power that these differences do not matter to them or are not relevant. This makes acknowledging and addressing these dynamics early even more important in order to avoid ongoing inequities on the research team.

It is important to keep in mind that power imbalances in research partnerships do not always involve the professional researcher having power over lived-experience partners. Partners themselves may view their role as guardians of their own community and exert their power to speak for that community. They themselves may hold advanced degrees, financial means, and other forms of power outside of the bounds of the research team. They may have research experience, and they are likely already strong advocates with deep connections both within and outside of their particular community. Therefore, we recognize that power can flow in both directions. However, more often there is a unidirectional power difference, where power flows from the professional researcher to the lived-experience partner.

Power differentials between researchers and partners: The most apparent avenues to power that professional researchers have are education, professional position, and income. Researchers usually have a master's, doctorate, or multiple graduate/professional degrees. They may also be service providers themselves and may thus be viewed as gatekeepers of these services. In addition, researchers may have higher incomes than the partners with whom they work, which may be interpreted as having a higher value within the organization and project.

Power differentials between lived-experience partners: Partners come from diverse communities with diverse perspectives. In situations where there are multiple lived-experience partners on a team, there can sometimes be differences of opinions or conflicting priorities that can foster tension between them. It is important to be aware of these dynamics in order to avoid problems during engagement. Some of the same avenues to power can exist within partners such as income, education, and research experience. Other types of power differentials may include language, immigrant status, or even the severity of the medical condition of the patient.

Appreciating and addressing power differentials: Clearly, power dynamics are complex and can exist between researchers and lived-experience partners, as well as between partners themselves. Table 1 below provides examples of different attributes of power and how they can exert both beneficial and detrimental impacts on the quality of patient-engaged research.

Table 1 Power Attributes*

Power Attributes	Definition	How it can benefit individuals/ groups/partnerships	How it can disempower individual/ groups/partnerships
Accessibility	The quality of being easy to approach, reach, enter, speak with, use, or understand; the quality of being suitable or adapted for use by people with disabilities.	Being aware of accessibility concerns and making accommodations allows people from diverse backgrounds to fully participate in the research process.	Individuals may be disenfranchised if they cannot participate in the process due to geographic, physical, timing, or other constraints.
Character	The combination of mental and ethical traits that distinguish an individual or group of individuals. Character may impact a person's perceived honesty, attractiveness, and worth.	People with certain character traits may find it easier to do things like getting buy-in from stakeholders or developing trusting relationships	Power in this context is based on perceived character. It may take significant time to develop this perception ("good" or "bad" character traits) and it may not be accurate.
Charisma/ Personal	An ability to garner a high degree of power or loyalty, often perceived as a sort of magnetic charm or appeal.	This trait can improve collaboration with partners, research team members, and other stakeholders.	Charisma is not equally distributed across a team, and so some stakeholders might be less able to engage effectively than others. Those who are not so charismatic may struggle to develop and leverage connections and in this their ability to contribute could be reduced.
Collective	People working together. Essentially, a sharing of responsibility among group members, in this case based on shared characteristics or interest.	Brings unity to the group by shared common goals.	May exclude smaller subgroups in the stakeholder group, which can be merged by ethnicity, language, common interest.
Coercive	Coercion occurs when someone is compelled, by any type of force or threat (direct or otherwise), to make a particular choice or engage in a particular act.	Coercive approaches can be used to encourage certain desirable behaviors among team members.	Coercion often fails to promote inclusion, can lead to reduced group cohesion, and can damage relationships more generally and in the long run.
Connection	Existing connections between entities can impact power dynamics. Manifestations of this include things like social capital, generational wealth, and access to opportunities and resources.	A strong sense of connection within a team may help people to be more forthcoming with their own views because they feel that they have a safe forum in which to share them. This in turn can help ensure that all voices are heard.	Connections can be lost after partnership ends, which can lead to future mistrust; Those with fewer or weaker connections may be at a disadvantage compared to those with strong connections and may feel left out or not heard. A person with strong connections may have more power.
Expert	An expert has a special skill or knowledge representative of their mastery of a given subject. This can be perceived or actual.	The presence of experts can benefit a team by providing high-level information, skills, and knowledge that can help guide the team in a productive way.	Experts may stifle the voices of those who think their opinion or information is less legitimate or who fear that the expert will withhold their expertise if challenged. This can contribute to "Imposter syndrome," which occurs when a participant devalues their own expertise.

Power Attributes	Definition	How it can benefit individuals/ groups/partnerships	How it can disempower individual/ groups/partnerships
Gatekeeper	The activity of controlling, and usually limiting, general access to something. The perceived or actual control over money and/ or resources that others need or believe that they need.	Control of access to resources grants a great deal of power to the person or persons who have that control. They may be able to leverage this power in productive ways.	Those who do not control resources may have to accept outcomes they don't want.
High Maintenance/ Unpredictable	The unpredictable or high-needs behavior of a team member can lead to other team members going out of their way in order to keep the individual calm and content.	Individuals exhibiting this pattern of behavior may be able to take advantage of its impact on team members and collaborators in order to move an agenda forward.	The agenda of the "high-maintenance" person may overrule that of others. This in turn may silence other team members, leading to resentment of the manipulator and a deterioration in overall team dynamics.
Information	Having access to relevant information. Access can come as a result of personal experience, education, connections, etc.	Access to reliable, relevant, and accurate information is an integral component of success in research.	May artificially suppress information from the group based on the source of information (see Expert); information may be inaccurate; people with different access to information may feel less/ more valued in the relationship. Members may disagree on what information is credible given their level of expertise/lived experience, possibly leading to frustration among the group.
Legitimacy	Comes from the shared organizational belief that a person has a right to make demands and/or to expect compliance and obedience from others based on legal, social, economic, or other positions within an existing power structure.	Can use legitimacy to disarm potential destructive interactions.	Legitimate power could be used to ensure that certain issues are prioritized that may be out of line with larger organizational goals. In addition, while legitimate power is definitionally not coercive when wielded, it may be acquired by coercive means. Can use to coerce/ suppress dissent.
Powerlessness	The expectancy that people's actions cannot determine the outcomes they seek.	Ensure that all members of the team are given the chance to participate in all aspects of the study; specifically invite less active members to voice their opinions.	May be an indication that an individual feels disempowered by the system or team and does not feel supported.
Privilege	Special rights, advantages, or immunities that are granted to particular people or groups. Privilege may stem from things like race, wealth, education, etc.	Can be shared to uplift others; can use to overcome problems of legitimacy.	Can be used to impose power over others in a coercive way. Individuals may not be aware of their privilege, which can lead to biased decision making and possibly disrupt team dynamics.
Reward	Something given or received in return or recompense for service, merit, hardship, etc.	Can be used to share resources, reward participation, and show appreciation in tangible ways.	May be or be perceived as favoritism in certain contexts.

Power Attributes	Definition	How it can benefit individuals/ groups/partnerships	How it can disempower individual/ groups/partnerships
Willingness to Walk Away	A person would potentially take nothing rather than meet the needs or desires of another.	May make a person or group more willing to collaborate.	Can be manipulative, and lead to an unnecessary negotiation and "giving up" of key interests.

*Adapted with permission from Amy Shollenberger and Action Circles at https://www.action-circles.com/ [9]

Recommendations

Dismantling perceived power structures: Equalizing power among partners and researchers starts with acknowledging potential power differentials in the group and actively addressing them from the beginning. Table 2 lists examples of how power domains may manifest and sample strategies on how to address each one.

Recruiting lived-experience partners: In identifying and recruiting potential partners, it is important to clearly consider the needs of your project while also cultivating an environment that will allow partner voices to be heard. Ideally, partners should be part of the community of interest; however, partners should not be expected to speak for the entire community, as if the community is monolithic. There is a fine line between representing a community and speaking for all its members. For example, just because a partner is Black, does not mean that they represent the views of all Black people.

It is imperative that partners have the power to voice disagreements and challenges and not feel pressured to comply with the professional research team. Working with well-established, well-respected family- or community-led agencies to identify potential partners and plan your project will help in this process and help reduce possible tokenism.

Orienting families and researchers to the partnership: Lived-experience partners, especially those new to partnerships or who come from disenfranchised communities, need onboarding, orienting, and possibly training in the research process, including methods and ethics. Chapter 6 discusses onboarding and orientation as part of the project management process.

Shared goal setting: Shared goals promote both personal and group interests as well as belonging, solidarity, and trust within a group. Setting shared goals involves identifying, prioritizing, and balancing the needs of both individuals and the project, mutual listening and observation, humility, and flexibility. Discussing the project's concept with lived-experience partners as early as possible in the planning process, even before the protocol is written, can help develop a study design that incorporates the perspectives of all the research team members.

Preventing the perpetuation of microaggressions and implicit bias: "Microaggressions are brief and commonplace daily verbal, behavioral, or environmental actions (whether intentional or unintentional) that communicate hostile, derogatory, or negative racial slights and insults toward members of oppressed or targeted groups."[10]

"Unconscious or implicit bias refers to the associations that are made between different qualities and social categories such as race, gender, or disability and are judgments that are made without conscious awareness."[11]

All team members must consider their own views and prejudices along with being aware of their speech and actions. There are many resources that address these two topics, including TED talks, articles in the business press such as Forbes magazine, and trainings sponsored by most univer-

sities and research institutions for their employees. Project leadership should explore options for implicit bias training at their institutions and whether it is available to employees and non-employees alike. Please also consult the Resources chapter at the end of this handbook for additional resources that may be useful in raising awareness and accounting for implicit bias.

Addressing conflict: Address conflict before it starts by setting group norms that are inclusive of all research team members, encourage discussion, and ensure that each member's input is considered. Helping partners advocate for themselves may be helpful. If partners feel they are being "shut down" or that their input is ignored by any member of the research team, they may stop participating in discussions or other aspects of the project. Investigators may not realize this is happening if partners do not make it known to the team or the principal investigator (PI). The PI should watch for a change in a partner's participation and ask about any concerns the partner may have that prompted them to decrease their participation. Tables 1 and 2 review etiologies of power dynamics and potential outcomes and remedies. Across the board, having shared leadership responsibility with partners and ensuring that there is a joint understanding between partners and researchers about their roles and perspectives, with shared mutual respect, is key to improving equity in research partnerships.

Conflict within groups: Like any relationship, patient engagement may have conflict and properly managed conflict can be a healthy way for a group to grow and move toward goals. Oftentimes group dynamics are such that the focus is on conflict avoidance. Not dealing with conflict or avoiding conflict can lead to the silencing of members for sake of peace rather than the advancement of science.

Training: Training is essential for all team members. Those who are not familiar with research should receive training on the research process, including methods and research ethics. There are some excellent resources for lived-experience partners that explain the research process (see Resources for a list). Research team professional partners, including research assistants and other co-investigators, may not have worked with lived-experience partners who are also co-investigators. Because this type of relationship is different from working with an advisory board, professional research team members should also be trained. There are resources for professionals such as the Patient-Oriented Research Curriculum in Child Health (PORCCH), which has modules for professionals who are new to working with lived-experience partners. See the Resources section of this book for training resources for both researchers and partners.

Budgeting/adequate compensation for the partnership: Appropriate compensation for lived-experience partners is a critical component of equitable engagement. Researchers are paid for their time for research, and it should be expected that lived-experience partners who participate in the research are also compensated for their time and expertise. This topic is discussed further in Chapter 6.

UNIVERSAL RECOMMENDATION: Start at a place of humility. Be open to your lived-experience partners and course-correct when necessary.

Table 2 Strategies to decrease the effect of Power Attributes*

Power Attribute	Example of dynamic	Researcher strategies	Family and patient/ stakeholder strategies
Character	A PI is trustworthy, honest, and has follow-through. However, trust has not yet been established and other members of the team are resistant to giving the new partner high-stakes work.	Be transparent, consistent, and follow through on commitments.	Use the orientation form in this handbook to ensure that you have all pertinent information. Ask questions when you don't understand.
Charisma	A team member asks for something that does not seem right using a condescending, but charming manner.	Honor the expertise of all team members by not "talking down" to them.	Remind the team of your expertise as a lived-experience partner, but ask questions if necessary.
Collective	Disagreement on some point, method, or analysis. All five of the "research professionals" on a study team agree on the way a set of survey questions is framed. The two research partners on the study disagree and feel that the questions need rewording.	Open the conversation to all and give team members permission to voice their disagreements and explain their rationales.	Be willing to state your case in a respectful but firm manner. Be willing to listen to others' rationales.
Coercive	A team member intimates that recognition, compensation, or other benefits will be withheld if the other members do not go along with his/her wishes.	Prior to study commencement, set clear role expectations but adapt as needed for both researchers and partners. Orient partners to their role and yours and ensure that they understand and feel empowered to ask questions.	Ask questions during orientation and beyond about your role. Try to understand the rationale for decisions, especially if you do not agree. Present your ideas or disagreements with your rationale.
Connection	A researcher has friends and colleagues who can provide tangible benefits to the project, and who also may have interests that are not related to or aligned with the goals of the project.	Use connections to benefit the research and team in ethical ways, not to enrich the project or team members, or alter the focus of the study.	Question benefits that seem disconnected from the goals of the project.
High Maintenance	A team member continually changes the goals or other important aspects of the project so that it is hard to keep up with what the goals of the project are.	Consult with team members when considering a change to the project goals, aims, methods, personnel, or other impactful areas. Ask their opinions and give your rationale before making the changes.	Point out how constant changes impact your ability to do your job. Ask for rationales if they are not offered.
Expert	A researcher tends to use medical jargon in situations where lay person language would be more appropriate. Partners feel left out of the conversation because they do not have the same type of background.	Be sure to use lay terms and plain language where possible. Provide a glossary. Check for understanding from all partners. Do not make anyone feel bad for not understanding.	Be forthcoming about understanding of terms and concepts. Even professionals don't always understand concepts that are outside their area of expertise. Be aware of your use of jargon that is prominent in your own community.

Power Attribute	Example of dynamic	Researcher strategies	Family and patient/ stakeholder strategies
Financial/ Gatekeeper	Funding, compensation, or other resources are withheld if certain tasks are not completed.	Stick to the budget and require accountability from all team members, regardless of experience or place in the academic hierarchy.	Have a conversation before starting work on the project about what you will be paid and any constraints you may have to accepting payments.
Information	A research partner withholds valuable experiential information because of perceived potential discomfort for team members.	Be transparent about the need to have all the information, regardless of its potential to cause discomfort. Work to cultivate a safe space for sharing.	Talk about your lived experience even when you think others may be uncomfortable. Do so in a sensitive way, but do not withhold important information for the comfort of others.
Legitimacy	A requirement that family and youth partners have high school diplomas, no criminal record, and a supervisor's recommendation eliminates many potential candidates from consideration, and perpetuates known racial biases within the community.	Analyze the potential bias attached to every decision leading to who your family partners are. Talk to members of the community about which qualities are important in the people who represent them.	Learn to recognize personal privilege and talk about how your privileges have impacted you. Share stories that humanize and validate those who aren't in the room. Recommend changing policies that are unnecessarily restrictive, and suggest alternate criteria that are more meaningful.
Position	A PI chooses who will have access to information on the project based on each person's position rather than as a contributor to the project.	The PI should give team members full power to contribute in their areas of expertise, as well as resources to start contributing in other areas.	Partners have knowledge that team members don't have. Be confident in the knowledge and expertise that you already have, and act to educate yourself in areas in which you wish to contribute more. Ask for information that you need or want.
Powerlessness	Partners feel marginalized or tokenized by not being consulted or asked to contribute to the discussion.	Remember that partners have a unique and important perspective to contribute that makes research better. They are fully vested members of the research team and must be treated as such.	Be confident in your knowledge and expertise. You are on the team because your experience makes the research better.
Privilege	A family partner is constantly complaining about all the barriers he encounters because he's a working father. The rest of the family partners are mothers who do not or cannot express how things are as bad or worse for working mothers, and the discussion of work-caregiving-life balance remains focused on how to help fathers.	Whenever possible, avoid situations where the division between researchers and family partners is reinforced by known privilege dynamics—for example, all researchers are white and all family partners are black. Look for humility as a key quality in family partners who are privileged over others in their group.	Continually work to understand your privileges and speak with humility about how your advantages have helped you. Do not speak for others, but DO talk about which of your own experiences helped you better understand their situation. (Note: If you are at the table you are privileged. No matter how hard we try, that will always be true.)

Power Attribute	Example of dynamic	Researcher strategies	Family and patient/ stakeholder strategies
Reward	Partners are never adequately acknowledged or rewarded for their contributions to the project.	Reward team members, especially partners, often with credit, praise, thanks, or tangible rewards. This is not the same as compensation or reimbursement. Ensure that all team members are credited appropriately for all deliverables.	Accept rewards graciously. You have earned them. Advocate for yourself and seek support if you feel that you have not been adequately credited or otherwise rewarded.
Willingness to Walk Away	Partner is tokenized or ignored during team meetings and is never meaningfully asked for their opinion or experiences. Partner decides that if they are not acknowledged they will just quit	The team should be inclusive of all team members; ensure that you are including partners by explicitly asking them to contribute to the discussions.	Partners may confront the team about their feelings and ask to be included in discussions, decisions, etc.

Group Discussion

1. Discuss the perceptions of power within your research team.
2. Talk with the community of interest about what research is important to them.
3. Create a plan to address concerns with research team members.
4. What types of training for both lived-experience partners and professionals would benefit the team and the project?

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Chapter 3

Engaging, Recruiting, and Retaining Diverse, Underrepresented, and/or Underserved Children with Special Health Care Needs in Clinical Research

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Introduction

The authors of this chapter are experts in involving children and youth and their families in the research process as research participants. This chapter speaks to that expertise. The editors recognize, however, that the information contained here is also applicable to lived-experience research partners from underserved communities who work as co-investigators on research projects.

To conduct relevant research and ultimately to provide optimal health care to children and youth with special health care needs (CYSHCN), it is critical to utilize the principles of health equity, diversity, and inclusion throughout the research process. Without the equitable inclusion of patients and families, the research findings that have the potential to translate into innovations in clinical care may not be generalizable to all patients.[1]

In this chapter, we present practical health equity, diversity, and inclusion strategies that are essential to engage diverse, underrepresented, and/or underserved children and youth who also have special health care needs, and their families, to participate in research. Henceforth in this chapter, we will refer to these children, youth, and their families collectively as "underrepresented in research" (UiR) children and families. UiR populations have multiple influences on their health outcomes.[2] Thus, researchers must utilize careful, thoughtful strategies in the design, conduct, and reporting of research involving UiR populations so as not to worsen or create additional health inequities.

To ensure that research is representative of UiR children and families, researchers must act with intention to recruit UiR participants who represent diversity and intersectionality in their backgrounds, perspectives, and life experiences. The diversity and intersectionality of UiR populations include, but are not limited to, recruiting participants from different racial and ethnic groups; those whose preference is to speak languages other than English; members of the lesbian, gay, bisexual, transgender, queer, and all sexual and gender minority communities (LGBTQ+); children with complex medical conditions; and those who live across a range of geographic regions (including urban, suburban, and rural/frontier). To conduct high-quality research, it is also essential to recruit and retain participants from across the spectrum of social, environmental, economic, and health experiences. In summary, in this chapter we present research-related strategies to increase the equitable inclusion, engagement, and retention of UiR children and their families in clinical research. These strategies also apply to recruitment and retention of lived-experience partners from UiR populations, who are invaluable in helping to ensure that research studies are relevant to the populations they are meant to help.

BECAUSE . . .

Research consistently biased in favor of privileged people has led to persistent, severe health inequities,

WE NEED TO UNDERSTAND . . .

How research that doesn't engage people underrepresented in research (UiR) continues to contribute to inequities,

AND PRACTICE . . .

Placing a strong focus on engaging with UiR populations as lived-experience partners and research participants.

Background

The lack of representation of diverse populations in adult and pediatric research is well documented.[3–9] Insufficient representation of diverse groups can have significant adverse impacts on research, compromising the generalizability and quality of the study.[1,10,11] Limited inclusion of certain pediatric populations in research may contribute to persistent health inequities as the delivery of evidence-based practices and services are not adequately evaluated in underrepresented and excluded pediatric populations.[1,10,12] Furthermore, research studies designed to inform clinical practice and policy should include those who benefit from the intervention being evaluated, which underscores the importance of including UiR children.

Potential barriers to participation in research are manifold and can also be specific to certain racial, ethnic, or demographic groups.[10,11] Several barriers to research participation by certain groups have been well documented, especially among people of color. These barriers include language; psychosocial factors including mistrust, concern for safety, and stigma; logistical issues such as transportation and child care; and research-related concerns including lack of opportunities for participation and restrictive eligibility criteria.[1,10–14]

For some UiR populations, "mistrust" and "lack of knowledge of certain UiR groups to understand the role of research" are commonly cited barriers to participation in research, but evidence is mixed regarding the actual impact of these cited barriers.[1] In fact, existing data suggest that when approached to participate, underrepresented racial/ethnic groups, including Black, Hispanic, and Asian, are not less likely than non-Hispanic Whites to agree to participate in research studies.[1,15,16] In addition, Wendler et al. identified that a primary barrier to participation in research is the reduced likelihood of being invited to participate.[15] Assuming that mistrust, lack of knowledge, and other participant factors are the primary barriers does not take into account the responsibility of the researcher, health care institutions, and health systems to explore more systematic barriers and create systems and processes to address them.[10] Therefore, building on a recent National Academies of Sciences, Engineering, and Medicine report, this chapter focuses on employing a health equity approach through action at the individual, institutional, and policy levels, conducting community-partnered research, and reducing barriers to participation at each stage of the "research study life cycle."[1]

This chapter focuses on employing a health equity approach through action at the individual, institutional, and policy levels, conducting community-partnered research, and reducing barriers to participation at each stage of the "research study life cycle."

Concepts

Health equity, defined as the opportunity for all individuals to be as healthy as possible, requires intentional and sustained action to reduce medical, social, and environmental barriers to good health.[17] Ensuring that UiR populations, who often experience inequitable health care access and suboptimal health outcomes, are equally represented in pediatric research studies is essential to promoting health equity. In particular, children and youth with special health care needs who have intersecting identities—including but not limited to those who are American Indian, Alaska Native, Asian, Black, Latino, or Native Hawaiian; from low-income families; from the LGBTQ+ community; and from families who prefer to speak languages other than English—should be equally represented in pediatric research studies to make certain that the findings from these studies will be generalizable to all populations. Existing health equity frameworks can provide an approach to including UiR children in research.[2] In addition, the collective experience of the authors has shown that to promote equity in research the approach must include intentional and practical actions that focus on the following domains: 1) the approach to the UiR participant; 2) academic medical center priorities and commitments; and 3) systems and policy alignment. The authors have identified these as ***"Equity in Research Action Steps"*** that will allow researchers to examine the current state and identify opportunities to change current research processes and structures that will increase UiR participation. In summary, it is action in all three domains that is required to support effective and sustainable change.

Equity in Research Action Step #1, Focus on the approach to the UiR participant and lived-experience partners

Critical to increasing participation of UiR children and families is the way in which individual research participants and potential partners are approached. The approach must be predicated on respectful interactions centered on cultural humility and awareness of unconscious bias, with study staff trained in both. Cultural humility is defined as a way of self-reflection, thinking, and acting that allows people to see beyond their own culture, and encourages them to appreciate and respect the beliefs, knowledge, and practices of others.[18] In addition, study staff should be trained to recognize and address their own biases (implicit and explicit biases) with respect to the UiR patients, parents/caregivers, and families with whom they are engaging.[19,20] Other recommended trainings for researchers include trainings to identify, avoid, and address microaggressions, racism, ableism, heterosexism, cissexism, and other forms of discrimination. Finally, every effort should be made to ensure the study team reflects or comes from the community of UiR children and partners being recruited.[19]

Addressing study design, and particularly methods that may influence UiR study subject eligibility, are equally important. Inclusion and exclusion criteria, often based on individual characteristics, could make it more difficult to recruit a sufficient UiR population.[21] For example, language is often an exclusion criterion that results in ineligibility for non-English-speaking participants.[21,22] As language is often cited as a barrier to recruiting non-English-speaking participants and partners, the increased access to interpreter and translation services for researchers is essential to involving these participants.[22] Finally, community-partnered research, described in detail in the "Community engagement, collaboration, and partnership" section below, is an approach that prioritizes the participation of community members in every aspect of a research study and can lead to increased UiR participation.

Equity in Research Action Step #2: Focus on academic medical center priorities and commitments

Academic medical centers (AMCs) must provide the scaffolding, including infrastructure, resources, and support, for researchers to consistently and efficiently engage and recruit UiR pediatric populations. Without this institutional commitment to engaging UiR participants and families, researchers within these AMCs and research institutions must expend extra resources or utilize their own (e.g., from their grants) to recruit UiR participants, which could in turn disincentivize researchers to make this effort.[1,23] Fundamental components of AMC-level actions to promote inclusion of UiR children and their families include prioritizing health equity, creating a culture of respect and cultural humility, and recruiting and retaining diverse research faculty and staff (e.g., diverse research managers, assistants, coordinators, lived-experience partners, etc.). Such strategic institutional changes require thoughtful and accountable leadership and planning, and these efforts must be well resourced.

Additional AMC infrastructure that can support UiR participant inclusion are institutional review boards (IRBs); indirect cost structures; support services for researchers that include both interpreter and translation services; and allocation of internal funding dedicated to promoting and advancing health equity in research. IRBs can support inclusion of UiR children and families by having efficient procedures in place to work with community partners, allow incentive structures to accommodate and promote UiR participation, and conduct equity-focused reviews to ensure all components of the research study protocol utilize current and rigorous health equity research methodology [Boston Children's Hospital Office of Health Equity and Inclusion, unpublished data, 2022]. In addition, health system institutional funding structures, such as indirect costs, could be used to provide research support services such as translation and interpreters, and foster community partnerships.

In addition, AMCs often have resources to provide researchers with seed grants or internal funding opportunities. These resources could be used to promote inclusion of UiR study participants as well as to support researchers who are underrepresented in medicine.[24] With respect to researchers who are underrepresented in medicine, the National Institutes of Health's (NIH) Notice of Interest in Diversity states the following: ". . . to help ensure that the nation remains a global leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds."[25] This should include not only researchers but research study staff. NIH defines the following groups as underrepresented in medicine: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders. In addition, the NIH has recognized that underrepresentation can vary from setting to setting.[25] AMCs must dedicate resources to building career pathways to increase the numbers of underrepresented researchers and research staff as diverse staff are essential to the health systems' strategic priorities and commitments to achieving health equity in their intentional and impactful action. In summary, AMCs must commit to providing researchers with infrastructure, resources, and support to increase inclusion of UiR children and their families in research.

Equity in Research Action Step #3: Focus on systems and policy alignment

If the infrastructure provided by institutions is the scaffolding on which researchers can conduct inclusive research, federal and foundation research funding policies and systems provide the foundation and can incentivize inclusion of UiR children and their families.[1] These funding mechanisms determine research priorities including what is allowable, funded, and thereby encouraged. For researchers, funding guidelines and availability can determine whether they are able to conduct inclusive research. Policies from federal and other funding agencies regarding recruiting, enrolling, and reporting, as well as measuring compliance, are important to advance equitable participant enrollment in research.[1] In addition to these policies, guidelines should be developed to include additional funding in grant budgets specifically to facilitate inclusion of UiR children and their families. This funding can be used to support interpreters and translation services, costs of transportation to and from the study visits, parking, child care for siblings in the household during the study visit, food for study visits, and even missed time from work for parents/caregivers, particularly for those who are hourly wage earners.[26–28] In addition, the funding could be used to pay lived-experience partners for their work on the study. Given the importance of the NIH in funding research focused on UiR study participants, federal policies and guidance can serve as an important example for other funding agencies and foundations.

Community engagement, collaboration, and partnership

Community-based engagement and partnership strategies represent a set of methods to engage UiR children and families in the research process and the implementation to promote their inclusion. These strategies range from gathering focused input from specific communities, such as parents/caregivers of UiR children, to equitably involving community members and researchers in all aspects of the research.[29,30] As described by Patient-Centered Outcomes Research Institute (PCORI), these methods seek to engage community members as ". . . equitable partners—as opposed to research subjects."[31]

Community-based strategies hold promise for engaging UiR populations. Community-partnered participatory research (CPPR), also called community-based participatory research, aims to include community members at each phase of the research process. Community members and researchers are equal partners in determining the research topic or target population of interest, study design, recruitment efforts, and research protocol, including consent, enrollment, data collection, data analysis, and interpretation.[27] Each step toward inclusion is facilitated by involving UiR community members to ensure their lived experiences, backgrounds, and perspectives are well represented, and that the resulting research findings will be useful to the community and not

create harm.[1] Research findings also need to be reviewed by community members to guide the interpretation and relevance of the findings to the community.[31] Finally, research findings should be disseminated to UiR participants, families, and their communities through "lay" (non-academic) summaries and community presentations.[32] Researchers may decide to engage in formal CPPR or include only some aspects of engagement described here.

Community advisory boards (CABs) are another mechanism through which researchers can include community members directly impacted by the research. CABs can inform the research team about many aspects of the research study, including recruitment, enrollment, and data interpretation.[1] The community can also be involved in research by participating in patient and family advisory boards (PFABs) at specific health institutions. PFABs often provide input regarding institutional policies and procedures and may play a role in guiding research agendas and studies that are more meaningful to the researchers and community alike.[32]

Engagement and partnership activities that are effective in one UiR community may not be the correct approach for other UiR communities. It is important for researchers to understand the experiences of UiR pediatric participants and their families and avoid making any assumptions. Yu et al. identify three critical themes for partnering with UiR communities:[29]

1. **Partnerships with underrepresented communities begin with investing time and resources into relationship building.**
2. **Partnerships require commitment from the research team to assess and learn the needs and dynamics of the UiR community of interest.**
3. **Research teams must show respect to community members, including positioning community members as experts, sharing power, and being responsive to community concerns.**

Community engagement, collaboration, and partnership methods occur along a continuum, providing researchers with a range of potential ways to include the UiR community. Researchers must ensure community involvement is at the center of research involving UiR pediatric study participants and their families. This important concept is highlighted well in a contribution to this chapter by a family partner of the Children and Youth with Special Health Care Needs Research Network (CYSHCNet) in the parent's very own impactful words:

"The person and families that are willing to be involved in research tend to be open to share a portion of their lives with [the] professional[s] that work with them 'IF' they are included as a meaningful part of the [research] program. That is to say that they are seen with having a particular set of skills unique to them that they are willing to share for the greater good of families, professionals, and the community." —Natilie Wooldridge, Parent

Researchers must ensure community involvement is at the center of research involving UiR pediatric study participants and their families.

The Research Life Cycle: Multiple Opportunities for Inclusive Research

In addition to community-partnered research, each step in the life cycle of a research study provides multiple opportunities to support inclusive research with UiR children and families. Specific approaches to access, recruitment, remuneration, informed consent, data analysis, interpretation, and results dissemination are presented here.

Study patient demographics

The collection of sociodemographic data from participants is critical to understanding the diversity of study populations and inequities in pediatric health.[33,34] Sociodemographic data, such as race, ethnicity, gender identity, and sexual orientation, must be self-reported by participants or parents/caregivers.[34] The process of collecting sociodemographic data should include providing participants and families with a clear rationale for data collection and response options that reflect the com-

munity of interest. Collecting data from a pediatric population has specific challenges, including collecting from parents/caregivers who may not be able to provide accurate responses and identifying the age at which it is appropriate to collect data from the pediatric participant.[34] While there are standards for the collection and analysis of specific sociodemographic factors, Tan-McGrory and her co-authors who are members of the Pediatric Health Equity Collaborative state that data collection should be tailored to the population being recruited.[34–36]

Access, recruitment, and remuneration

A critical step in increasing inclusion of UiR pediatric participants and families in clinical research is ensuring both they and their communities are fully aware of opportunities to participate in research studies. Making direct and repeated outreach efforts to families, community-based organizations, and medical providers can increase awareness and promote more diverse enrollment in clinical research.[23,37] Research shows parents/caregivers prefer to hear about research opportunities directly from their child's pediatrician or during urgent care visits;[38] thus, increasing provider knowledge of clinical research opportunities is an important step in improving diverse study enrollment. A multi-stakeholder approach has the potential to increase awareness of research opportunities and improve communication and trust between research teams and potential UiR participants.

There are other logistical factors to consider when designing recruitment strategies to encourage enrollment of UiR children and families. Factors such as study site locations, child care, transportation (or lack thereof), remuneration, and other potential study-related costs represent potential barriers to participation if not addressed. Researchers should consider performing study procedures as close to participants' communities as possible or conducting studies virtually.[27] If study visits are in person, this may mean traveling to rural areas or areas not easily accessible by public transportation. However, even for families who may have
easier access to study sites, travel may be prohibitive due to the inability to get time off work, find or afford child care, and/or cost of transportation.[26,27] In summary, research teams should consider paying for and coordinating transportation, providing on-site child care for study visits by resourcing existing resources within their medical centers, as well as performing study visits remotely when possible.

Participant remuneration is often a key component to study recruitment. Participant remuneration aims to mitigate the financial burden associated with study participation. There is significant debate regarding the appropriate amount to reimburse participants for their time and incentivize participation, but not so high as to be coercive.[39] Participant remuneration involves multiple considerations, such as reimbursement for study-related expenses, compensation for the time burden of participating, and incentives for participation. Specific attention must be paid to travel, food, lodging, child care, and any medical care that may arise from the study procedures.[40,41] Compensation should also consider lost wages for time spent in the study, as well as attempting to work around families' work schedules.[40] These expenses should be explicitly stated in the informed consent process and covered by the research team or institution when possible, realizing study-related costs may disproportionately affect participants who have lower socioeconomic status.[26]

The successful recruitment of UiR children and families in clinical research is multifaceted with many factors most likely operating synergistically. Thus, utilizing singular interventions will likely be ineffective. The best way to ensure UiR participant enrollment is to create a recruitment plan with a multipronged approach that is specifically tailored to the study.[23] There is no single prescription for increasing UiR enrollment in pediatric clinical research, as the disease or condition being studied, the pediatric population of interest, and differences in study design will inform the recruitment strategies best suited for increasing UiR enrollment. To ensure the study population is diverse and

representative, community members, other key stakeholders, and health equity, diversity, and inclusion subject matter experts should be consulted during the research protocol development phase,[24] and enrollment should be continually monitored and adjusted if needed, to reach and be equitably accessible to potential UiR study participants.

Informed consent

Informed consent serves as the foundational entry point for clinical research. Its goal is to educate research participants on essential study information, allowing them to make autonomous and voluntary decisions regarding whether to participate. A meaningful informed consent process must not only disseminate important relevant study information, but also ensure complete comprehension by all participants and/or their parents/caregivers.[42] The process should encompass an ongoing communication and information exchange between the research team and UiR pediatric participants and/or their parents/caregivers.

The informed consent process has been criticized as being overly complex and prioritizing documentation over comprehension. Informed consent becomes even more complex in pediatric research as children over the intellectual age of 7 years old are generally viewed as being capable of providing their own informed assent to study participation.[43] Despite the American Academy of Pediatrics (AAP) acknowledging this as the legal age to provide assent, recent studies demonstrate that children may be limited in their ability to comprehend all necessary study information and thus are not able to provide complete consent, even when older than 7.[43] Health literacy, though important for all consent procedures, takes on special significance when engaging with young children and their legal guardians, especially for children who may be neurodivergent, who prefer to speak languages other than English, and/or have challenges reading written documents or comprehending verbal and/or written communications.[26,44,45] Though the literature is limited, existing data suggest that employing strategies such as shortened informed consent documents, digital tools, and enhanced informed consent forms with graphics and narrative form writing have been shown as potential ways to improve both health literacy and overall participant-reported satisfaction with the informed consent process.[46–50] It is also important to pay close attention to the readability of materials; the American Medical Association recommends patient materials be written at no higher than a sixth-grade reading level.[51]

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It is also imperative to consider ways to improve the informed consent process for participants who speak languages other than English. Studies have found language discordance between study team members and parents or caregivers can be a significant obstacle with respect to study enrollment.[37] It is suggested all study-related documents not only be translated into languages other than English, but also that there are members of the study team who are able to speak the languages of the participants and families being enrolled.[27] This can help to promote trust, understanding, and comfort for families, as opposed to solely relying on interpreters.

Study retention

Study attrition can be of special concern when conducting studies with UiR participants. Reasons for study attrition can include transportation challenges, time constraints due to long working hours or having multiple jobs, economic hardship, and greater health challenges due to health disparities.[28,52] To reduce time burden, study teams should conduct only the minimum necessary study visits and should be vigilant during study design to ensure only the study procedures required for study outcomes are included. Also, study teams should consider whether it is possible to conduct follow-up study visits remotely, utilize electronic surveys, conduct visits via video or telephone, or use a research-specific mobile application.[27,37] Regular follow-up with participants also is advised to encourage study retention. "Thank you" cards, holiday greeting cards, or letters with study updates are examples of ways study teams can show their appreciation to families while remaining in contact with study participants.[28]

Data analysis, interpretation, and results dissemination

In the data analytic phase of a study, researchers must give special consideration to stratified analyses that involve UiR groups. More specifically, the study team should have a plan in place to address missing data pertinent to UiR status, such as race/ethnicity, gender, and/or geography. A high percentage of missing data will produce biased results.[53,54] The study team should have an analytic plan in place to address the possibility of a high percentage of records with missing socio-demographic characteristics used to determine whether a UiR participant is in their dataset.[53,54] It also is recommended that sensitivity analyses be performed on the excluded and included cohorts to understand if and how they may differ.[53,54]

Researchers should be aware of the risk their findings may exacerbate existing biases and need to be cognizant of how to mitigate this possibility. For example, research studies focusing on differences by race/ethnicity have the potential to perpetuate theories of biological inferiority and discriminatory behavior.[55,56] While the research study team cannot influence how others interpret their work, they can help to ensure their findings do not perpetuate biases by paying close attention to the language used in the title, abstracts, presentations, and manuscripts that present study findings.[57]

Another important aspect of disseminating results is reporting results directly to study participants and/or their parents/caregivers. The default in clinical research has been, at most, the reporting of aggregate results to study participants.[58,59] Often this would mean sharing scientific publications, which are difficult for individuals outside of the scientific community to understand. Nonetheless, studies have shown that a preponderance of research participants desire to be notified of their individual study results.[60,61] Though it is not always feasible to provide individual results, when possible, all efforts should be made to offer results to families. The research community is starting to rethink the basis for solely sharing aggregate results, as reporting individual-level results may provide direct benefits to participant health, improve trust between study participants and researchers, and encourage enrollment in future research.[62] Here is one of many areas where lived-experience partners can have a significant impact. As co-authors on papers, they can help ensure that participants are notified of findings and cultivate trust in the community.

Results, whether individual or in aggregate, should be conveyed in understandable language, with attention to health literacy in forms that are accessible to participants, such as infographics, video presentations, letters, emails, or telephone calls.[63,64] Researchers should utilize training in cultural humility in their approaches to disseminating results, as different communities may have different perspectives when it comes to learning about results, and families with children with certain diseases/conditions may find results distressing.[62] Like all other areas of research study design, strategies for disseminating results should be study-specific and UiR communities should be consulted when study teams are developing this portion of the protocol. Lived-experience partners can often be the liaisons to the community and advise the research team on community perspectives and how best to convey results to them.

Lived-experience partners can often be the liaisons to the community and advise the research team on community perspectives and how best to convey results to them.

In summary, several important methods should be implemented at various points in the research life cycle to promote inclusion of UiR children and their families as study participants. Funding agencies, AMCs, and researchers should commit to including these more equitable and inclusive methods in their approach to research.

Recommendations

1. A health equity approach to research requires action across three domains to produce sustainable mechanisms to promote inclusion of children and families who are underrepresented in research and also have special health care needs. The three domains are listed below:
   a. Approach to the underrepresented in research (UiR) participant
   b. Academic medical center (AMC) priorities and commitments
   c. Systems and policy alignment
2. AMCs should prioritize and commit to equitable strategies for increasing participation of UiR children and their families.
3. Community-partnered participatory research approaches should be utilized to increase UiR participation in clinical research. Researchers need training to develop and implement community-partnered research strategic relationships that will successfully engage UiR children and families in participating in every aspect of the research study—i.e., from the study design to the interpretation and dissemination of the research findings.
4. A collaborative partnership with UiR pediatric study participants, their families and communities can facilitate their participation.
5. Recruitment strategies should reflect an understanding and involvement of the community.
6. Community partners and research staff should be members of the community of interest; and whenever needed, researchers should have access to and resources for translation and interpreter services.
7. Policies and guidelines for grant budgets should include funding to facilitate research participation for UiR children and families; and to increase the numbers of researchers who are underrepresented in medicine.

Future Directions

1. Advocacy for policies to ensure health equity, diversity, and inclusion in pediatric trials and research, including for UiR children and families.
2. Development of a "research navigator" role on the study team to assist UiR children and families in understanding and participating in research, with special consideration of (but not limited to) culture, cultural humility, unconscious biases, and preferred language.

Group Discussion

1. In what ways can researchers reduce the barriers to participation by UiR children and their families?
2. How can researchers ensure UiR children and/or their parents/caregivers fully understand the informed consent process?
3. When and how are the research team engaging community partners?
4. What is the research team doing to ensure its research staff are properly trained in cultural humility and unconscious bias; and that they are representative of the UiR population being recruited?
5. Does the research team's approach utilize intentional and practical *"Equity in Action Research Steps"* focused on the: 1) approach to the UiR pediatric study participant; 2) AMC priorities and commitments; and 3) systems and policy alignment?
6. What additional resources are needed?

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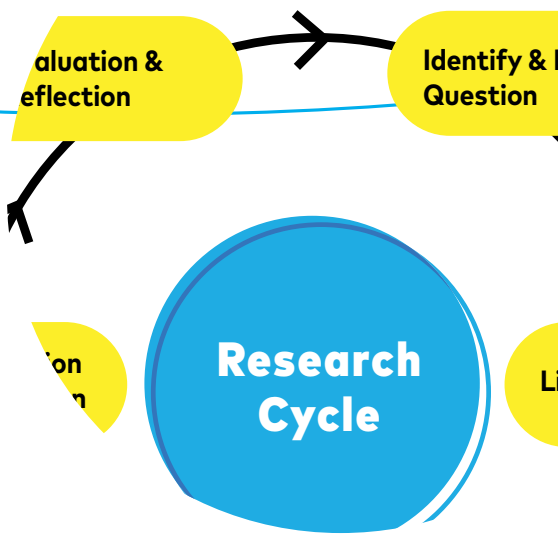

Chapter 4

Family-Driven Research Design

Ryan Coller | Lisa Maynes

Introduction

Patient- and family-centered care is a framework that influences how services are delivered and is a widely recognized standard in the health care field. The core principles of patient- and family-centered care stem from the belief that a family has the greatest influence on the care and well-being of each of its members. As such, the patients and caregivers as partners must be listened to, respected, and valued as part of the individual's care team. The result is a mutually beneficial, trusting relationship that results in better care outcomes. This framework provides an excellent foundation for the incorporation of those with lived experience into the research design process.

Throughout this chapter we use several terms interchangeably—families, parents, guardians, caregivers, patients, and lived-experience partners. The goal is to keep the writing clear and concise. Regardless of the word used in a section, the intention is to promote as inclusive of a concept as possible, recognizing that the way an individual might define themself or their role can vary greatly.

Though participatory research has involved families and individuals with lived experiences for many years, it remains an evolving approach to research that aspires to achieve a balance between the influence patients and families have with that of research teams (Figure 1). To begin bringing those with lived experience in from the onset of research design is the next promising area of evolution, but requires the development of partnerships and relationship building as core elements to successfully include families and patients as equal partners in the research process. Early trials of such research partnerships have shown a positive impact and identified some of the potential challenges to expect.

Benefits

The benefits of lived-experience partnerships in research are numerous for all involved. Families often desire to make a difference, not only for themselves but also for others facing similar circumstances. This gives them an opportunity to act in a professional role doing work that may improve systems of care for their children. Having a parent partner can bring a higher level of credibility to the project by engaging stakeholders at a high level. It can help with the recruitment of participants, and data- gathering activities such as surveys, focus groups, or interviews.

Different perspectives are likely to shed light on aspects of the project that might not otherwise have been acknowledged. For example, if a study is looking at the efficacy of in-home services for children with special health needs, a parent who has experienced these services will have unique ideas for the study and may even help identify possible areas that may have been impacting those outcomes. A parent might note that sibling presence can alter a child's response to therapy at any given moment in time. A parent partner at CYSHCNet shares her story:

I worked on a research project about the understanding of pediatric palliative care among parents with children with complex medical needs. I was part of the project from the beginning and had input into the research question. Indeed, it is a topic I know well from my personal experience as a

BECAUSE . . .

Lived-experience partnerships are either built in, or locked out, during the research-design phase,

WE NEED TO UNDERSTAND . . .

How a well-designed study makes use of lived-experience contributions,

AND PRACTICE . . .

Designing research goals and activities to maximize the impact of lived-experience partners.

parent and from my professional role; after my child died, I joined the hospital as a manager of two clinics for these populations. I've seen firsthand how pediatric palliative care helps with pain management, decision support, and quality of life despite misconceptions among parents and some [health care] providers that it entails end-of-life care only.

I always felt that I was an integral part of the project and had a perspective that was respected and valued. The other team members listened to me, expressed curiosity by asking me questions, and acted on my suggestions. I had meetings with the research team about structuring the research question, reviewed the initial application and focus group questions, joined several focus groups, met regularly with the team throughout, and have begun coding the transcripts of the focus groups.

I believe to my core that parents and caregivers are essential partners in the research process. When my child became sick and a huge medical team took nine months to diagnose him, they told me again and again that I was a necessary part of their team. This is true in the case of research. Researchers can and should reinforce this message for parents and recognize that some parents don't get that message in the clinical setting. —Sandra Clancy, Parent and Lived-Experience Partner

Background

The concept of family-driven care is relatively new. It was not until the 1980s that a publication by Knitzer discussed the idea that families needed to be part of the solution to children's mental health concerns.[1] Extrapolating from that idea, the idea of patient- and family-centered research takes the next step toward ensuring that those most affected by research findings and clinical care are intimately involved in the processes that directly affect their health, quality of life, and well-being. By putting patients and their families at the forefront of research, studies can be directed to investigate topics that are most concerning to the people who are affected by the findings.

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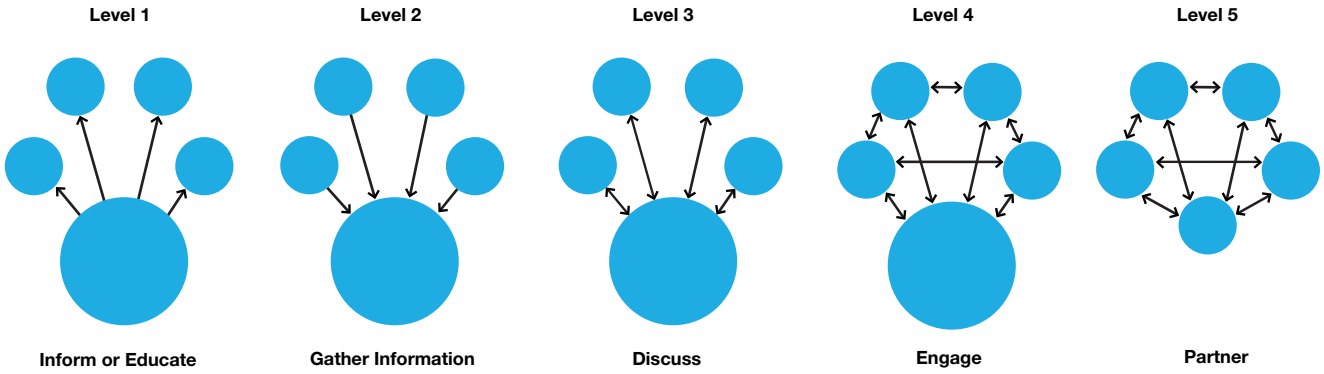
Many health researchers and research teams have an inherently strong interest in conducting family-driven research, but they face the daunting challenge of not knowing where, or how, to begin. In some cases, the timing of lived-experience partnership may be unclear, and researchers may fear their idea is either too under- or overdeveloped to engage with outside stakeholders. For example, a research team might feel their project is not sufficiently polished to present to a family partner, so they continue to refine the plan without engagement. Another research team might feel uncomfortable engaging with a family partner after already having a fully formed idea; or worse, they may feel too firmly committed to their vision to want the additional family input. Researchers may also not know which lived-experience partners to engage, or what they should say when approaching stakeholders. And some researchers may have existing personal or professional relationships with stakeholders that can complicate a partnership. For example, a physician-researcher may be considering engaging with a family stakeholder whose child is a patient of theirs. In other cases, researchers may fear they are burdening families, and a research project may not yet have the resources to support compensation for a partner. Certainly, other barriers to patient- and family-driven research design exist. As with all aspects of research conduct, with careful planning, support from experts, and current evidence, research teams can overcome many if not all of these challenges.

However, there is a continuum of engagement where, while the design of the research may be patient- and family-centered, the reality of the interaction is not necessarily fully involving the lived-experience partners. In Figure 1 below, arrows depict information flowing between research teams (larger circles) and lived-experience partners (smaller circles). At Levels 1 and 2, research

teams communicate with or gather information from lived-experience partners, respectively. At Level 3, research teams both communicate with and gather information from lived-experience partners. At Level 4, research teams and lived-experience partners engage with one another; however, a key distinction in Level 5 is the equality in the size of the circles to reflect that research teams and family partners have more balanced participation and influence with one another.



Adapted from Health Canada's Public Involvement Continuum[2]

Research from patient and family engagement in health care systems also provides useful frameworks that can be adapted to illustrate family-driven research (Figure 2). In such models, engagement exists on a continuum that is influenced by a variety of factors across multiple levels. For example, in the figure below adapted from Carman et al.,[3] each box further to the right indicates an increasing degree of family participation and collaboration. The extent to which patients and families are engaged in research is influenced by their individual characteristics, the organization, and broader societal context

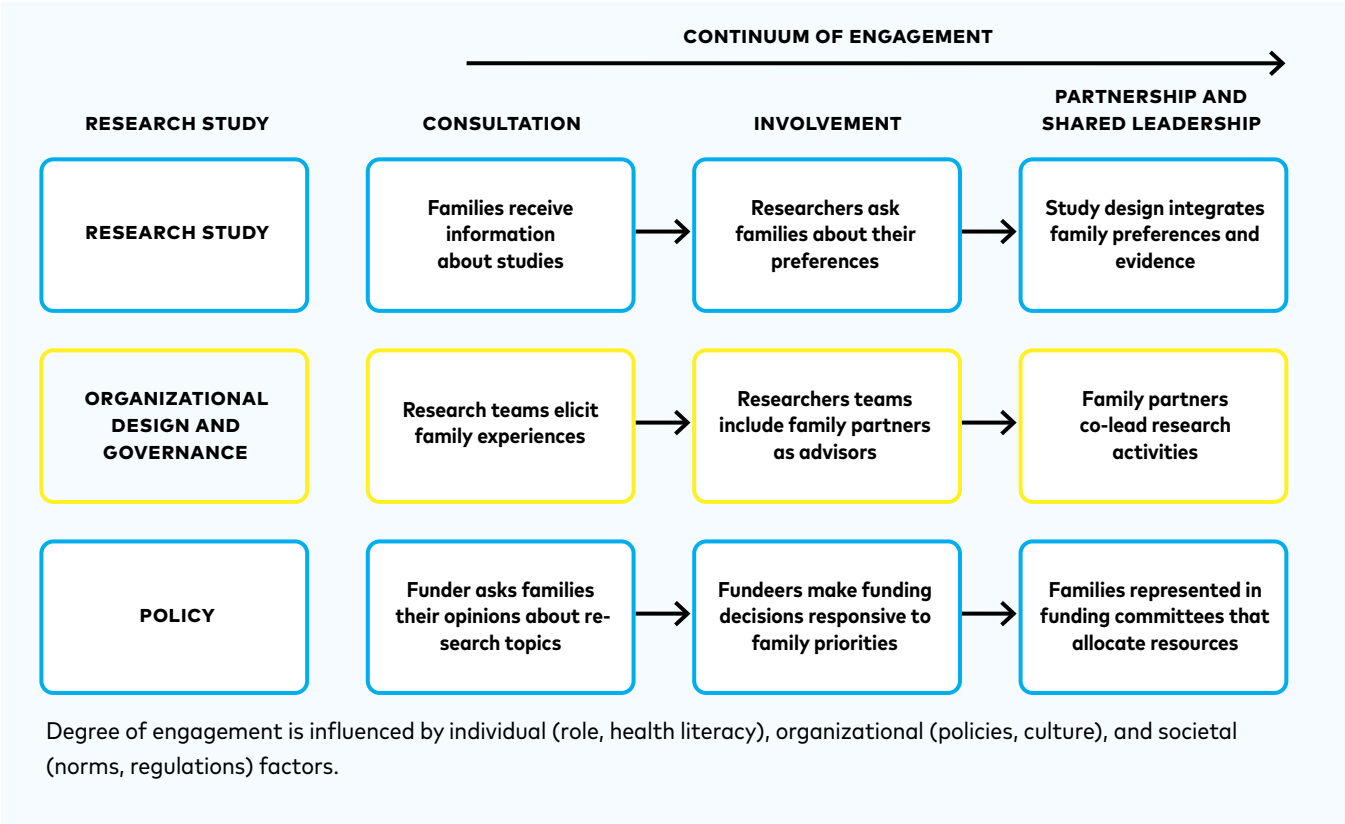


Figure 2. Adapted framework of patient engagement applied to family-driven research involving individual, organizational, and governance levels.

Before embarking on a project with lived-experience partners, there are several considerations to consider to improve the success of the partnership. Diversity of perspective and social experience is an important priority; however, historical influences may cause families from underrepresented and diverse communities to feel like less of a true partner. (For more on working with diverse communities, see Chapter 3.) Other factors that are critical to the partnership included consideration of personal boundaries for patients and families and an appreciation that these might change over time. Understanding the effort that is required to make the partnership work on the part of the lived-experience partners who may be stretched very thin is critical. Finally, the roles and responsibilities of the project members are critical to everyone involved with research, but this is especially true for lived-experience partners who may need additional training to achieve equal participation in the project.

Concepts

Inspired by rich experiences from our own research and guidance from leading organizations focused on stakeholder-engaged research, including the Patient-Centered Outcomes Research Institute, the National Institute for Children's Health Quality, Family Voices, and others, we propose a practical structure for those interested in conducting patient- and family-driven research. We discuss general considerations followed by specific approaches to study design, conduct, analysis, and dissemination, all from the perspective of increasing the family voice in research studies. Although the content of this chapter is directed at research teams, family partners interested in research will likely find the content valuable as they prepare to engage in a research study.

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Foundational Considerations

A research team can be made of one or many individuals, having a wide array of personal and professional backgrounds. Whether the research lead identifies as a health care provider, scientist, family stakeholder, trainee, other professional, or even a combination of these, the principles described here are applicable. A critical early step for research leaders is to plan for family engagement. One particularly helpful structure to support comprehensive planning is offered through the Patient-Centered Outcomes Research Institute's engagement rubric.[4] This rubric highlights potential engagement activities for patient/family stakeholders when planning a study (e.g., developing research questions, minimizing disruption to stakeholder participants), conducting a study (e.g., serving on the study's data safety monitoring board, reviewing protocols), and disseminating a study's results (e.g., participation in dissemination efforts, identifying partner organizations for dissemination). This tool has been used in research to improve asthma care by integrating clinician and patient perspectives on who should deliver an asthma intervention, and when and how it should be delivered during routine care.[5]

Simultaneous with planning, defining the research question pursued by the research team is a dynamic, iterative, early step. Finalizing the research question is so fundamental to research design that it influences all subsequent decisions about the study's execution—the specific methods, data sources, analyses, etc. But it has other critical implications. The research question indicates what the researchers believe is the most important next step to solve a problem, and therefore reflects the values and priorities of the research team. It can even determine who might be considered a stakeholder. For example, a researcher may be impassioned to study whether training school teachers on proper inhaler mask/spacer technique for asthma care reduces steroid courses; and it may turn out that different processes (e.g., training the school nurses or parents) or outcomes (e.g., improves school attendance) are far more important to families.

With this in mind, the ideal is to refine the research question with lived-experience partners very early in the process. One reason this can be challenging, or even a vulnerability for a young research partnership, is that once a research question is fairly mature, a researcher may not be comfortable

modifying it. At the same time, during early iterations of defining the research question, the researcher may not yet feel sufficiently prepared to attempt meaningful partnership (e.g., they may feel unready to complete the "planning" step). Several strategies can help researchers and lived-experience partners navigate this process. Researchers should vet their research ideas with patient or family stakeholders before the research is too far along, and then be prepared to incorporate this feedback. Researchers whose work is rooted in, and grows from, a history of patient and family partnership will have an easier time with this. Often, researchers may base their research questions on local family experiences and feedback (e.g., from a clinical parent advisory council, or recent challenges faced through routine care). Researchers may also draw research questions from existing research priorities or agendas developed with patient and family partnerships. Using such resources significantly increases the chances that the research question will align with the priorities of patients and families.

Patient and family engagement experiences on a research team will naturally be dynamic. Without deliberately monitoring the state of this relationship, teams may lack awareness of highs and lows, or what is driving successes and challenges. Deciding how to evaluate the relationship over time is an important element of planning. (See Chapter 7 for a complete discussion on evaluation.) A number of tools exist, several of which are included in the Resources chapter. Child health research teams may find those developed in partnership with families focused on children with special health care needs to be particularly relevant. For example, the National Institute for Children's Health Quality Family Engagement Guide includes a self-assessment checklist for leaders involving family advisors and partners on projects (https://www.nichq.org/sites/default/files/resource-file/Family_Engagement_Guide_FINAL.pdf).

Research teams can use this tool both to plan for family engagement, but also to monitor improvements over time.

Research teams can use this tool both to plan for family engagement, but also to monitor improvements over time. Alternatively, another tool is available in the toolkit created by Family Voices, the Family Engagement in Systems Toolkit (https://familyvoices.org/familyengagementtoolkit/). This pragmatic toolkit facilitates team planning, evaluation, and improvement, using transparent engagement metrics that highlight strengths and opportunities in areas of commitment, transparency, representation, and impact. A tool to measure systemic-level family engagement is the Family Engagement in Systems Assessment Tool (FESAT). We suggest discussing and agreeing on the evaluation plan with team members. One approach could be to measure engagement at the "baseline" of a partnership. After discussing the results as a team and adjusting where needed, engagement can be monitored according to an agreed-upon frequency (e.g., quarterly, annually, biannually). Leaders should plan to celebrate areas of success, and (as with any relationship) expect to find opportunities for improvement to be approached honestly and constructively.

Designing and Conducting Patient- and Family-Driven Research

Team Formation. All research teams benefit from clear role delineation among team members, and a clear definition of the role(s) of lived-experience partners is a direct extension of this. There is no specific number of partners needed for a project to achieve the goals described in this chapter. A project may involve one or many individual partners, and even one or many organizations representing stakeholders. Having multiple partners can offer added value in multiple ways: brings different perspectives, partners might cover for one another at times, peer support or mentorship, avoid tokenism, lower risk for a gap in partnership if a partner has to step back, etc. Although ideal patient- and family-driven research will involve genuine partnerships across the entirety of the project, the role that any individual partner plays will vary widely based on interest, availability, skills, experience, and the needs of the research team. For example, an experienced partner might lead a study's recruitment, designing recruitment materials, connecting with participants, and even managing consent and enrollment. Regardless of the specific role(s) played by an individual partner, important characteristics include comfort, confidence, willingness to share ideas or concerns, reliability, patience, and organizational skills. Research skills are not necessary for making

meaningful contributions. Important characteristics for research teams engaging with lived-experience partners include compassion, flexibility, open-mindedness, clear and transparent communication, and effective project management. Team leaders should have open conversations and document all team members' roles in a freely accessible location early in the project.

Recruiting, Training, and Sustaining Lived-Experience Partners. Identifying and recruiting lived-experience partners can be one of the more challenging aspects of patient- and family-driven research. In particular, outreach and recruitment of partners who reflect the culture and experience of the work are critical. Various avenues exist from which a research team might identify partners, and researchers may need to pursue several simultaneously to achieve diverse and representative partners. Clinicians might already have relationships with patients or family partners from prior initiatives to draw from—e.g., clinical work, quality improvement projects, previous research collaborations, etc. Many hospitals, clinics, and health systems have patient and family advisory councils and researchers may be able to ask to join a meeting to promote this opportunity. At times, a council such as this might even work closely with the research team and serve in a partnership role. Community, policy, and advocacy organizations representing patients and families can also help either serve as lived-experience partners or assist with the recruitment of partners—e.g., your state or territory Family to Family Health Information Center, Family Voices, state Title V programs, veterans' organizations, or other patient advocacy groups. Social media, particularly family groups often centered around a specific condition, may provide opportunities to advertise and meet potential partners.

Partner organizations who assist with recruitment can also help guide partner onboarding and support for partners over time, with a budget for the time the organization staff puts into it. Training checklists and orientation materials written for partners are helpful to provide an efficient and comprehensive introduction to all partners who join research teams. Early in their experience, the opportunity to shadow other partners can help newer partners gain confidence in their role. All questions should be encouraged and respected. Lived-experience partners should be included and promoted at team meetings and introduced as team members. Scheduling standing check-ins between team leaders and partners provide the opportunity to give bidirectional feedback and troubleshoot as the partner is gaining familiarity with the work and the team members.

Most of this chapter's activities contribute directly to sustaining partnerships over time. Additional strategies to maintain a partnership include clearly defining the duration, scope, and responsibilities of the partnership, which can be complemented through a written job description. Common elements of a job description include 1) a brief summary of the research program and the role of partners; 2) responsibilities; 3) skills and any special requirements (e.g., background check, regulatory training); and 4) compensation, time commitments, and timelines. This level of transparency, whether through a written job description or not, helps partners decide whether a commitment is realistic for them, and will help select partners who are well aligned to the goals of the research. Researchers should also recognize that, just as with other research professionals, unpredictable circumstances or poor alignment can prematurely end a partnership. This is natural, and teams should attempt to learn from these situations through exit interviews and open feedback. For example, were the team's expectations realistic? Were the partners' expectations realistic? Was the partner adequately prepared and supported? Did the partner have a voice and feel valued? What advice would the partner give to the research team when working with their next partner?

In some cases, a partner might simply need to step back temporarily or redefine the extent of their participation (perhaps redistributing some duties to others).

In some cases, a partner might simply need to step back temporarily or redefine the extent of their participation (perhaps redistributing some duties to others). Offering this flexibility can ultimately be a wise strategy for research teams by yielding the benefits of a longer-term, continuous partnership. Some research teams may even wish to plan for such possibilities in advance, openly with partners. Asking "How do you think we should approach the situation if you have to step back from the team at some point—if your child needs to be hospitalized, for example?" A compassionate and committed stance from the research team can help solidify a bond with partners: "We know

your level of participation might need to vary over time because your child's health is fragile and you have many other responsibilities; we understand and respect that. We are comfortable facing those challenges together when they arise." Moreover, experiencing these circumstances with partners can enlighten research teams to a better appreciation for the lived experiences of their partners.

Scheduling and Conducting Meetings. Scheduling meetings while considering partner schedules is important to promote diverse and inclusive partnerships. Because ideal timing is tremendously variable person-to-person, discussing openly what works best for team members is most practical. Because partnership credibility and effectiveness are strongest when time commitments are met, monitoring attendance and adjusting meeting times as needed to embrace partner participation is important. Creative options for meeting scheduling can include virtual attendance, alternating timing (e.g., evening vs. day, morning vs. afternoon, week vs. weekend, or other), transportation or parking support, and even child care assistance for special events.

Beyond meeting attendance, research teams and partners should also focus on meaningful participation during meetings. Some strategies that research teams can use to create an inclusive environment are introducing individuals/roles but minimizing the use of titles and hierarchies; welcoming and respecting all comments and translating technical language and concepts (written and spoken) into understandable and accessible language for all meeting participants; and paying attention to partner body language and degree of participation and addressing concerning signs. General meeting management strategies that apply to any meeting are relevant to supporting partners—e.g., preparing agendas, setting meeting goals, taking minutes, providing materials to review in advance, etc. Distributing minutes and/or recording virtual meetings provide opportunities for all team members to stay up to date when conflicts inevitably arise.

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Compensation. See Chapter 6 on Project Management.

Funding and Grant Writing. Lived-experience partnership through the proposal development process for a grant or contract is a natural way to ensure research questions and team structures best reflect the perspectives of the partnership. Including letters of support that speak to the strength of the partnership can convincingly highlight authenticity in a partnership while validating the importance of the research to this stakeholder group. However, the inability to compensate partners for their help developing a funding proposal, and partner discomfort with proposal writing, can be substantial barriers to partner inclusion. One practical strategy can be to have a consultation with partners. For example, during a meeting, research leaders can bring high-priority decisions to partners for feedback. High-priority decisions frequently include finalizing research aims, the budget for partnership, general team structure, and the dissemination plan. Based on mutual interest and availability, partners may be able to help draft or revise such relevant sections of a funding proposal.

Research Project Life Cycle. Once a research plan is finalized, and the team is assembled, most research projects work through a common set of activities (Figure 3). The main steps include regulatory approvals, recruitment and/or assembly of a research cohort, data collection, study interventions (if an intervention study), data analysis, and dissemination of findings. In more complex research studies, these activities may not be linear or sequential. For example, a quality improvement research study might have multiple rounds of interventions followed by data collection and analysis, where each round builds from what was learned in prior rounds. Across the research study, patient- and family-driven research has partnerships provided by one or multiple specific individuals (or organizations) across the entirety of its work. In addition, one partner might focus their work on a limited set of these activities. For example, with the right interest, availability, and training, a partner may lead or co-lead the dissemination of findings to academic (e.g., abstracts, papers, etc.) and non-academic (e.g., social media, webinar, policy, etc.) audiences.

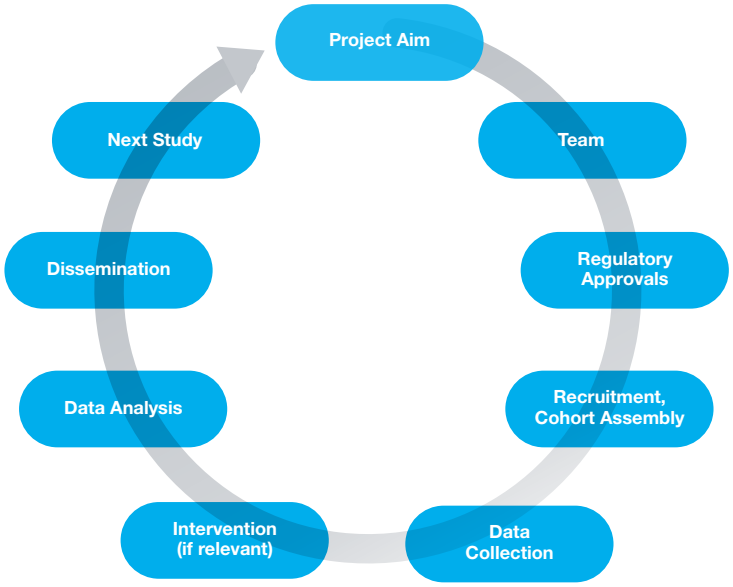

Figure 3. Traditional project life cycle of major activities in a clinical research study with partnership at every step. Based on project and partner decisions, an individual partner may focus intensively on one or more of these areas.

Disseminating Research Findings. Research dissemination can take many forms, all of which benefit from lived-experience partnership. Planning dissemination even as the study is just beginning is a valuable way to ensure partner input is considered in the strategy, and that partners are included in project outputs. Dissemination often serves two purposes: information sharing (communicating new knowledge) or promoting the spread of innovations (dissemination and implementation). In both cases, lived-experience partner involvement is essential. Traditional academic products (e.g., published manuscripts and conference presentations) should offer partners the same opportunity for authorship as other research team members. In addition, lived experience bring unique expertise about specific organizations that could benefit from hearing about research findings. Relationships between partners and community or advocacy organizations can also create opportunities and interest in sharing research findings. Lived-experience partners may have distinct social media connections that provide avenues for research messages to reach broader audiences. A valuable role partners often play is ensuring that dissemination materials are designed to be accessible to all consumers of research. Some stakeholder groups, such as policymakers or administrators, may better connect with materials that have been created for non-technical audiences compared to materials created by researchers themselves. At times, presentations of research findings are more compelling when delivered by patients or families, particularly because they bring inherent credibility when endorsing the relevance and impact the research has on children and families.

Group Discussion

1. You are a parent partner, flattered to be asked to join a team starting a study that aims to improve the management of challenging symptoms like those your child experiences. You are passionate about the topic, but nervous about fitting it in with your very busy schedule. What might you need to negotiate for yourself, and how will you approach potentially uncomfortable topics such as compensation? What parts of this partnership will be most important to you? What will you discuss with the team leaders?
2. You are a researcher who wants to better integrate family participation in your study. Why is this important to you? How will you handle recruitment? Who can assist you in navigating this process?
3. As a research team member of a relatively new collaboration, you sense that there are growing differences of opinion between the clinician and lived-experience team members about measurement plans being chosen for their study. Clinicians think that collecting surveys about transitions to adult care during a hospitalization will be convenient, while lived-experience team members

are concerned that this will be too stressful, and might exclude perspectives of families experiencing greater stress from hospitalization. What are some ways you can bring this up to the team? How can the team best navigate through what might be some difficult conversations?

4. During a debrief after a study, a lived-experience partner shares that they felt respected and valued; however, they noted that it took them until the study was nearly finished to feel comfortable speaking up during meetings. They said that they did not think they really understood their role until about half-way through the study. What would you say to the family partner? What might the team do differently in the future?

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Chapter 5

Co-Production

Introduction

In this chapter, we will introduce a family of strategies that ground collaboration between researchers and lived-experience partners. We selected co-production as a blanket term that captures a number of practices starting with "co"—such as co-learning, co-creation, co-presentation, co-authorship, co-design, co-building, co-governance, co-management, co-delivery, co-implementation, and the original co's, collaboration, cooperation, and community. A lot of these terms have sprung up somewhat independently to capture different aspects of collaboration. Some of them overlap, some of them are very general, and some of them are very specific. We chose to focus on co-production because it is the most general of all and flows through all parts of the research process. While we love the meaning of the word "collaboration," we are afraid that that word is worn out from being overused and under-delivered. To avoid that pitfall, we need to think about co-production and all the different pieces that need to come together to make co-production of research meaningful and impactful.

Some examples of co-production include:

- **A new school building includes a section of wall, prominently visible within the entryway, that is reserved for a mural to be designed and painted by the first cohort of students in the school.**
- **A medical equipment company convenes a community panel to partner with human factors engineers in an overhaul and redesign of their line of mobility aids, including wheelchairs and walkers.**
- **A state-level Medicaid program submits policy changes to a citizen oversight board for review, revision, and approval before making any changes that affect Medicaid users.**

Co-production should not be treated as a public relations ploy. Consider the first example above—it is the mural that was co-produced, not the entire building. If the school administrators had given the children a single wall to paint, then used that to claim that they worked with the children to make a child-friendly school, that would be an example of tokenism, not of co-production.

One of the essential features of co-producing research with lived-experience partners is partnership at all phases of the research project. In this chapter, we will get very specific about what that means, what it looks like, and how it is accomplished. Researchers are often trained to think of the research process as a cycle with four parts: planning, implementation, analysis, and dissemination. Co-production of research includes the corresponding parts of co-design (both during proposal writing and after funding is received); co-management; co-analysis; and co-dissemination (in the form of both co-presentation and co-authorship). In addition, the practice of co-learning continues throughout the research process, as research partners and lived-experience partners work together and learn from each other (see Figure 5.1).

BECAUSE . . .

We achieve our best results when lived-experience partners contribute to all phases and activities of research,

WE NEED TO UNDERSTAND . . .

Co-production as a blanket term that covers a range of "co" terms, including co-design, co-management, cooperation, and community,

AND PRACTICE . . .

Collaboration, capacity building, and co-learning to make our co-produced results more impactful.

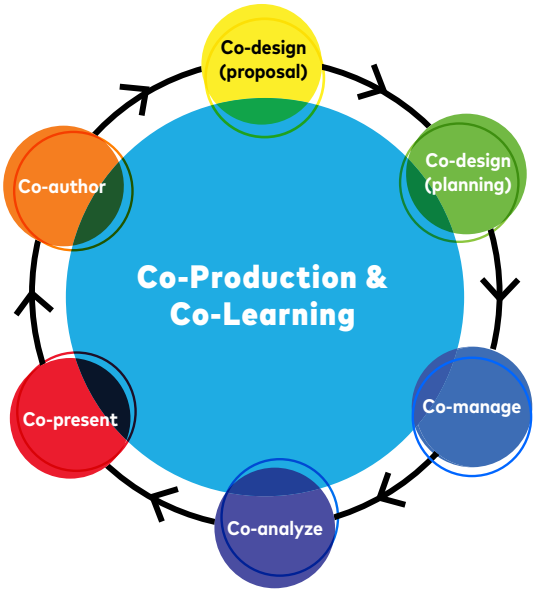

Figure 5.1 The co-research cycle

Background

The idea of community-based production is not new. In fact, it is universal and normal—everyone who has taken part in a play or a potluck has done it. However, it has suffered some major scalability problems as some of our cities and institutions have achieved an inconceivable size. Much of the time, it is impossible for a medical researcher to know everyone involved in researching topics related to their own, much less to know every patient who is impacted by their research. To co-produce successfully under these circumstances, we need to draw on best practices that were developed for co-production operating at this scale.

The term co-production originated with broad applications to services and material products, across the private and public sectors.[1] Co-production is defined as "the process through which inputs used to produce a good or service are contributed by individuals who are not 'in' the same organization."[2] This practice is so widely used and valued today that it is hard to believe that in 1996, some researchers still viewed it as "radical."[2]

Co-production is a central feature of several well-known research approaches, including community-based participatory research (CBPR),[3,4] participatory action research[5], empowerment evaluation,[6] and integrated knowledge translation[7] and of the related field of critical pedagogy.[8] More recently, the Patient-Centered Outcomes Research Institute has worked to normalize patient engagement as a required element of patient-centered outcomes research (PCOR).[9] Our own approach to co-production is based mainly on CBPR and PCOR, and also draws on the strong tradition of co-production of government services within the Health Resources & Services Administration Maternal and Child Health Bureau.

A CO-PRODUCTION PIONEER

Elinor Ostrom (1933–2012) developed the concept of co-production through work with the Workshop in Political Theory and Policy Analysis that she and her husband, Vincent, founded at Indiana University in 1973. A Nobel laureate in Economics who had been refused admission by UCLA's Department of Economics—her PhD was in political science—it isn't hard to imagine how Ostrom learned to value the importance of underrepresented perspectives. Ostrom's most significant academic contributions related to her work on the concept of community commons. Although examples of **community commons** exist all over the world, popular economic theory in the 1970s held that the community commons was an inherently unstable arrangement, based on the so-called "tragedy of the commons." Ostrom challenged this school of thought and developed a theory base that described the mechanisms communities use to manage shared resources. The spirit of Ostrom's work is summed up in Ostrom's law, coined by Lee Anne Fennell in 2011, which states that **An economic arrangement that works in practice can work in theory.**[10]

Concepts

Community: When people come together with shared needs, a shared sense of purpose, or a shared identity, they form a community. Communities can be based on where people live, where they worship, the work that they do, how they identify themselves, or how others identify them. Health-related research brings together various communities, including:

- **A community of people who are expected to benefit from the research (people who are diagnosed with the health condition being researched, for example).**
- **A community of researchers linked together by the topics that they research.**
- **A community of researchers linked together by the institution that they work for.**
- **The new community that is formed out of the people who are connected to the research itself.**

There is a certain amount of tension or even controversy over whether a community can be defined around sharing a single characteristic such as a medical diagnosis. As a family caregiver in the cystic fibrosis community, I (CH) can say with total confidence that diagnosis communities exist. However, some research partners may need help understanding how a diagnosis community comes to be and what it means.

Priority community: The **priority community** is the community of people who are expected to benefit the most from the research. This might include people who have a particular diagnosis, who live near the institution where the research takes place, or who are impacted by health care inequities that the research promises to address. When we talk about **lived-experience partners**, we mean members of the community of people who are expected to benefit from the research, and particularly members of the priority community or communities. **Research always has a priority community.** Failing to identify the priority community doesn't make research equitable and generalizable to everyone. In fact (and of course), it makes research less likely to be equitable. One of the first contributions of lived-experience partners in the planning phase of research should be identifying important divisions that exist within the patient community. Generally these divisions are connected to unequal access to appropriate health care, and are based on race, ethnicity, language, age, where people live, type of health insurance, and other familiar factors that are linked to health inequities.

When we talk about **lived-experience partners**, we mean members of the community of people who are expected to benefit from the research, and particularly members of the priority community or communities.

Iterative process: A process is called **iterative** if it repeats the same steps again and again and builds on what went before each time it repeats. The co-research cycle shown in **Figure 5.1** is an example of an iterative process. Every time a research team starts a new research project, and a new research cycle, they are building on what they built and learned in earlier projects. Researchers are also expected to learn from and build on research projects completed by other teams doing research related to their work. **The iterative nature of research is particularly important to co-produced research**[4] because iteration supports the ongoing dialogue between research findings and lived experience.

Co-Learning: Co-learning describes the interaction when collaborators learn together and learn from each other. This approach is built on the assumption that everyone has lots to learn and everyone has knowledge and experiences to share. The group discussion questions that we provide at the end of every chapter in this handbook are intended to support co-learning. If you discuss these questions with your research team (or some other mixed group of researchers and lived-experience partners), you will learn things from each other that we can't teach you with a book alone. What will you learn? We don't know—although in some cases we can guess. In promoting co-learning, we have accepted a trade-off that gives us less control over what information you receive, but gives you information that is more memorable and (too likely) more valuable to you.

The group discussion questions that we provide at the end of every chapter in this handbook are intended to support co-learning.

Co-Design: In Figure 5.1, we break **co-design** out into two different phases of the research process: the proposal writing phase, and the planning phase. We did this because the proposal writing phase is often thought of as before the project truly starts, and therefore before the start of co-production. We obviously don't agree with that, and we want to share some questions that research partners and community partners need to answer together as part of the pre-funding part of co-design.

- Is the research question something that the patient community cares about?
- Will it realistically have an impact on how healthy patients are?
- Do patients agree with the criteria that researchers are using to measure that impact?
- Are there communities with health inequities who should be prioritized in this project, and if so who and how?

All of these questions relate to decisions that are made during the proposal writing phase, that will be hard to fix if lived-experience partners find problems with them later on.

On the other hand, there are other questions that can be put off until the co-design phase that comes after a proposal has been funded. These might include:

- Adding secondary outcomes to the primary outcomes that will be used to measure impact.
- Identifying venues for recruiting study participants.
- Deciding the type and number of materials that will be developed to educate patients.
- Developing approaches to respond to priority communities that were not recognized in the original proposal.

To postpone decisions like these until after the project is funded, write a proposal that describes how you will work with lived-experience partners to address these issues. This approach is discussed in more detail below under Recommendations. ("Protect flexibility while writing the proposal with handoffs to lived-experience partners and contributors in later steps.")

Co-Management: We use **co-management** to describe the most essential role that lived-experience partners must play during implementation of a research project. However, implementation of a study covers a lot of different activities, and many different kinds of opportunities for lived-experience partners to take part in the study. In practice, many of the contributions of lived-experience partners who co-manage a study take the form of identifying other ways for lived-experience partners to take part in implementing the study. For example, if the study includes focus groups, lived-experience partners may have suggestions about community venues that can host the focus groups, skilled individuals from the community who can act as facilitators, or ways to recruit so that the community is well represented. Lived-experience partners may also make suggestions about implementation that really can't be turned down. Thinking about focus groups again, it's fairly common for lived-experience partners to recognize that a focus group MUST have a member of the community acting as a host or facilitator. Depending on the questions asked and baseline levels of trust, this may be the best or only way for a focus group to succeed at its goals.

Co-Analysis: We use the term **co-analysis** to recognize the role that lived-experience partners play in making sense of the data collected during research. It may be difficult for lived-experience partners to make meaningful contributions at this point if the plan for data collection was developed without lived-experience input. However, if the data collection plan was well designed (in other words, if it asked the right questions in the right way), lived-experience partners will be able to help keep data analysis grounded in real-world implications. The key to successful co-analysis is to set up a dialogue between the researcher interpretation of data and the lived-experience interpretation. (Note that researchers who believe that there is only one way to look at data may struggle with this step.) Through dialogue, researchers can come to understand aspects of the data that

We want to share some questions that research partners and community partners need to answer together as part of the pre-funding part of co-design.

their prior training did not cover adequately. For example, the time and labor required to complete a particular treatment at home may have been overlooked, or the importance of a particular symptom may have been underestimated.

Co-Authorship: Co-authorship means writing together, sharing ideas, and mentoring lived-experience partners and other community partners to be full contributors to the public narrative of the project and its findings. Co-author guidelines for lived-experience partners in academic journals are equivalent to the guidelines for other co-authors; however, it may be helpful to think about lived-experience examples in interpreting these guidelines.[11] Lived-experience partners may also be helpful in authoring materials intended for non-academic audiences, particularly when the primary audience is members of their own community.

Co-Presentation: Lived-experience partners **co-present** to put a public face on how lived-experience partners contributed to the research project. They also help members of the community connect with and understand the research findings in the presentation. For researchers watching the presentation, lived experience co-presenters play a similar role to the roles they played throughout the research project, including keeping the research grounded in real-world implications.

Recommendations

Define the priority community carefully, including making implicit limitations explicit: During the planning (proposal writing) step, conceptualize your research project within the context of a clearly defined priority community (or communities) of people who are expected to benefit from the research. In medical research, this step should be completed along with selection of the medical criteria for study participation.

Define the priority community carefully, including making implicit limitations explicit

For example, to research an intervention relating to poorly controlled diabetes, we might start out with "patients with A1C over 8." If the research will only be conducted in English, then that should be included in the description of the priority community. If the research is focused on the patient's relationship with their spouse, then the priority community is people who are married. Our priority community statement now reads "patients with A1C over 8, who speak English and are married." If we examine this more carefully, we might start to wonder: Everyone who speaks English, or do they need to read English at the high school level? Everyone who is married, or are we assuming that spouses are cis/het? Do we want to accept these built-in limitations or do we want to take the necessary steps to make meaningful changes in who belongs to our priority community?

Design a lived-experience partnership plan around the priority community: Once you have identified a priority community or communities, develop a strong plan for how lived-experience partners will support your work for those communities in each step of your project. In particular, working with lived-experience partners from the community is essential for addressing health equity.[12] In addition to working with lived-experience partners as co-investigators, a well-rounded partnership plan will use dynamic, adaptable approaches to supplement the knowledge of lived-experience partners. This may include focus groups or key informant interviews designed to target particular segments of the priority community; surveys that gather input from large numbers of people without requiring big time investments from them; town hall meetings to share preliminary research results and get community feedback on what they mean; and employing members of the community as staff on the research project.

Think of research as on ongoing cycle, not a one-off

Think of research as on ongoing cycle, not a one-off: This point is related to the concept of **iterative process** described above. It is important for research to build on previous research rather than asking the same questions over and over again; however, this is only one of several reasons why it is important to recognize each research project as one loop in an ongoing cycle. Another important reason relates to the emotional needs of lived-experience partners. While lived-experience partners should receive immediate rewards, such as being paid for their work, this isn't the

reason most lived-experience partners get involved in research. We get involved because we believe in the work itself, because we want to help others in our community, and because we want to see something good come out of the challenges we have suffered through. Under these circumstances, a research project that ends up going nowhere isn't just a setback, it's a new emotional wound added to the burdens that we already bear. Whether by publishing null results or by designing a project to generate multiple kinds of findings that can be applied in later research, research that includes lived-experience partnerships needs to produce tangible results that let lived-experience partners take meaning away from the work.

Protect flexibility while writing the proposal with handoffs to lived-experience partners and contributors in later steps: The proposal writing step of a research project is usually the step with the least resources and the least input from lived-experience partners. To avoid getting locked into decisions without adequate input from lived-experience partners, specify the areas of work that need to be decided collaboratively. When using this strategy, lived-experience partners during the proposal writing step can focus on identifying the areas that need to remain flexible. For example, a proposal could say "Body mass index (BMI) will be the primary outcome of interest. Past work with this community suggests that we should also be looking at body type and how it interacts with BMI. Once we have convened our advisory council, we will work with them to identify the best way to measure body type and to potentially identify other secondary outcomes that they expect to be important to our research question." This statement establishes that BMI and related outcomes will be a major area of interest but also leaves an opening for deferring to what lived-experience partners have to say about these outcomes.

Future Directions

In many ways, co-production will define its own future. Every field of study and every research question offers a distinct set of opportunities for lived-experience partners to set new priorities, reframe existing knowledge, and challenge deeply held assumptions. Fortunately, lived-experience partners are not the only part of the research community taking on these opportunities. We are part of a larger trend recognizing that the best science results from community endeavors that expose researchers to a wide range of perspectives. Multidisciplinary research, translational research, and stakeholder engagement are all motivated by similar needs and goals, and will help make the path of the lived-experience partner easier to follow.

The following chapters on project management, evaluation, and ethics will lay out key aspects of the culture shift that needs to happen within research to make co-production standard practice. One immediate concern relates to how co-production is reported in the products of research. The expectation has yet to take hold that co-production can—and must—be specifically and concisely described in the methods section of every resulting article. While standards have been established for what should be reported,13 we caution that the barriers here are not just about how to write up co-production. Co-authors may encounter resistance that is intent on preventing lived-experience partners from stepping out of their designated role as research subjects. We still occasionally find ourselves making the argument that, no, it is not a breach of confidentiality to acknowledge lived-experience partners for their contributions to the work. Establishing and maintaining standards for how co-produced work is published will be a critical step toward establishing and maintaining standards for how co-produced work is practiced.

We are part of a larger trend recognizing that the best science results from community endeavors that expose researchers to a wide range of perspectives.

Group Discussion

1. What is your favorite "co": co-learning, co-creation, co-design, co-building, co-management, collaboration, cooperation, or something else that isn't on this list? What are the values and practices that this term holds for you?
2. What communities are you part of? Which ones are most important to your role in co-produced research?
3. Have you taken part in co-production outside of research or medicine (for example, at your church, school, or workplace)? What was that experience like?
4. What do you think is most important in the relationship between researchers and lived-experience partners to make co-production successful?
5. What will co-production look like in your current partnership? How will it happen, and what will it accomplish?

Resources

The Community Toolbox maintained at the University of Kansas (https://ctb.ku.edu/en) is a long-standing archive of materials, training, and best practices for co-production.

Abeysekera, 2015 [1] provides a summary of literature on co-production as well as a general overview.

The Integrated Knowledge Translation Research Network (https://www.biomedcentral.com/collections/IKT) maintains an annotated archive of concept papers relating to their work on co-production of research.

Richards et al., 2020 [11] provide guidance on how to apply academic co-authorship guidelines to lived-experience co-authors.

Staniszewska et al., 2017 [13] present guidelines for reporting co-production of research using the GRIPP2 (short form).

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Chapter 6

Project Management

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Introduction

Researchers have to manage many parts of a research project, from collecting data to making sure each team member knows what they have to do. Focusing on project management helps the project leaders figure out how to lead in a way that meets the needs of the project and team. Successful project management of any research study requires detailed planning, from start to finish. In this chapter we present the principles and concepts of project management as detailed in the Project Management Institute's *Project Management Body of Knowledge (PMBOK)*.[1] We relate those principles and concepts to research projects specifically and add considerations for working with lived-experience partners such as compensation. We chose to focus on *PMBOK* because it is a readily accessible and trusted resource. The Project Management Institute offers a widely recognized certification in project management. We want to recognize that there are many other excellent resources available to help in successfully managing projects; however, *PMBOK* offers a comprehensive jumping-off point for successful management of projects.

Project management is not just about sticking to a timeline or a budget; it involves getting a project started on the right foot; managing relationships, roles, and tasks; tailoring the project; ensuring high quality; being adaptable; and closing the project. In some cases, project management also involves learning new concepts during the process and learning how to do new tasks. Good project management can ensure that the study goes smoothly, that the needs of the research team are met, and that products are delivered on time and in budget. A smoothly running project is beneficial to the project team, the funder, and ultimately to the people the study findings are meant to benefit.

Background

Involving lived-experience partners as co-investigators on studies is a fairly new concept. Since working with lived-experience partners is still a relatively new part of research, there is a good chance that members of the research team have not worked with lived-experience partners in this way before. Investigators have not always wanted to involve lived-experience partners because of concerns about how to do it in a way that is ethical. There may be a tendency to treat lived-experience partners as assistants or as advisory group members. Neither of these roles is appropriate. Lived-experience partners are co-investigators. They are employed to help ensure that the study—from start to finish—is patient- and family-centered. Foundations and governments that pay for research have begun requiring the involvement of lived-experience and community partners in meaningful ways.[2]

When student researchers are introduced to research, they usually learn about the types of studies and data, how to use the data, the ideas behind different types of research, and maybe a little about writing grants. They almost never learn about project management, even though project management skills are important for anyone leading studies, especially if the project is large and involves multiple locations and a team of people.

Over time, multiple tools have been developed to help with managing a project.[3] Tools to help with project management can include charts or spreadsheets, and more complex programs like Microsoft Project, Asana, Trello, Wrike, ClickUp, and many more, which can help with bigger projects that have more people and budget items.

BECAUSE . . .

Lived-experience partnerships need time and investment to mature and are often abandoned when projects run short of resources,

WE NEED TO UNDERSTAND . . .

The basics of project management as they apply in a research setting,

AND PRACTICE . . .

Evidence-based methods for planning and managing projects so that they can achieve their stated goals.

The Project Management Institute, the world's leading authority on project management, partners with approved companies to offer classes in project management. Researchers who are managing large projects and/or multiple projects at the same time should consider coursework and/or certifications to gain project management skills. These companies teach about the complexity of managing a project and provide guidance to help the team work together in an efficient way. The Project Management Institute publishes the industry standard *Project Management Body of Knowledge (PMBOK)* guide[4] that outlines the principles of project management along with project performance domains. We review the principles and domains below and apply them to research with lived-experience partners.

Concepts

Project management requires the research team, and especially the principal investigator (PI), to pay attention to many parts of the project—not just the data. Lived-experience partners can help with project management in several ways. They may have experience in specific areas like budgeting or administration, they can be assigned to manage some part of the project, or they can help by keeping track of some portion of the project such as the number of responses to a survey or being responsible for sending reminders to participants. Lived-experience partners should have roles and tasks that match their skills and interests. These roles should be discussed with the PI and agreed upon. In the end, lived-experience partners are there to share their experiences, but being an important part of the research team means they can have a lot more to offer.

The recommendations found below expand on these two concepts and offer suggestions and rationales for thinking deeply about involving lived-experience partners.

Recommendations

Our main recommendation for leading a project involves organizing your thinking around the key principles of project management.[1] *PMBOK* identifies the principles of good project management and the specifics of how to use the principles in the project performance domains. The recommendations below are built around these principles and domains. We want to emphasize that in all aspects of a project, from beginning to end, lived-experience partners should be paid for their work. However, we also want to recognize that in crafting and submitting a proposal for funding, all parties are working without pay. If the proposed project is not funded, there is a possibility that there will not be funds available to pay team members who worked on the proposal. This possibility should be discussed with lived-experience partners up front, but if possible, funds should be secured to pay them for their time regardless of the outcome of the proposal submission.

Before you begin

Consider the study you want to create. Think about the question you want to answer (research question), goals, hypotheses (educated guesses about what you might learn), the people you want to learn about, and what you hope to see as a result of the study. Before you begin, you find a funder and start creating the proposal you will submit. This is the time to think about how you will involve lived-experience partners and how they will be paid—how much, how often, and in what form—so the budget includes enough funds to pay lived-experience partners fairly. This is also the time to begin recruiting lived-experience partners for the study. Connecting with a community-based organization can help you find people from the group you want to learn about in your research. You might want to start with family-run organizations like Family Voices, veterans' organizations, community or civic groups, faith-based groups, and many others. You may have patients or colleagues who can suggest people who would like to serve as lived-experience partners.

BECAUSE . . .

The biggest barriers to lived-experience partnerships are often the result of early decisions made during the planning phases of the research project (for example, about budget and staffing),

WE NEED TO UNDERSTAND . . .

Principles of project management that set a lived-experience project up for success,

AND PRACTICE . . .

Systematic approaches to project planning and management that support lived-experience partnerships as part of the project's structure.

CONSIDER

- **Research question**
- **Community of interest**
- **Outcome you hope for**
- **Funder**
- **How partners will be involved (roles)**
- **How/how much partners will be paid**
- **Who will be the liaison**

While you find and choose your lived-experience partners, think about the work they will be doing (their roles) and how you will compensate (pay) them for that work so that you can begin to put together a realistic budget.

Principles of project management

According to the 7th edition of PMBOK, there are 12 principles of project management that should guide behavior on projects.[6] The principles are:

These principles reflect an overall commitment to excellence and working collaboratively with the team and stakeholders. Research projects are complex and often go in unexpected directions so the team needs to be able to pivot, tailor, and adapt to those changes. In doing so, the project leader or PI needs to bring the team along and ensure that each member is meaningfully engaged.

Project performance domains:

The 12 project principals will guide the eight project performance domains: stakeholders, team, project life cycle, planning, project work, delivery of the product, measurement, and uncertainty. We discuss the domains here and selected sub-domains such as tailoring. We also include information on closing the project, which is an essential step to quality improvement in the next project.

Stakeholders (lived-experience partners):

In this case, we are talking about lived-experience partners and how they are supported by the project team and the PI; however, stakeholders generally include anyone who is affected by or has an interest in the study findings. These may include patients, families, policy-makers, insurance funders, and others. Partners should agree on the project objectives since the findings will apply to them and their communities. Identifying partners from those communities is a first step. The project lead and/or project team should regularly engage partners using communication techniques such as emails, status meetings, meeting minutes, and data reports. The PI and/or project lead should be careful to create a safe space that encourages lived-experience partners to openly voice their opinions, disagreements, and/or ask questions. A feedback loop is useful here: making sure that partners understand the content and asking about what might be missing in the discussions about the project.

Project Performance Domains:

- **Stakeholders**
- **Team**
- **Project life cycle**
- **Planning**
- **Project work**
- **Delivery of the product**
- **Measurement**
- **Uncertainty**

Sub-domains:

- **Tailoring**
- **Closing**

Since working with lived-experience partners is still a relatively new part of research, there is a good chance that members of uthe research team have not worked with lived-experience partners in this way before. There may be a tendency to treat lived-experience partners as assistants or as advisory group members. Neither of these roles is appropriate. Lived-experience partners are co-investigators. They are employed to help ensure that the study—from start to finish—is patient- and family-centered.

Lived-experience partners can make sure that:

The research question is relevant to the community

The language in surveys or interview guides meets the needs of the community being studied

The needs of participants are considered

Diverse populations are represented and recruited in culturally appropriate ways

1. Orientation of all research team members:

Orientation to a study or project is an important step. Both the research team and the lived-experience partners need orientation to the project. They also need to know how to work together. Often the professional research team members have not worked with lived-experience partners before and are unsure of their roles and abilities. For the project to run smoothly, both lived-experience partners and the research team need to understand what the project involves and how they will work together. We address training of both lived-experience partners and the research team later in the chapter. Use the template at the end of this guide to help you think through all the areas in which the whole research team needs to be oriented.

Tasks to Remember:

- Assign a primary contact person to work with lived-experience partners.
- Be flexible when you schedule meeting times.
- Explain the roles of lived-experience partners to professional members of the research team.
- Provide training in basic research methods and review a glossary of research terms with lived-experience partners.
- Have honest and clear conversations with lived-experience partners about compensation and reimbursement.
- Ask about accommodations, such as interpretation or assistive devices, that will allow lived-experience partners to participate fully.

A person on the professional research team should be assigned to be the primary contact, or liaison,[7] with lived-experience partners. This person is responsible for addressing any questions and concerns that arise and should have the authority to solve problems.

Be sure lived-experience partners are aware of scheduled meetings, calls, and deadlines. Even if they are not responsible for meeting a deadline, it is important that they know what is happening in the project. Lived-experience partners may have day jobs that prevent them from meeting during the business day. Plan to have at least some meetings during times when they can participate. If lived-experience partners will be co-presenting or attending a conference, give them as much notice as possible so they can arrange for child care and other needs.

Lived-experience partners should think about their schedules and let the PI know when they are available so the meetings can be scheduled when they can attend. Lived-experience partners should also be proactive in making their needs known to the PI. They should tell the PI about their schedules, along with any expenses they need reimbursement for. This includes child care and any accommodations to help them participate in meetings, such as interpreters or assistive devices, training on research or the project, and any other needs that will help them be fully involved. Everyone participating in the project should be aware of power differences and be sure that all members of the team feel safe expressing their opinions, especially when they differ.

2. Team

The team members, including lived-experience partners, should share ownership in the project. Each member should be allowed to display leadership. The PI should work to motivate and enable the partners to participate and contribute their experiences. The PI can also lead by ensuring that all team members have ample opportunities to contribute in their own way. Clear roles and responsibilities and guidance of the team toward the project objectives are the responsibility of the team leader or PI. Some ways to achieve these objectives include:

- Establishing an environment for safe and respectful communications through positive discourse, courage to respectfully disagree, and support through providing encouragement, showing empathy, and active listening
- Being transparent
- Celebrating success
- Trust
- Adaptability and resilien787

3. Project life cycle

The life cycle includes the deliverables, timeline of deliverables, and how the deliverables will be created and delivered. All team members should be aware of the timelines, deadlines, milestones, and, where possible, how they are expected to contribute. The diagram below shows a simplified version of the research cycle. A project does not usually go smoothly from beginning to end, rather the sections are revisited based on adapting and tailoring the project to the needs of the community, the data, the literature, or other situations. Feedback throughout the project is essential to strong lived-experience partner engagement.[8]

4. Planning

Planning is the heart of project management. The most amount of time should be spent in the planning phase. Time you spend here pays off in the end. While there are many aspects of planning your project, we focus here on how you plan to get both the lived-experience partners and the other members of the research team familiar with each other (build relationships) and with the project. We discuss how planning helps anticipate the needs of the team and the project for effective management of the project.

Set clear goals, objectives, and outcomes.

Plan the design and methodology carefully.

Understand potential challenges and barriers.

Decide who will be on the team and what they will do.

Define the deliverables.

Develop a realistic budget and timeline.

Plan ways to communicate information to the team.

4.a Budget and Compensation (payment):

Paying lived-experience partners for their work on the project is essential. They are contributing information that is important to the quality of the research. Fair compensation means that the amount they are paid reflects the value they bring to the project. Researchers, funders, and others know how important fair compensation is, but sometimes they do not know how or how much to compensate lived-experience partners. Because of this, compensation can involve anything from pizza to $100+ per hour, with no real explanation of the differences in payment. Compensation is not just about having the money; many barriers can hinder fair compensation beyond a lack of funds. Richards et al.5 list eight reasons fair compensation doesn't always happen:

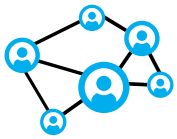
- Lack of awareness about patient partnership
- Institutions that are not flexible
- Policy guidance from funders
- Compensation not prioritized in research budgets
- Leadership that may not want to create a new system
- Culture of research teams
- Preconceived beliefs about the skills and abilities of patient partners
- Expectations placed on patient partners

These barriers show why it is important to change the culture of research teams and institutions so it is seen as normal to work with lived-experience partners as co-investigators.

Lived-experience partners play a unique role in research—they understand how the health care system actually works and what specific information is relevant to their needs. They have experience navigating health care and are experts in their own or their family members' health needs. Health systems research is working to improve the systems of care, the treatment of disease, access to health care, and affordability of health care, among other areas. Partners with lived experience in these areas can speak about the reality of how health care affects their lives, which makes them a great value to researchers. Lived-experience partners spend many hours working on studies, so paying them for their time and expertise is not different from paying any other member of the research team.

Some benefits of paying partners include:

Helps them participate in studies



Expands the pool of lived-experience partners

Honors their unique knowledge and contributions to the quality of the studies on which they work

When planning the budget for lived-experience partners, we suggest a minimum starting rate of $25 per hour, plus expenses.[9] This is based on the average pay rate for an entry-level research assistant, with a bonus for lived experience. The rate should be increased depending on the lived-experience partners' experience, education, and role in the project. A lived-experience partner with relevant experience, who can write or edit a manuscript, who is analyzing data, or who is helping to manage the project should be paid for their skills and expertise.

The needs of the project should be thought out during the creation of the budget because once the project is funded, it is difficult to ask for money to fund extra personnel. Management of a project that includes lived-experience partners on the research team involves careful consideration of the lived-experience partner's role throughout all parts of the project. When thinking about involving and paying lived-experience partners, it is important that the research team consider the needs of the project. For example,

- Do you need lived-experience partners who have experience working on projects and a working knowledge of methods and data analysis?
- Do you need help with understanding the needs of the population or condition being studied?
- What is the scope of the project—clinical trial, multi-site, or small pilot?
- What funding is available from the grantor for compensating the lived-experience partners?

Once the needs of the project are thought out, a budget can be planned. Some questions to ask to help plan the budget are:

- What are the potential and/or defined roles and responsibilities that the lived-experience partners can have on the project?
- What skills or qualifications will lived-experience partners need to carry out those roles?
- What training and orientation will lived-experience partners need to be effective in their roles?
- What is the time commitment of the lived-experience partners? Will the lived-experience partners be involved throughout the full length of the project period?

You will need to have discussions about how to structure compensation. Types of payments might depend on what the lived-experience partners need and what the institution requires. For example, lived-experience partners who receive benefits like Medicaid may not be able to receive cash

payments because the income may put them over their income threshold. The institution may have rules about how to pay non-employees; for example, lived-experience partners may have to register for supplier or contractor status. The PI should check with the institution's accounts payable or research grants department for guidance on required forms and rules for payment. Community groups may be helpful in paying lived-experience partners. Sometimes they will have funds available or they may be able to help individuals who speak languages other than English to fill out forms or explain the different types of payments. In the case of young investigators such as students who may not have an adequate budget to pay lived-experience partners, community groups can sometimes help to fill the gap. Some questions to help guide you in structuring payments, amounts, and institutional policies about payments are:

- What documents are required by the research institution to onboard the lived-experience partners?
- What mechanisms are in place for compensating lived-experience partners? Is a discussion with accounts payable or the grants team necessary to ensure compensation for the lived-experience partners?
- What is the appropriate compensation based on the defined roles and time required on the project?
- How can I find potential lived-experience partners?

Finally, compensation for work on a project is not the same as reimbursement for expenses. Expenses that lived-experience partners might have for work on a project can include transportation, child care, travel expenses, interpretation, or parking. These expenses are not counted as income and should be paid separately and documented as reimbursement. The research team should be clear about what can be reimbursed according to institutional policy or the project budget. Compensation is income, while reimbursement is not. Lived-experience partners and the PI should be clear on how compensation will be paid (check from the institution, gift cards, or other types of payment) and make sure that the payments do not put the lived-experience partners at risk of losing benefits.

A Standard of Compensation for Youth, Family, and Patient Research Partners (SoC) is a publication of CYSHCNet. It includes specific information about methods of payment, considerations for partners who have benefits that are based on their income, and recommended compensation for lived-experience partners. The SoC is available at no cost at www.CYSHCNet.org.

A Standard of Compensation for Youth, Family, and Patient Research Partners (SoC) is a publication of CYSHCNet.

4.b Training:

Lived-experience partners may not have formal research training, even if they have worked on projects in the past. In our evaluations of lived-experience partners, we have found that almost all would like to have some research training; however, few, if any, training programs are in languages other than English. CYSHCNet is working with some of its partners to create research training in Spanish and French. In the reference section of this guide is a list of some excellent training resources for lived-experience partners, several of which can be completed in six hours or less. Many are free and can be completed at one's own pace, and some programs offer a certificate of completion. We recommend that lived-experience partners be paid for completing training. The investment for training at the $25 per hour rate is minimal and will help to ensure that lived-experience partners feel that they are true partners in the project.

Providing basic education and resource material such as this guide, a glossary of terms, and a thorough orientation to the project—its purpose, aims, protocol, and deliverables—is necessary for a successful partnership.

5. Project work:

Once you have oriented the research team and lived-experience partners, completed any required paperwork, discussed concerns and answered questions, scheduled meetings, and other preliminary tasks, you are ready to begin the study. Based on your planning process and orientation, move forward with the project plan. Recognize that training may be ongoing, especially if parts of the project such as participant recruitment, data collection methods, or analytical methods change.

6. Delivery of the product:

As the project progresses, the team should be thinking about which products will be delivered to the funder and to stakeholders. Lived-experience partners provide value in that their outside perspectives enhance the ability of a project to be relevant to a larger constituency. Research studies almost always result in a paper that is submitted to a professional journal, but many other types of products can also be created. Common products may include presentations at local, regional, or national conferences; posters; informational brochures; white papers; webinars; policy briefs; social media postings; web pages; and reports. A funder may specify which products they want, but other products can be included.

Live-experience partners should participate in the design, creation, and dissemination of all products from start to finish. They can help ensure that language is appropriate for the audiences receiving the products, discuss nuances in the way information is presented so that the information is culturally relevant and appropriate, and they can contribute by writing, photographing, or creating content to include in the products. Lived-experience partners should be co-authors on articles and other products based on their contribution to the project.

Products should explain and reflect the intended outcomes of the project such as how the findings of the study relate to the intended purpose of the study and how the findings are relevant to the intended audiences or stakeholders. Lived-experience partners can be instrumental in making sure that findings are described in ways that resonate with stakeholders, especially non-researchers and non-academics. In other words, how can the average person understand and use the findings to help improve their health, quality of life, or well-being? Occasionally, the results of a study may have multiple levels of interest—researchers may be interested in one aspect of the findings, but families and patients may be interested in a different one. Lived-experience partners can help tease out the different parts of the findings to increase the relevance of the study to different stakeholder groups.

Lived-experience partners can help tease out the different parts of the findings to increase the relevance of the study to different stakeholder groups.

7. Measurement:

Measurement or evaluation of the lived-experience partnership is an important component of successful partnership. In Chapter 8 of this handbook, the authors discuss evaluation in depth. For now, the PI, lived-experience partner, and the research team should be aware of how the partnership is going. The PI should take responsibility for ensuring that the partner is involved fully in the project and that any concerns or questions are promptly addressed.

8. Uncertainty:

There may be uncertainty in how to work with lived-experience partners, whether a partner feels confident in their ability to do the work, what roles should be assigned to lived-experience partners, and more. Transparency is key here. PIs know that projects take twists and turns and there are sometimes unexpected complications. Keeping partners apprised of how the project is going and presenting any unforeseen circumstances or changes to their roles keeps trust intact. For lived-experience partners, the same applies—family, work, and other commitments may change how they participate. Partners should be transparent about any possible changes to their ability to participate.

Tailoring

Tailoring in the context of project management is "deliberately adapting the project management approach, governance, or process to suit the environment."[1] For working with lived-experience partners, tailoring involves understanding the partners' experiences, needs, and interests to help determine what roles they should have on the project. Empowering partners to fully use their skills and experiences is important, but it comes with understanding how much supervision and direction is needed. Tailoring also involves creating a team that is diverse and including lived-experience partners that reflect the population being studied.

A liaison should be assigned who has the ability and authority to solve problems or answer questions and concerns. Often, the PI is the liaison, but on larger teams, a different person may be the go-to person. Be sure to keep lived-experience partners informed of all parts of the project through reminders, calendar invites, contact information, notes from meetings, and any changes to the project plan. The liaison should check in with lived-experience partners periodically to ask about any questions or concerns they may have.

Paying lived-experience partners is an important task that may need to be tailored to the organization's policies. This might involve completing paperwork or forms, registering as a consultant, completing training, or other requirements. Based on the timetable for paying lived-experience partners (for example weekly, monthly, or quarterly), invoices or other required paperwork should be submitted so that lived-experience partners receive payments without delays.

The cultures of both the lived-experience partners and the research team are important to consider. For example, are there language differences that require an interpreter? Are there accommodations necessary for partners to fully participate, especially if participation is in person instead of virtual? Examples might include child care, transportation costs, or an attendant. Are there cultural practices that should be noted, including working during cultural holidays, food preferences if working in person, etc.

Closing

Once the project is completed, evaluate the impact of having lived-experience partners on your project. A process evaluation will help both the researchers and the lived-experience partners on the next project. Creating a "lessons learned" document is also valuable for the team. For more on project evaluation, see the Evaluation chapter of this guide.

A process evaluation will help both the researchers and the lived-experience partners on the next project.

Limitations

There are so many tools available to track projects that it may be overwhelming to decide which ones are best for your needs. There is a lack of multilingual training resources available for lived-experience partners. While work is underway to translate some of the resources listed in the Resources chapter, you may need to work with translators and interpreters to make sure your materials and training are accessible.

At the end of this chapter is a template to help PIs orient lived-experience partners to a study. A copy of this sheet should be given to all research team members. It is important that plain language is used to fill out the sections and that the PI be as succinct as possible. All of the items can be discussed in more detail at team meetings; this form acts as either a checklist for PIs or a reference for lived-experience partners.

Group Discussion

1. What policies and resources in your institution support lived-experience partners in research projects? What policy changes or resources are needed?
2. What are your ideas for how to orient your team to a new project?
3. Discuss the most important information that should be part of an orientation to a project.
4. Are there any barriers that affect compensating lived-experience partners in this study?

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Sample Checklists for Orienting Lived-experience Partners

Project Name:
SAMPLE PROJECT INFORMATION

PROJECT DESCRIPTION	
Start date & anticipated duration	October 2021, 12 months duration
Project type (qual, quant, mixed)	Qualitative
Research Question	What are the best ways to support families who work on research studies?
Aims	1) To learn about what supports families want 2) To design a program to support families
Data collection methods	One-on-one interviews, focus groups
Expected end products (paper, conference abstract, presentation, etc.)	Paper, conference presentation
What is the expected use of the findings? Who will benefit?	Findings will add to knowledge of how best to support lived-experience partners in research. Research team and lived-experience partners will benefit by enhancing trust and learning how teams can support partners.

PARTNER ROLES	
Activities (meetings, data analysis, interviews, authorship, etc.)	Participate in biweekly meetings, help revise interview guide, help analyze interviews, read and comment on the paper, be a presenter at national conference (if available).
Timing (when/how often meetings are held, deadlines, how far into the project are you?)	Coding meetings will likely be weekly or biweekly (exact schedule to be determined).
Explanation of each role (what are partners expected to DO in their roles—i.e., administer surveys, etc.)	Talk about your lived experience in all areas of the project and help craft interview guide using plain language that participants can understand.
Amount of time expected to participate in or complete each role or task (hours per week/month, hours per task—e.g., leading a focus group)	Approximately 3-4 hours weekly (read interviews, discuss during biweekly meetings).

RESEARCH TEAM	
Names of all team members (including other family partners	Sue Smith (PI), Anne Johnson (PI mentor), Rusty Gonzales (qualitative methods advisor), Joe Lagos (research assistant).
Go-to person for questions or concerns	Sue Smith (ssmith@internet.edu)
Roles of other team members	Principal Investigator (PI): runs the study Research assistant: provides observational feedback during interviews, code interview transcripts Qualitative methods advisor: assists during coding meetings, provides expert guidance PI mentor: helps guide the PI through the project All team members: participant recruitment, help revise the interview guide, analyze data, write and edit the manuscript, other duties as required

COMPENSATION	
How much will the partner be paid? (hourly, lump sum, etc.)	$25/hour for 50 hours
When can they expect to be paid? (weekly, quarterly, etc.)	Monthly
Is a time sheet required?	No
What reimbursement is available? (child care, transportation, internet access, etc.)	List any reimbursement available

ORIENTATION OF PROFESSIONAL RESEARCH TEAM MEMBERS	
Names & experience of family partners	La'Shaun Miller: new to research, parent of 17-year-old child with complex medical history. Extensive caregiving and parental advocacy experience. Second family partner to be identified.
How family partners will interact with professional team members (co-I, tasks performed, etc.)	See tasks as listed above. Family partners will serve as co-collaborators.
Have team members worked with family partners in the past (not in CBPR)?	Most team members have worked with family partners.
Any limitations to participating: schedule, language differences, etc.	La'Shaun works part time during the day, so team should consult with her on a schedule that works. She can meet during her lunch hour or on her days off.

TRAINING OF FAMILY PARTNERS	
Has family partner had research training? Formal (classes) or informal (participated in >3 projects)	Yes: PI certifies that family partner has had training.
No: Register and take the training below.	
URL for PORCCH training	www.PORCCH.ca
Certificate or résumé required to show completion (depending on documentation offered by the training program	Please submit certificate when training completed. You will be paid $100 for completing this training.

Chapter 7

Evaluating Lived-Experience Partner Engagement in Research

Clayon Hamilton | Toni Hines

Introduction

Engagement of lived-experience partners has become an important aspect of doing good scientific health research. Lived-experience partners are the ultimate end users of health research. The practice of engaging lived-experience partners in research continues to increase in recognition, frequency, and scope. As this happens, there is a need to ensure that lived-experience partner engagement is being done well and to demonstrate the value it brings to health research. These important needs require thoughtful evaluation of lived-experience partner engagement in research. As we do this, there is an important idea to bear in mind: "What is measured is important, and what is important gets measured." Evaluation of lived-experience partner engagement in research can help teams work together to see what works and what does not.

The importance of evaluating health services user engagement in research has been the subject of discussions and research for many years. Over time, research studies have led to the development of several tools to help in formal evaluation efforts. Most of the available tools help to tell the story of the engagement experiences and contributions of lived-experience partners in words, but relatively few actually measure those experiences and contributions. New tools are becoming available that provide valid ways to quantify the experiences of lived-experience partners who engage in research. Notably, the 22-item Patient Engagement in Research Scale (PEIRS-22) provides measures of meaningful lived-experience partner engagement in research from the point of view of lived-experience partners. While the PEIRS-22 measures the experience of lived-experience partners, there is a lack of tools specifically designed to quantify the experience of the other members of research teams and the impact of lived-experience partner engagement on research outcomes. We expect continued development within the next few years on how, when, and what to measure regarding lived-experience partner engagement in research.

Background

There are multiple reasons to evaluate lived-experience partner engagement in research. One important reason is that evaluation provides vital information to improve partnerships with lived-experience partners in research projects and across research groups such as networks and organizations. Information gathered through evaluation can be used to shape better lived-experience partner engagement strategies, address the direct needs of current lived-experience partners, and recognize the rewards and any potential pitfalls to lived-experience partner engagement within a particular context.

These reasons for evaluation are important regardless of whether the practice of engagement is viewed from the lens of engagement being driven by a need for it to benefit the research endeavor (benefits-based) or is situated within the right for people to be involved in research that ultimately affects them or their loved ones (rights-based).[14]

Our research for this chapter revealed a number of developments over the last 20 years to support the evaluation of lived-experience partner engagement in research. The scope of some of this work went beyond lived-experience partners to include other research partners such as the public or consumers. Here we present a selective summary of work that is oriented to lived-experience partner engagement in research.

BECAUSE . . .

We recognize the hazards of tokenism and the need to make sure that lived-experience partnerships are meaningful and impactful,

WE NEED TO UNDERSTAND . . .

The importance of evaluating and improving the quality of the approaches we use in lived-experience partnerships,

AND PRACTICE . . .

Evaluation of the quality of the partnership from the perspective of lived-experience partners.

In 2008, Oliver et al. published a conceptual framework that would be useful for analyzing patient involvement in health services research across three categories: type of people involved, the degree of public involvement, and the initiators of engagement with an emphasis on whether the engagement initiative was planned or unplanned.[1] In 2010, Wright et al. published a set of nine appraisal criteria that align with the stages of a research process for "assessing the quality and impact" of patient engagement in research.[2] In addition, Wright et al. provided specific questions for assessing ethical considerations when involving patients in research.[2] Deverka et al.'s 2012 article on stakeholder engagement in comparative effectiveness research provides a conceptual model for guidance on four categories (types of evidence, methods of combining evidence, decisions, and outcomes) and with their corresponding elements to assess engagement in research.[3] In Khodyakov et al.'s 2013 article on measuring community participation in research the authors presented two assessment approaches: 1) a three-model approach that differentiates between the levels of community engagement, and 2) the Community Engagement in Research Index (CERI).[4] CERI is a 12-item questionnaire with items corresponding to a continuum of research activities along the research cycle for which persons indicate if they were consultants, actively engaged, or "don't know."[4] The resulting total scores range from low to high engagement.

In a key paper published in 2015, Esmail et al. provided guidance to better align evaluation of engagement with the promised benefits of patient engagement in research.[5] They presented three categories for evaluation (contextual, process, and impact) with several dimensions to measure for each based on the published promises of patient engagement.[5] The article also emphasizes the limited qualitative assessments and lack of quantitative assessments aligning to each dimension. In 2016, Abelson et al. published the Public and Patient Engagement Evaluation Tool (PPEET) to support assessment of engagement in health system organizations across four evaluation domains: integrity of design and process, influence and impact, participatory culture, and collaboration and common purpose.[6] While PPEET was developed for use in health system initiatives, it has been used to assess lived-experience partner engagement in health research. An important feature of the PPEET is its separate questionnaires for assessing episodic and ongoing engagement activities and the perspective of three different partner groups (patients, managers, and organization leaders).[6] A follow-up article in 2019 by Abelson et al. on the implementation of the PPEET showed several issues with the tool and led to its further refinement without a current interpretation of it scores.[11]

Esmail et al. provided guidance to better align evaluation of engagement with the promised benefits of patient engagement in research.[5] They presented three categories for evaluation (contextual, process, and impact) with several dimensions to measure for each based on the published promises of patient engagement.[5]

In 2017, Dillon et al. published the Critical Outcomes of Research Engagement (CORE) as a tool to assess how patient engagement affects the "process and outcomes of research studies."[8] CORE contains 11 components (patient-centered, meaningful, team collaboration, understandable, rigorous, adaptable/integrity, legitimate, feasible, ethical and transparent, timely, and sustainable) which are defined and have corresponding measures. Their work is ongoing to finalize and test these measures.[8] Boivin et al.'s 2018 systematic review identified 27 evaluation tools for patient and public engagement in research and health system decision making.[10] They concluded that available tools need greater scientific rigor and patient engagement in their design process. In 2019, Goodman et al. published validation work on a measure of community engagement in research and identified a set of eight engagement principles and 32 corresponding questionnaire items.[12] They planned to conduct a validation study of the questionnaire's properties for measuring engagement. In Forsythe et al.'s 2019 analysis of patients and others engaged as partners in Patient-Centered Outcomes Research Institute (PCORI)-funded projects, they provide a useful evaluation model of three phases of a research project (design, conduct, and disseminate) with corresponding sub-phases.[13] The project phases intersect with two overarching categories for assessing impact: contributions of engagement and effects of contributions. Furthermore, from their findings, they provided four key categories to summarize the impact of engagement: research feasibility, acceptability, rigor, and relevance. Most recently, in 2021, Eva Vat et al. published the

Patient Engagement Monitoring and Evaluation Framework that was created for organizations involved in the medicine development life cycle to self-evaluate the progress and impact of their patient engagement efforts. The framework has four components (input, activities/process, learning and change, and impact) that are accompanied by a distribution of 87 metrics. A fifth component of the framework covers 15 contextual factors. The authors provided no validated instruments for measuring these metrics.[23]

There are two recently validated measures that can be used in the evaluation of lived-experience partner engagement in research. The eight-item Public and Patient Involvement Assessment Survey (PAS), published in 2019, is validated for measuring the satisfaction of patients with their engagement in basic science and preclinical research.[20] In 2018, Hamilton et al. published the Patient Engagement In Research Scale (PEIRS) as a 37-item questionnaire to assess patient engagement from the point of view of patient partners.[18] In 2020, a refined 22-item version of the PEIRS called the PEIRS-22 was published as a validated self-report questionnaire to measure meaningful patient and family caregiver engagement in research from the perspectives of those partners.[19]

There is currently no tool that is accepted as the primary measure for supporting evaluation of lived-experience partner engagement in research. The recent development of tools reflecting important components for qualitative and quantitative assessment of lived-experience partner engagement in research represents important progress. These developments include the PAS and PEIRS-22, which are validated measurement tools that quantify the engagement experience on research projects of lived-experience partners.[19,20] There are still ongoing discussions on the evaluation of lived-experience partner engagement in research to address gaps. Work continues on some of the above-mentioned tools and in large studies to provide guidance on the evaluation of lived-experience partner engagement in research, such as the creation of a national framework for Canada.[15]

Concepts

Research to define "success" in lived-experience partner engagement has focused on a range of different engagement components. However, it is particularly useful to categorize aspects of lived-experience partner engagement into three overarching components as described by Esmail et al.[5] These components are context, process, and impact.[5] According to this approach, context is defined as "the conditions required for engagement to have an impact,"[5] process "refers more to how the involvement is done,"[5] and impact is the effect of engagement, whether beneficial or negative.[5,14]

Evaluation can be conducted using quantitative methods, qualitative methods, or a mix of both approaches. Qualitative methods, such as those involving interviews and focus groups, can provide deep insights from the participants of the evaluation, but tend to require significant resources for data analysis. Quantitative methods that use validated measurement instruments to produce scores can save time and provide findings applicable to large populations and varying groups of people. When evaluation uses a validated mixed-methods measurement tool, such as a survey that has closed-ended and open-ended questions for a mix of quantitative and qualitative analysis, the results may provide greater insights where data from the open-ended questions provide supporting insights for the data from the closed-ended questions.

In an effort to measure lived-experience partner engagement in research from the perspective of the partners themselves, Hamilton et al. conducted research that led to identifying the components and a definition for meaningful patient engagement in research.[17,18] Meaningful patient engagement in research is the planned, supported, and valued involvement of patients or their surrogates within a positive research environment in a research process, which facilitates their contributions and offers a rewarding experience.[17,18] This concept transcends the context, process, and impact of lived-experience partner engagement in research.

Meaningful patient engagement in research is the planned, supported, and valued involvement of patients or their surrogates within a positive research environment in a research process, which facilitates their contributions and offers a rewarding experience.

While there are currently no dominant approaches to evaluating lived-experience partner engagement in research, the PEIRS-22 is a sound tool for measuring the degree of meaningful patient engagement in research from the perspective of lived-experience partners.[19] The PEIRS-22 was designed to capture lived-experience partners' ratings on 22 items of their experience working on a research team or project. The 22 items are divided across seven sub-domains that align to the eight components of the Patient Engagement In Research (PEIR) Framework, which was designed to foster better practice and evaluation of patient engagement.[17]

Recommendations

Determine the purpose and scope of the evaluation (Why and What?)

Evaluation can be conducted with various purposes and scopes in mind. The purpose could be, for example, to identify areas of success and areas of engagement to improve in a project. Examples of scope could include: At the level of the project team, across a number of projects, across a number of teams, a one-time engagement event, or across a project with multiple engagement events. It is also important to specify why the evaluation is being done, what parties will be interested in the findings, and what the interested parties might do with these findings. Consider specifying if the evaluation covers the context, process, and impact of lived-experience partner engagement.

Here are examples of two completely different evaluation purposes:

1. **To determine the effect of a lived-experience partner engagement strategy on the patient partners' perceived experience of being meaningfully engaged since the start of the project.**
2. **To determine the effect of lived-experience partner engagement on the research process and outcomes.**

These two examples would require different evaluation tools designed for lived-experience partner engagement. Both purposes speak to the success of lived-experience partner engagement in the research study; the subject differs between them, however. Patient partners are the subject of the first purpose, whereas research is the subject of the second purpose. The first looks at how lived-experience partner engagement (including its context, process, and impact) was shaped by a particular engagement strategy. The second looks at the effect of lived-experience partner engagement on the research project. Identifying the scope and purpose of an evaluation can be supported by developing a logic model outlining the inputs (resources), outputs (activities and participants), and expected outcomes, whether short term or long term, of lived-experience partner engagement.[16]

It is worth noting an important tension regarding evaluating the impact of lived-experience partner engagement in research: Impact. Impact is determined by indicators including number of citations, uptake in practice or policy, and timeline to implementation, as well as other similar factors. There is often a desire to understand how engaging lived-experience partners affects research impact. This desire poses the challenge of demonstrating relative impact of research through a comparative effectiveness study of lived-experience partners-engaged vs. non-lived-experience partners-engaged for a particular study. This pursuit might not be practical for many reasons, including the dynamic nature of dissemination and implementation of research findings influenced by a myriad of contextual factors. Another means of demonstrating the impact of research with lived-experience partners for individual projects would be to specifically provide a causal link to short-term outcomes such as getting the research published, its impact on informing policy, or its longer-term impact on health services. Outside of the realm of individual projects, systematic studies would be able to demonstrate the impact of lived-experience partner-engaged vs. non-lived-experience partner-engaged research with a focus on specific contexts. The guidance provided by the GRIPP2 and similar reporting frameworks support this latter option as the quality of reporting engagement of people with lived experiences as partners in research becomes more widespread.

Another means of demonstrating the impact of research with lived-experience partners for individual projects would be to specifically provide a causal link to short-term outcomes

Select methods and tools for the evaluation (How?)

As covered earlier in this chapter, there are several existing tools designed to help evaluate lived-experience partner engagement in research. Most of the tools are still in developmental stages and are not validated for use and interpretation of their results. These tools are typically designed for qualitative methods of evaluation. Below we demonstrate how the PEIRS-22 is useful for quantitative methods of evaluation. Its use aligns with lived-experience partners being the subject of the evaluation in order to determine their experience on a project.

Use the PEIRS-22 to evaluate meaningful engagement in research (How?)

Here we provide guidance on using the PEIRS-22 to evaluate the degree of meaningful lived-experience partner engagement in research from a partner perspective. The PEIRS-22 is valid and reliable for assessing the degree of meaningful patient and family caregiver engagement in research. Each item requires respondents to reflect on their experiences as a research partner in a specific project. PEIRS-22 captures key elements of eight themes from a conceptual framework for meaningful engagement in research. These themes align with the seven sub-domains of the PEIRS-22: procedural requirements (7 items), convenience (3 items), contributions (3 items), two themes combined as "team environment and interaction" (2 items), support (2 items), feel valued (2 items) and benefits (3 items), depicted in Figure 1. Each item uses a five-point Likert scale ("strongly agree" to "strongly disagree") that is scored 4 to 0.

Figure 1. Depicts the seven sub-domains that combine to form the PEIRS-22 for measuring meaningful patient engagement in research

Use the PEIRS-22 only after lived-experience partners have experiences to share (When?)

TThe PEIRS-22 should be used when lived-experience partners already have experience on a project such that they can report on their experience. Otherwise, it can be used at any point during a project, with the most important consideration being that there is experience for the partner to report on. This could also mean that time has passed since the lived-experience partner became involved but activities have continued without their involvement. This too would be an experience accessible using the PEIRS-22.

Review experience of an individual lived-experience partner (Who?)

The PEIRS-22's data from individual lived-experience partners can be used in a discussion about their experience on a research project. The lived-experience partner can complete the PEIRS-22 with or without supplemental open-ended questions. The person leading the partnership can calculate the total score and sub-domain scores for the PEIRS-22. This can then be used to generate a profile of the partner's experience across key areas of engagement, providing an overall sense of how meaningful their engagement has been. The research lead can then prioritize the items or sub-domains with the lowest scores to discuss with the lived-experience partner in order to find ways to improve the quality of the partnership. Items identifying low meaningfulness would have responses of "neutral," "disagree," or "strongly disagree."

Review experience of a group of lived-experience partners (Who?)

Interpretation of PEIRS-22 scores can go beyond a single total score for all lived-experience partners. Evaluators can look at the distribution of the overall degree of meaningful engagement and the distribution of low meaningful experience within the individual sub-domains. Evaluators can go even further and determine which items are driving low scores across the various domains. This can be done by prioritizing items with "neutral" or disagreement responses by 20 percent or more patient partners in small samples and even lower percentages in larger samples. The absence of a low score is rewarding and achievable. We have emphasized embracing a quality improvement approach to act on lessons learned through each evaluation.

How to interpret and use PEIRS-22 scores

PEIRS-22 scores can be interpreted to indicate "extremely," "very," "moderately," and "low" degrees of meaningful experience in patient engagement as shown in Table 1. The sub-domain scores can be interpreted to indicate either "low" or "not low" degree of meaningful experience within that sub-domain using the corresponding cut-point shown in Table 2.

Table 1. Degree of meaningful engagement and PEIRS-22 scores for interpretation

Degree of meaningfulness	PEIRS-22 scores
Extremely	>92.0 to 100
Very	82.7 to <92.0
Moderately	70.1 to <82.7
Low	<70.1

Table 2. Cut-point for low degree of meaningful engagement within each PEIRS-22 sub-domain

PEIRS-22 sub-domain	Number of items	Cut-point for low meaningfulness
Procedural Requirements (PR)	7	22.3
Convenience (CN)	3	9.6
Contributions (CT)	3	9.6
Team Environment & Interaction (T)	2	6.4
Support (SU)	2	6.4
Feel Valued (FV)	2	6.4
Benefits (BE)	3	9.6

Profile of meaningful engagement for lived-experience partner

Below are two different profiles of lived-experience partners that show how their experiences varied with the overall degree of meaningful engagement and their experiences across the seven unique domains.

Profile 1 Very meaningful

Domain	PEIRS 22 Score	Procedural Requirements	Convenience	Contributions	Team Environment & Interaction	Support	Feel Valued	Benefits
Degree of meaningful	Very	Not Low	Not Low	Not Low	Not Low	Not Low	Not Low	Low

Here we see that the lived-experience partner's overall experience of engagement is very meaningful, but that they also have a low experience of the benefits of partnership. A deeper look into the specific items driving this low benefits score revealed that the

lived-experience partner disagreed with the item stating "I made an impact on the decisions in the project/activity." In a situation where engagement is ongoing, the researcher and lived-experience partner could have a discussion on ways to improve their experience of meaningful engagement overall, and to specifically address their experience of benefits. If, on the other hand, engagement is no longer ongoing, a PEIRS-22 score profile can be used as an opportunity to close the loop on engagement in a conversation with the lived-experience partner.

Profile 2 Low meaningful

Domain	PEIRS 22 Score	Procedural Requirements	Convenience	Contributions	Team Environment & Interaction	Support	Feel Valued	Benefits
Degree of meaningful	Low	Low	Not Low	Not Low	Low	Not Low	Low	Not Low

Here the lived-experience partner has experienced an overall low degree of meaningful engagement, driven by low meaningful engagement within three domains. As with Profile 1, the individual items could be examined to gain a better understanding of the issues that need addressing in order to improve the experience of the research partner.

Interpreting—Individual items

Figure 2 below distributes the 22 items of the PEIRS-22 across three levels of meaningful engagement in research. Advanced engagement (gold level) is the most difficult to achieve as positive experiences of those important elements of meaningful engagements are least often reported by lived-experience partners. By identifying where on the infographic items are that indicate low degrees of meaningful engagement, the evaluator will have more information for strategies to improve partners' experiences of meaningful engagement in research and research-related activities.

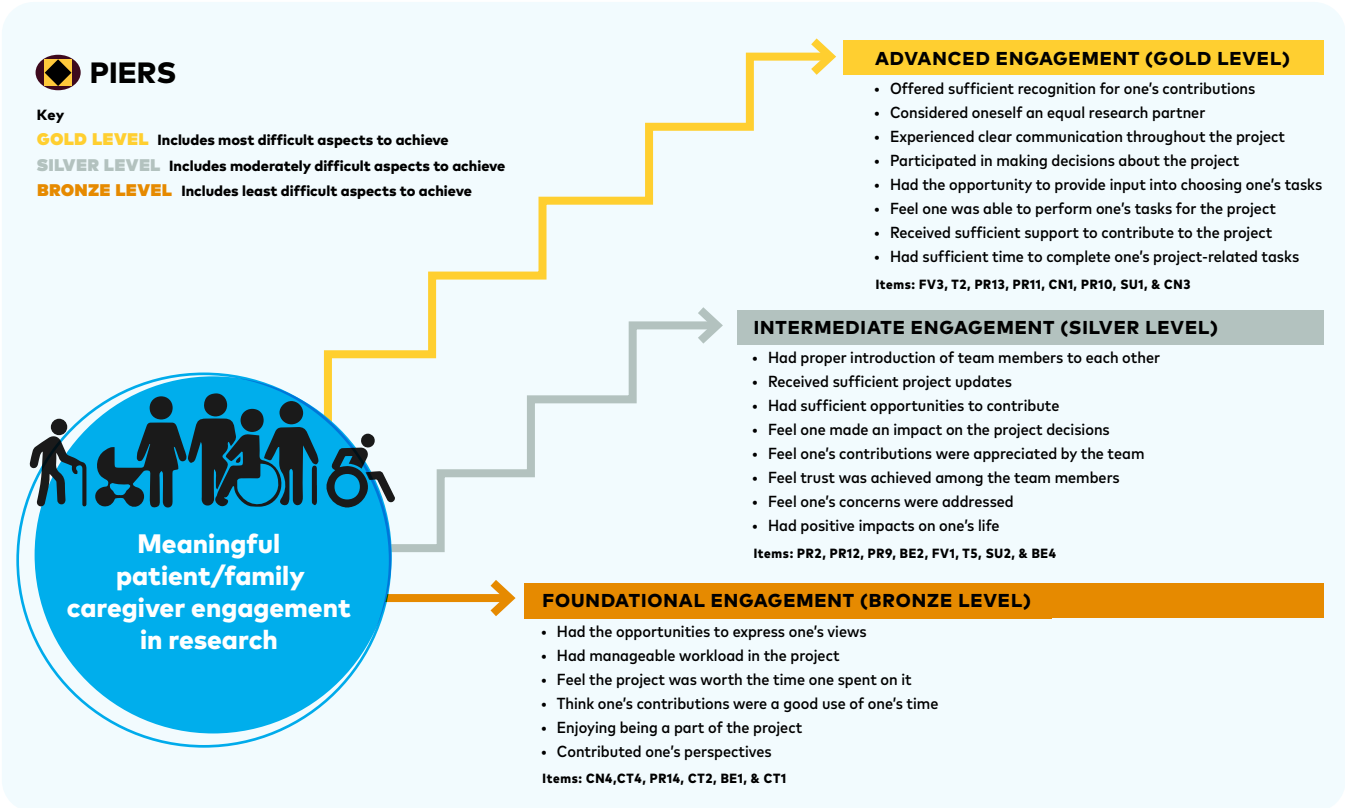

Figure 2. Infographic shows the least to more difficult elements of meaningful engagement to experience

Review impact of engagement on research project

The impact of engagement has been investigated mainly by using qualitative methods. One such study that stands out identified the impact of engagement for published studies funded by the Patient-Centered Outcomes Research Institute.[13] Table 3 below is an adapted version of their results table. This table is a useful tool that evaluators can use to identify areas in which to focus their investigation of engagement impact. Each project phase can be expanded based on that project type. For example, the design of an intervention study could include subsections such as research focus, research design, and intervention, as used by Forsythe et al.[13] Some of these areas can be assessed quantitatively by using a portion of the Ways of Engaging—ENgagement ACtivity Tool (WE-ENACT)—Patients and Stakeholders 3.0 Item Pool, which are a pool of items for describing engagement from a patient and stakeholder perspective.[13]

Table 3. Categories for the impact of engagement on a research project

Project phase	Contributions of engagement	Effects of contribution
Design (planning the project)		
Conduct (carrying out the project)		
Dissemination (sharing the project findings)		

A higher-level assessment of the impact of engagement on research would be to look at the effects on feasibility, acceptability, rigor, and relevance of research as defined by Forsythe et al.[13]

An Example of the PIERS-22 in Action

This example describes a self-study of the Strategy for Patient-Oriented Research (SPOR) Evidence Alliance patient and public partner engagement model.[21] The SPOR Evidence Alliance is a Canada-wide multi-stakeholder health research organization providing national-level support in knowledge synthesis, clinical practice guidelines development, and knowledge translation. The SPOR Evidence Alliance has created an environment where the public, patients, and their caregivers are actively involved in its governance, research priority-setting and conduct, and capacity building to deliver the best available evidence to inform health policy and improve patient care. The study was designed with patient and public partners to evaluate their engagement experience at SPOR Evidence Alliance and identify opportunities for improvement.

To reflect on the experiences of patient partners in the first three years since SPOR Evidence Alliance's creation, 15 patient partners completed the 22-item Patient Engagement in Research Scale (PEIRS-22).

The PEIRS-22 score and domain scores were calculated for each patient partner.

1. A table was created to visualize the profile of the group and each patient partner. Of the 15 patient partners, based on the PEIRS-22 score, the experiences were extremely (n = 6), very (n = 3), moderately (n = 2), and low (n = 4) meaningful. Low meaningful engagement was identified for patient partners, based on the domains scores, in each of the seven domains of PEIRS-22: procedural requirements (n = 4), convenience (n = 2), contributions (n = 1), team environment & interaction (n = 4), support (n=2), feel valued (n = 3), and benefits (n = 3).
2. The main items revealing low meaningful engagement were identified where 20 percent more of patient partners had unfavorable responses of "neutral," "disagree," "strongly disagree" to the item. A total of eight items met these criteria, each representing a unique element of meaningful patient engagement in research.
3. Each item was mapped to the difficulty level (see Figure 2) to determine its corresponding level of meaningful engagement. It was determined that four items revealed low meaningful experience within the intermediate engagement (silver) level and four items revealed low meaningful experience of elements within the advanced engagement (gold) level.
4. The evaluator engaged with researchers and patient partners in a workshop that identified strategies to address the low degrees of meaningful engagement using the eight items as the basis for discussion and having a focus on the domains of those items. This provided recommendations for improving the experience of meaningful lived-experience partner engagement in research and research activities at the organization.

Future directions

More validated tools for evaluating the lived-experience partner engagement in research will emerge over the next few years. There is, however, still a clear lack of validated measure tools for evaluating the experience of the researchers and other professionals who are members of the research team working alongside the lived-experience partners. The current focus on evaluating engagement in health research, particularly its impact, has been criticized as risking distorting how lived-experience partner engagement is practiced and missing the negative impacts.[14] With a strong focus on the benefits of lived-experience partner engagement in research, little attention has been placed on evaluating potential risks such as from lived-experience partner exposure to unwanted or harmful information.[22] Another important gap is a lack of evaluation tools linking lived-experience partner engagement to the impact of research. For example, Esmail et al. found that there were no evaluation tools for how lived-experience partner engagement connects to changes in research dissemination and health outcomes including population health and morbidity.[5]

Another important gap is a lack of evaluation tools linking lived-experience partner engagement to the impact of research

Group discussion component

1. What does quality improvement mean within the context of a lived-experience partner-engaged research project? What are the usual mechanisms that assure research is of high quality?
2. What is the difference between evaluation and research? Is it OK to complete evaluations even if they aren't publishable? Is it OK to publish the results of an evaluation even if it was primarily intended to improve the quality of research?
3. How does the PEIRS-22 relate to key aspects of working with lived-experience partners discussed in this guide, such as creating equitable partnerships and capacity building?

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Chapter 8

Ethical Engagement of Lived-Experience Partners in Research

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Introduction

After all that you have read so far, the benefits of engaging with lived-experience partners may seem self-evident. Lived-experience partners have unique knowledge and a distinctive position and perspective, which can enhance our pursuit of knowledge and the improvement of health and social care. However, there are obstacles to widespread adoption of partner engagement. Not all researchers, contexts, funders, journals, and policymakers are able or willing to recognize and embody the value of partnered work.

Directly involving lived-experience partners is disruptive to traditional research approaches; rather than doing research on young people, patients, and their families, we now must do it with them. How, and importantly why, should we shift from the more traditional model of research, in which people from the population of interest are research subjects, to involving individuals from the target groups as co-investigators and partners on the research team? How do we ensure that their participation as research team members is ethical, meaningful, and beneficial to both the research and the people the research is meant to impact? What ethical precedents exist that demand this fundamental shift?

This chapter revisits the foundations of normative research guidelines in the context of partnered research and seeks to provide ethical guidance and philosophical context on why and how to implement these cultural shifts. It explores the ethical underpinnings of engaging lived-experience partners in research (LEPR), ethical issues that can arise (these can be quite extensive, and space prevents a thorough exploration), an example in the appendix, and provides recommendations to help guide researchers and people with lived experience as they begin and continue to ethically partner in research (the how of LEPR). We hope this chapter will help those involved in LEPR to be able to identify and resolve ethical issues to foster authentic lived-experience partner engagement (i.e., ethical preparedness for conducting LEPR).

BECAUSE . . .

The actions of researchers and lived-experience partners have ethical motivations and ethical implications,

WE NEED TO UNDERSTAND . . .

Ethical guidance on why and how lived-experience partnerships should happen,

AND PRACTICE . . .

Integrity in how we represent the importance and contributions of lived-experience partners.

Background

Traditional Research Ethics Guidance

Research with human participants is guided by core ethical principles that are designed to protect the safety, dignity, rights, and well-being of research participants. The three main ethical principles that traditionally guide research on humans in North America, as outlined in the Belmont Report,[1] are:

- Respect of persons (respect for autonomy)
- Beneficence (maintain well-being, do not harm),
- Justice (fairness in who benefits and who is burdened by research).

The Belmont Report, published in 1979, identifies basic ethical principles for doing research with human subjects. The report continues to guide researchers in ensuring that human participants are treated ethically. Research must be designed based on these principles, with consideration of

informed consent, confidentiality, risks and benefits, fair selection of research participants, and so on. On this basis, research involving human participants has to be evaluated and subjected to approval by ethics committees (institutional review boards or IRBs, research ethics boards or REBs, etc.) before the recruitment and involvement of human participants.

These ethical guidelines were conceived with the intent of protecting research participants. However, the principles outlined in the Belmont Report do not apply directly to those who work as co-investigators on a study, including lived-experience partners. The presence of this gap demonstrates the need to properly identify the standards and best practices that should inform and guide the ethical engagement of lived-experience partners in research.

The Moral Value of involving lived-experience partners

Research is rapidly evolving to be more inclusive of people with lived experience (PWLE) as research partners, but there is little explicit guidance on how to involve them ethically. This lack of guidance begs the question of whether there is an overarching moral imperative to include people who have experienced the way the system functions to help drive what research is done and how it is conducted. Is the involvement of lived-experience partners in itself good? How is the moral value of this type of research understood?"

Research is rapidly evolving to be more inclusive of people with lived experience (PWLE) as research partners, but there is little explicit guidance on how to involve them ethically.

Certain scholars argue that involving people with lived experience is in itself a moral imperative; that is, it should happen because it is the right thing to do. Domecq Garces et al.[2] argue that, since patients are the "ultimate user of research evidence," LEPR is morally compelling. Solomon et al. argue that community priorities are better met with research that involves lived-experience partners, because it builds "trustworthy research that communities can believe in."[3] LEPR is ethically appropriate, according to Hardavella et al., because it lays the groundwork for the partnership—based on core values such as openness, transparency, and public accountability—between patients and researchers that benefits both.[4]

Building on classical ethical theories, Shippee et al. argue that both thinking about the nature of duty and the consequences of having lived-experience partners can ground research. The nature of duty demands that research be based on "a moral/ethical drive to empower lay participants in an otherwise expert-dominated endeavor and ensure civically responsible research."[5] Thus, such a perspective would require both involving and empowering those affected by research and health care in general.

Better, more relevant and more impactful research outcomes can help justify involving people with lived experience.[5] Established theories of ethics including the aforementioned idea of duty (deontology) and the theory that something is good or bad depending on its outcomes (consequentialism) can also be rationales for including people with lived experience. A third classical tradition, virtue ethics, may also justify the involvement of lived-experience partners. Virtue ethics means that a person shows high moral standards—they do what is right just because it is right. In this sense, moral researchers would seek to make sure that their work represents benevolence, fairness, respectfulness, and even courage.[6]

These theories are not the only ones to lay the foundation for the moral imperative (many other approaches in ethics are equally suitable for doing so), but they are necessary to establish the need for it. We therefore have good reason to believe that LEPR creates a moral imperative for research and its actors (which include, but are not limited to, researchers, patients, families, research ethics boards, institutions) to conduct authentic LEPR, as often as possible.

The benefits of working with lived-experience partners have been discussed throughout this handbook. Among these benefits is making the research more ethical for the participants by:

1. Increasing the relevance of research by asking the questions important to the target population
2. Determining what and how research outcomes are measured
3. Determining acceptability to patients, especially for what may seem like controversial or sensitive research such as informing on acceptable level of risk, trial design, consent procedures, timing of recruitment/follow-up, when and how to collect sensitive information, community-specific ethical concerns
4. Improving the informed consent process by ensuring information needed is clearly communicated in a culturally appropriate way that addresses the interests and concerns of potential participants so they are more likely to understand what being asked of them
5. Improving the experience of being a participant in research—for example, methods, times (both length of processes and time when performed), and demonstrating respect for the participant, as well as reducing the burden of participating
6. Improving the communication of the results to those for whom it could make a difference as well as the public.[7]

Indeed, an examination of the engagement in early projects funded by the Patient-Centered Outcomes Research Institute (PCORI) has shown engagement can make "valuable contributions to research feasibility, acceptability, rigor, and relevance."[8]

Main Ethical Issues

Beyond the demonstrated need, ethical imperative, and potential benefits, it is important to examine the ethical issues that arise in LEPR, and more specifically with lived-experience partners. While several studies have attempted to catalogue these issues, it is not easy to inventory all the ethical puzzles that LEPR and the involvement of lived-experience partners may give rise to. Different studies have taken different approaches to this. Some have attempted to classify the types of issues or to analyze LEPR in light of a particular ethical framework. Others have sought to identify chronologically, within a research project, the ethical considerations that arise, and so forth.

It is important to examine the ethical issues that arise in LEPR, and more specifically with lived-experience partners.

In a scoping review of ethical issues in LEPR based on peer-reviewed papers published from 2007 to 2017, Martineau et al. identified numerous issues, with most of them being shared from the researcher's perspective and relevant throughout the research process (for example, lack of compensation for patients, lack of training on patient partnership). The authors have classified them into four broad categories:

1. **Research Ethics:** Traditional research ethics or those issues that are typically considered when involving patients as research participants (e.g., confidentiality).
2. **Research Integrity:** Concerns around how research is actually conducted.
3. **Organizational Ethics:** The practices, programs, structures, etc. needed to support the ethical and responsible conduct of members (e.g., managers, employees) and to cultivate "ethical and responsible relationships with stakeholders" (e.g., lack of institutional support or resources for partnering, structures that hinder partner compensation).
4. **Relational Ethics:** Relationships with patient partners in research teams/institutions and the quality and sincerity of engagement.[9]

Ludwig et al. take a different approach in a sub-analysis of a systematic review for engaging frail and seriously ill patient partners and related ethical considerations to the underlying foundation-

al ethics principles of autonomy, non-maleficence, beneficence, and justice. Considerations such as promoting the desired level of involvement, addressing relational and intellectual power, and facilitating knowledge and understanding of research were related to the ethical principle of autonomy. Similarly, protection from physical and emotional suffering or financial burden was linked to "non-maleficence." Creating conditions for putting things right for others, showing value-added, and providing support fell under "beneficence." Finally, seeking diverse representation, ensuring mutual respect for contributions, and distributing risks and benefits was equated with "justice."[10]

Still, other authors have surveyed researchers to better understand their perspectives on these ethical issues. Bélisle-Pipon et al., for example, surveyed early-career researchers about the ethical implications of LEPR and found that the most pressing issues for them were:

- Professionalization of partners: Professionalization ensues when lay people are no longer contributing their lived experience to the research team, but are contributing knowledge gained through their professional association and training with the project. They begin to contribute knowledge based on a professional understanding rather than based on their experiential knowledge.
- Payment of lived-experience partners for their work: Based on the Standard of Compensation (see Resources chapter)
- Fair recognition of lived-experience partners' contributions: for example, authorship on papers, recognition in presentations
- Tokenism: symbolically including individuals for "ticking a box" rather than involving them in meaningful ways[11]

What emerges from these and other studies is imperative to consider the ethical issues of partnership research in a way that can help conceptualize the transition from more traditional health research to engaged research, and clearly define the ethical expectations and principles that should guide lived-experience partners' engagement in research. As a result, funders, institutions, research networks, and individual researchers have taken up the mantel and are actively putting ethical considerations into practice, setting a precedent for normalizing partnered research. Partnered research, however, remains less common and researchers and their teams often struggle to support lived-experience partners in their roles as co-investigators; thus, a tailored approach becomes necessary.

Need for a Distinct and Tailored Normative Approach

Perhaps most of the ethical problems that arise in research involving lived-experience partners are not deliberate or malicious; however, when good practices are ignored, some voices are not heard, and some perspectives are discounted, the trust may be broken and tokenism can occur. To understand this, let's look together at some examples from testimonies of lived-experience partners on social media that present such situations and where suboptimal and/or unethical practices have led to situations where lived-experience partners have been tokenized, dismissed, not valued, or simply not listened to.

"I was once asked to write a letter for a grant proposal, outlining my proposed volunteer participation. I did. They got the grant. I offered the services they'd outlined in their proposal. They never got back to me. But did ask for another letter for their next grant proposal" —@LGSentinal[12]

Such examples are common and exemplify what led to the creation of the hashtag #HowNotToDoPatientEngagement. Twitter's user expresses their dismay at feeling instrumentalized and part of a box-ticking exercise rather than a genuine attempt at patient engagement. The example illustrates how lived-experience partners' engagement can be inauthentic and fail to address the

very reasons why the involvement of people with experiential knowledge is necessary and enables research to be done differently. These stories are many and all too common.

The following quotes are examples of situations that attest to a lack of appropriateness between (traditional) research practices and the needs/specifics of lived-experience partner engagement, which leads to tokenization, and devaluation of patient engagement.

"Say you offer compensation for your #pt partners. Who knew reimbursing travel costs was considered 'compensation?'" —@couragesings13

"When hospital staff presents a new initiative/program to patient advisors after it has been developed asking for feedback (i.e., rubber stamp)" —@ShariBerman6814

The problem of value and/or contribution recognition of lived-experience partners is obvious and also attested to in the scientific literature. Certain researchers are questioning the very abilities of patient partners to help set research priorities or maintain research integrity;[15] question why the lived experience of the patient partner should be seen as equivalent to the expertise they bring to the project gained through extended university studies and research experience,[16] and can even be surprised that patient engagement is successful.[17] Unsurprisingly, a recent study found that more than 30 percent of editors do not believe that patient partners should be co-authors on published research papers.[18]

Often compensation is not adequate or even available for lived-experience partners. Expecting partners to give their time and expertise for free hinders engagement and favors the emergence of tokenization.

"Pay for doctors to speak at conference but do not pay for patients to speak at the conference"

—@Prostatenews[19]

"When a SPOR-funded entity doesn't have a patient partner compensation policy . . . aka they aren't compensating patient partners . . . .😐😐😐I've started declining requests that don't acknowledge our time & expertise." —@kylierpeacock[20]

"I am starting to head down that path, especially when not acknowledge expertise. I am not a token patient!" —@Virginia_McI[21]

Practices that do not acknowledge experiential expertise can have a direct effect on the recruitment and retention of patients and lived-experience partners. These practices not only fuel distrust in the experiential communities, but also contribute to a sense that they do not belong in the research ecosystem—even within a research approach that claims to be more inclusive than traditional approaches to health research. Because research has traditionally been done without the input of stakeholders at the level of co-investigator partnerships, changing to a partnered method where individuals with varying levels of education, academic connections, or research expertise are on an equal footing with academic investigators is disruptive to the traditional research process. Little guidance has been available for professional researchers on the nuances of working with lived-experience partners; however, that does not excuse attitudes that contribute to tokenization or devaluing their experiences as the experts on their conditions, families, or children.

Often researchers, lived-experience partners, staff, administrators, funders, journals, and other involved stakeholders do not have a consistent understanding of all that LEPR requires so the requirements for conducting LEPR are elusive to them.[22] Lack of communication, not involving lived-experience partners sufficiently at an early stage or at the right time, and not considering sufficiently their perspectives and experiences can contribute to ethical problems. But certainly, another significant factor is the lack of resources that makes it more difficult to conduct responsible and ethical LEPR[11]. These include a lack of institutional support, the increased time required

for researchers to conduct projects, the lack of staff to support lived-experience partners in the research process, and so on. Some questioned the impact of LEPR processes that, if not adequately resourced, would inevitably undermine the relationships and trust of lived-experience partners and diminish the value of their experiential knowledge and participation in the research.[16,23] One important thing that the COVID pandemic has shown is how fragile the foundations of LEPR can be; being largely a relational research approach, any disruption in the social fabric of research puts the proper functioning of LEPR at risk.[24]

Understanding how lived-experience partners view their roles presents an opportunity for better LEPR practices and more ethical and respectful involvement of lived-experience partners. While researchers are trained in ethics regarding human participants in more traditional health research, the ethical issues that can arise from engaging with lived-experience partners can be different but no less important.

The goal here is not to provide a course in bioethics, but an overview of how ethical principles serve to guide practice and how that can help inform research practices involving lived-experience partners.

Concepts

Ethics (or bioethics) can be seen as a daunting field for some. Yes, we all have moral intuitions about what is good, bad, just, unjust, fair, etc., but it is not always obvious how to translate these into rigorous and critical insights. The field of bioethics aims to help identify ethical issues, relevant moral considerations, and valuable analytical frameworks, and to translate this ethical guidance into insights that can inform a practical situation. The goal here is not to provide a course in bioethics, but an overview of how ethical principles serve to guide practice and how that can help inform research practices involving lived-experience partners.

At the root of ethical reflection are usually values and principles that serve to ground what is morally adequate. Jull et al.[25] offers an interesting definition that is situated within the framework of participatory research: Value and principles should be seen as to "conduct knowledge-user-researcher partnership work in an ethical way demonstrated by reflection on ethical concepts and/or concern with particular values and research conducted in ways reported as meaningful, respectful, inclusive of those in the research partnership." Thus, the principles, as articulated so well by Frank et al.,[26] provide the "ethical" backdrop to patient-centered outcomes research. To illustrate this, we can imagine that the principles form the framework in which our lives take place. Using a theatrical analogy, we can imagine that the classical principles of bioethics (respect of the person, beneficence/non-maleficence, and justice) form the stage on which the actors play and that the scenery that set the tone for the play consists of the principles such as trust, honesty, co-learning, transparency, reciprocal relationships, partnership, and respect that guide engagement. This is not to say that engaged research should be considered fiction, but the analogy holds because of the many details that need to work together for a play to be successful. This analogy can be taken further if one considers the whole research team as the actors bringing unique experiences, talents, and skills to the stage. No matter whether the part they play is considered large or small, they are all needed for the play to make sense to the audience. Best practices are those activities such as clear roles and expectations, training, mentoring, relationship building, compensation, etc. that support the production of the play (or research). The principles and the practices should be seen as clearly related as much as possible throughout the stages of a project unless specific to one or more stages just like the backdrop and the scenes of a play should relate to one another.

The premise of this chapter is that these core principles should underpin not only research **on** humans but research **with** humans (i.e., engaged research that includes at the heart of its functioning the lived-experience partners).

Partnering with children and youth

Lived-experience partners have their contingencies and important questions may arise as to the specifics of LEPR involving lived-experience partners. While most, if not all, of the ethical issues of LEPR apply to lived-experience partners, the act of partnering with youth and members of the same family can create additional concerns.

First, the very notion of engaging minors may be seen as being challenging, if not tricky. Pediatric research, as much as pediatric ethics, often requires the adaptation of methods, modalities, and normative guidelines to best respect the particularities of the researcher-minor relationship. However, young people who are capable of forming their views have a fundamental right to express their views in all matters about them.) and this includes research. Article 12 of the U.N. Convention on the Rights of the Child states, in part, "States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child."[27]

While most, if not all, of the ethical issues of LEPR apply to lived-experience partners, the act of partnering with youth and members of the same family can create additional concerns.

Second, while power relationships in a research project are often presented as occurring between researchers and partners, these power relationships may take place within a family. There may be additional power dynamics between the adult partners and the youth partners even in cases where the youth and adult partners are not from the same family. Within the family context, whose voice will be heard: parents, youth, or both? Flynn[28] also reports that the social norm that "adults know best" combined with the perception or experience of youth that adults are not collaborative and non-judgmental may be a barrier for young people to share their perspectives. LEPR projects must therefore be designed in a way that allows children and youth to express their own opinion on issues that matter most to them, with the opinions of a young person being considered and respected in proportion to how old they are. This may require adapting the research team's practices, for instance, by holding a separate meeting with children "to avoid parents dominating the conversations"[29] Respecting children's self-determination is key for meaningful lived-experience partners in LEPR. And this helps to go beyond the traditional view of paternalism that arises from researchers, by also recognizing it may also occur between an adult and a youth coming from the same family entity. Therefore, it is necessary to be vigilant about the forms that power asymmetries can take with lived-experience partners.

Third, children and young people come with their knowledge and experience that can challenge researchers but should be listened to and their ideas acted upon.[30] Youth perspectives can be quite different from those of parents. This is evident from an epistemic and experiential perspective: Young people experience issues differently than their parents/relatives might. Attention must be placed on the experiences and knowledge of young people, to be valued at their true worth. But precisely in terms of worth, what should be the compensation practices in LEPR for lived-experience partners? The issue of compensation is a complex one for younger partners; an issue on which very few guidelines are available.

Fourth, it is also necessary to take into consideration that lived-experience partners are subject to different contingencies and what may affect their life course. This requires adaptation on the part of research teams as well as offering greater flexibility in the design and conduct of a project. For instance, there needs to be an additional consideration for flexibility for young people, so they do not miss school/university or for families busy with the care of medically complex children. Flynn[28] presents beautifully that "busyness of parenting, work schedules, and diverse family structures"—[are] unique challenges of child health (i.e., working with vulnerable populations, developmental challenges)." This adds to the complexity of working with lived-experience partners but is an integral part of the contingencies of this population, and part of the richness of having them on board a LEPR project.

Faced with these considerations and challenges, researchers may feel reluctant to work with youth who are deemed vulnerable, not by age, but by experience (e.g., those with life-limiting conditions, and those with lived experience of mental health issues such as self-harm or suicide). Researchers may be worried that engaging these youth as partners may lead to harm (greater than the benefit arising from the research). As Wilson et al. put it: "Concerns about their competence to be involved in research or worries that involving them could harm them lead to hesitation about involving young people in health research."[31] Perception of youth may hinder their engagement. This can play a role in the disavowal of young lived-experience partners who may be seen as a community that simply receives services rather than a stakeholder.[32]

In agreement with Martineau et al.,[9] the challenges or barriers to authentic patient engagement tended to represent ethical issues. Many ethical issues can arise when working with lived-experience partners. Ideally, the team will be proactive to prevent these issues and act reflexively should issues occur. Working with lived-experience partners should be ethical and meaningful. As we move into the next section, you are referred back to the definition of meaningful engagement given in the chapter on evaluation (Chapter 7) as "the planned, supported, and valued involvement of patients or their surrogates within a positive research environment in a research process, which facilitates their contributions and offers a rewarding experience"[33] and posit that meaningful engagement should be ethical and that planning well is key. How might that be done?

Frameworks

There are many different frameworks of lived-experience partner engagement that have been used to guide patient engagement. A general definition of a framework is "a basic structure underlying a system, concept, or text." Greenhalgh et al.[34] have indicated that "a single, off-the-shelf framework may be less useful than a menu of evidence-based resources that stakeholders can use to co-design their frameworks. Nguyen et al.[35] have suggested 12 frameworks to consider particularly for guiding engagement with lived-experience partners by early-stage researchers. Nguyen's suggested frameworks include those published by the Patient-Centered Outcomes Research Institute (PCORI) in the U.S. and the Canadian Institutes of Health Research (CIHR). Hersh et al.[36] have created the in the context of aphasia indicating "that ethical practice is not simply a stage but rather an orientation across the research process, permeating research practice, and starting well before the formal ethics process begins." They propose that preparing for partnership should be a separate stage in the research life cycle (deemed Element 0) that "involves educational and attitudinal preparation for both researchers and people with aphasia to work together." Such preparation for engagement can similarly be seen in the foundational elements for PCOR described by Frank et al.[26] These foundational elements include internal factors such as being aware of the PCOR principles and methods (i.e., education), valuing the patient perspective (i.e., attitude), and a genuine interest (i.e., attitude) in doing PCOR, and external factors such as ways to communicate or interact as research partners, resources and infrastructure to support the engagement, and policies that, at a minimum do not hinder, and hopefully enable this work. In practice, this preparation could include training for researchers on working with lived-experience partners, understanding the roles that are appropriate to the study, identifying the population of interest, thinking about representation on the study team, determining what organizational structures they have access to that can support this work, reflecting on their rationale for and commitment to engagement, and examining potential bias. From the lived-experience partners' perspective, this could be an introduction to what it means to partner in research and the research process and reflect on their own life, commitments, and passions to evaluate whether or not this is something that can work for them.

A general definition of a framework is "a basic structure underlying a system, concept, or text."

Salerno et al. stated that traditional biomedical ethics are insufficient due to the nature of the relationship between stakeholders (or partners) vs. participants.[37] This changed relationship of "doing research **with**" vs. "doing research **on**" is illustrated throughout this handbook. They proposed a framework where the core ethical principles guiding traditional research on human subjects/participants are integrated with the principles of patient engagement set out by PCORI (transparency-honesty-trust) and CIHR, and together support best practices in stakeholder engagement. Frameworks specific to youth include the McCain Model for Youth Engagement, which is guided by the principles of mentorship and co-learning, and has more recently been applied to partnering with family members. Mitchell et al.[30] have developed a framework for working with young people in the context of young people advisory groups (YPAGs, a common model in the UK) where some members have increased levels of engagement, beyond being advisors. They list the steps of ethical partnership with young people include:

- Prioritizing partnering with children and young people.
- Agreeing on language, and working toward a shared understanding of tasks (i.e., clear communication and expectations).
- Maximizing the benefits and minimizing the risks to young people.
- Ensuring equity of access to partnership.
- Providing training for the researcher.
- Offering training to young people.
- Providing funding and recognition.

A narrative review by Harrison et al.[38] catalogues foundational principles for engagement as well as best practices that support partnering in research. Some of these are illustrated in Figure 1, which presents a simple model for incorporating ethical principles into engaging lived-experience partners throughout the research cycle. We note that best practices for engagement include the concepts presented in this handbook and they apply throughout the research cycle.

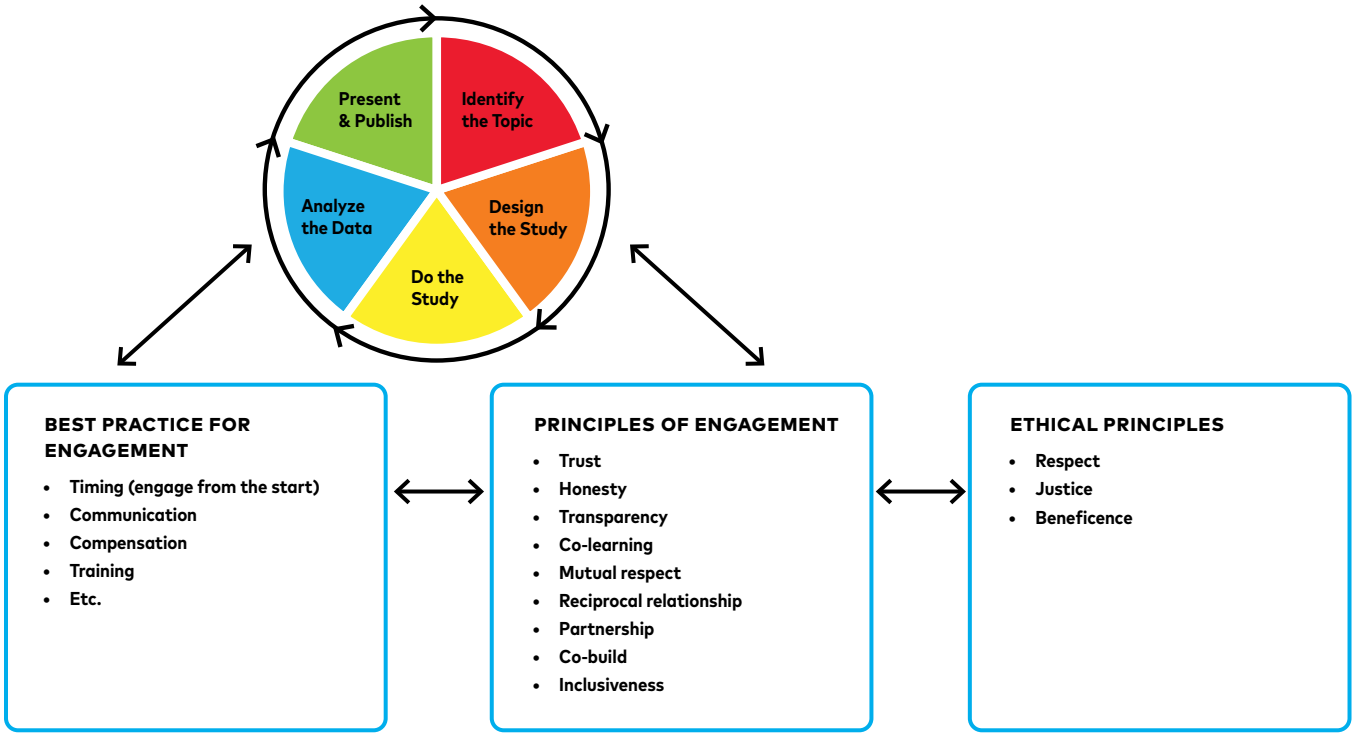

Figure 1. Incorporating ethical principles into engaging lived-experience partners throughout the research cycle

Recommendations

The recommendations presented here integrate the concepts presented in this chapter, but also relate to recommendations and concepts included throughout the handbook. Ethical principles are not meant to stand alone, but to be integrated into every aspect of the research process and into concern for every stakeholder.

Involve as early as possible: Involving lived experience partners early can set the stage for genuine, non-tokenistic involvement throughout the research process. It can also help to guide questions that are meaningful to the target population and make the research question more applicable to the community being studied. Early involvement also helps the research team determine the methods of study that will be most appropriate to both the question being asked and the cultural practices of the population being studied.

Involve as meaningfully as possible: Lived-experience partners want to know that their voice has made a difference. Spend time talking with lived-experience partners to discover what would make their involvement most meaningful to them. To the extent possible, structure their roles to match their expertise and interests and provide support throughout the project.

Discuss and reassess roles, contributions, and involvement as early and as often as possible (terms of reference): The rules of research ethics do not apply to LEPR in the same way they apply to participants. Thus, the lived-experience partners involved do not have to sign a free and informed consent; however, the conditions of involvement must be clear enough to allow voluntary and informed participation in full knowledge of relevant roles and benefits.

Discuss authorships, acknowledgments, and intellectual property in a transparent and frank way: Research is often perceived as a meritocracy based on very specific recognition tokens. These include scientific publications (ideally in leading journals with a high impact factor, which means that they are highly visible and that there is a good chance that these articles will be cited by other people or groups), presentations at conferences, research funding, prizes, etc. This so-called meritocracy is a tokenocracy, where it is not so much merit as the recognition of merit that is too often important in research. Although the very spirit of partnered research attempts to move away from this type of paradigm that is detrimental to the very research endeavor (by placing lived-experience partners at the heart of intentions, benefits, and processes), the standards and expectations toward research outputs may have a great impact on the structuring and conduct of the research partnership. Therefore, discussions, even misunderstandings, and conflicts are to be expected, if they are not managed in advance.

The best remedy for preventing conflicts over the distribution of merit and the order in which it should be awarded is to start by addressing these issues at the outset of the partnership. This may seem like a sensitive topic (and it is) and thus many people often feel very awkward about these subjects, but the discomfort will potentially be even greater when issues of recognition come up and undermine human relationships, collaboration, and project success.[39]

The best remedy for preventing conflicts over the distribution of merit and the order in which it should be awarded is to start by addressing these issues at the outset of the partnership.

Be wary of multiple roles on the lived-experience partners' and researchers' side: Multiple roles are common; it is not possible to think that one occupies only one activity. Thus, our various occupations and commitments can contradict each other and sometimes create delicate situations to manage. A classic example in research is a physician who recruits people with whom he or she has a fiduciary relationship (e.g., patients in his or her care). This is often seen as a source of commitment conflict where the multiplication of roles can cause them to contradict each other, clash, and ultimately interfere with the person's decision making. Using the example of the physician-researcher, the research interest may be so great that they bias the physician's clinical judgment in favor of research decisions that may have a significant impact on their patients. In LEPR, the issues will not be presented in the same way, however, role conflicts exist as well. Thus, it

is advisable to ensure that relationships within a research team are strictly research-related and that other relationships (fiduciary, familial, kinship, or employment) are not at issue. This may unduly create problematic situations that will be to the disadvantage of either the research or the individuals involved.

Authenticity and transparency modulate trust: Relationships are key. According to Leese et al.40 "Genuine, reciprocal relationships are characterized by the presence of a sense of trust, full disclosure, mutual benefit and respect, and understanding of each other's needs, capacities, and goals."

Provide training or access to training: Often, lived-experience partners are new to research and unfamiliar with terms and modalities. This unfamiliarity can undermine their confidence in contributing to a project. Providing access to basic training on research methods, providing them with a glossary of research terms, and providing explanations during meetings can alleviate some of the potential discomfort felt by new team members. In the Resources chapter of this handbook are several excellent training resources, many of which are free.

Track/report patient engagement: Evaluating engagement in every project is a positive step in improving a researcher's competence in working with lived-experience partners. Using evaluation throughout the project can help the team address concerns before they become problematic to the team and the project. Reporting engagement is an excellent way to normalize lived-experience partnership in research generally and can also fulfill requirements by funders and others to meaningfully engage lived-experience partners. Reporting engagement can be done within articles, conference presentations, and reports to funders.

Group Discussion

1. What is your motivation for partnering on a research project? Do you believe that engaged research is worthwhile?? How might your preconceived notions about engaged research impact your ability to do it?
2. Think about one ethical issue you may have encountered or one you think you might encounter partnering in research. Now, imagine yourself as having a different role in the project (i.e., if you are a FYP or someone considering becoming an FYP, try to think about this from an academic or clinician researcher perspective or vice versa). If you try to envision yourself in the other role, does it change your perspective on the ethical issue and, if so, how does it change?

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Appendix A

Resources for Researchers and Partners

Jonah Stoller

This appendix is intended to provide you with a range of tools and resources that you can use to help plan or guide a partnered research project, evaluate engagement quality, or train/educate yourself and others on how to conduct or otherwise be involved in this sort of research.

Most of the resources listed here (particularly those in the "guides" section) are intended for use by research professionals. However, some of these may still be useful for other members of a research team. We recommend that you take the time to examine these resources and determine for yourself if they might be useful for you, your project, and/or your research team.

These resources are sorted by intended audience. For these purposes:

- **Research Professionals** refers to principal investigators, research assistants, and other individuals for whom research is their primary vocation.
- **Research Partners** refers to non-research professionals who are members of a partnered research team.
- **Everyone** refers to members of both of these groups.

Please bear in mind that research professionals may still find significant value in materials designed for research professionals and vice versa, and so the utility of any of these resources in a given context should not be discounted based on target audience alone.

These resources are further sorted into three different types:

- **Rubrics and Assessment Tools** are used to assess the quality of engagement in a partnered research project.
- **Trainings** are more structured, often interactive materials that are intended to provide an individual or group with the information and skills needed to engage or promote engagement in the research process in a meaningful way.
- **Guides** are less programmatic and more specific than trainings and provide a more functional level of detail in order to enable an individual or research team to carry out a particular process, task, or set of tasks. Guides tend to be targeted toward research professionals, but they may also be useful for other audiences.
- **Communication Tools** are tools that are specifically designed to help avoid or translate jargon and ensure more meaningful communication within a research team. They are not targeted at any particular group and do not include advantages and disadvantages (see below).

Advantages and Disadvantages are provided in order to help you fine-tune your search for resources. All of the resources listed here have the potential to be useful. However, as with any tool, they all have different ideal uses, and these advantages and disadvantages are here to help you determine at a glance the extent that each tool might meet your needs.

Please note that while this handbook uses terms like "lived-experience partners" or "people with lived-experience", externally there are a range of terms used to refer to the same or similar positions. As a result, there may be inconsistencies between resources in this regard. These tools have been developed for use across a variety of different fields and audiences, and differences in word choice are difficult to avoid. With that in mind, please be sure to evaluate these sources in terms of their potential usefulness to your project, recognizing that these linguistic differences should not necessarily be taken as an indicator of resource quality, intended level of inclusivity, or utility in a given context. However, please always also bear in mind that the choices that we make around language are important; they can and do represent and perpetuate deep-seated preconceptions about the groups or activities to which they refer.

Rubrics and Assessment Tools

For Researchers

Patient-Centered Outcomes Research Institute: Updated Engagement Plan Template[1]

- **Type:** Rubric/Assessment Tool
- **Link:** https://www.pcori.org/sites/default/files/PCORI-Updated-Engagement-Plan-Template.pdf
- **Description:** This template is specifically designed for PCORI-funded projects to help outline their engagement plans. It walks investigators through all of the components of operationalizing patient engagement for their projects. While intended for PCORI projects specifically, it could still be a useful planning tool in other settings.
- **Advantages:** This could be a helpful planning tool for ensuring that a research team has accounted for all of the core areas of engagement.
- **Disadvantages:** This template is organization specific and designed for PCORI grantees. Therefore, it may not be applicable in some settings.

Patient and Public Engagement Planning Template (Newfoundland & Labrador Support for People and Patient-Oriented Research and Trials)[2]

- **Type:** Rubric/Assessment tool
- **Link:** https://nlsupport.ca/wp-content/uploads/2022/07/Patient-and-Public-Engagement-Planning-Template.pdf
- **Description:** This template divides the process of planning for patient engagement into different phases, ranging from the "why" of doing partnered work to the details of implementation and evaluation. For each category, the template offers a checklist for each category to help users identify their needs and goals at each phase.
- **Advantages:** This tool offers a means for researchers to critically assess their needs and goals ahead of engagement, which is an important component of successful partnered research.
- **Disadvantages:** May not place enough emphasis on early/continuous engagement.

SCPOR Patient-Oriented Research Level of Engagement Tool[3]

- **Type:** Rubric/Assessment tool
- **Link:** https://static1.squarespace.com/static/5c869fd0e666695abe893b3b/t/5d9cbdd75048cd167b-b17c29/1570553304185/Patient-Oriented+Research+Level+of+Engagement+Tool+PORLET+2019+09+30.pdf
- **Description:** The SCPOR Patient-Oriented Research Level of Engagement Tool is a self-assessment tool for scoring five core criteria for Patient Oriented Research (POR) as defined by the Saskatchewan Centre for Patient Oriented Research (SCPOR). This rubric aims to provide an opportunity to reflect on how well POR criteria are being met on a variety of dimensions. This is a useful tool for assessing progress toward meeting those criteria.
- **Advantages:** This tool is fairly quick and easy to use, and is helpful for gauging how well you're meeting these criteria in particular.
- **Disadvantages:** The instructions for using this tool are somewhat minimalistic and subjective. While useful for evaluating a project itself, this rubric would be less functional as a research tool on its own.

Community Engagement in Research Index (CERI)[4]

- **Type:** Rubric/Assessment tool
- **Link:** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3665736/
- **Description:** The CERI is a 12-item inventory designed to capture the degree of community participation in a project in a multidimensional way. The CERI asks about engagement in specific research activities in order to assess engagement.

While this tool is reasonably well validated, additional research may be needed in order to ensure its validity in a broader range of contexts and with a more diverse slate of participants. That said, it is still likely useful in comparable contexts. Scores range from low- to high-engagement.

- **Advantages:** The CERI is relatively short, has good face/content validity, and covers a range of engagement domains.
- **Disadvantages:** It appears that more research is needed to verify the usefulness of this tool across settings.

The Public and Patient Engagement Evaluation Tool (PPEET)[5]

- **Type:** Rubric/Assessment tool
- **Link:** https://ppe.mcmaster.ca/our-products/public-patient-engagement-evaluation-tool
- **Description:** The PPEET consists of three questionnaires:
  - **Participant Questionnaire:** Participant assessment of the engagement initiative
  - **Project Questionnaire:** Review and assess how engagement impacted the project
  - **Organization Questionnaire:** Assess how engagement is being carried out within the larger organization

Importantly, the PPEET also has two different sets of these three questionnaires. One is intended for evaluating one-time engagement, and the other is for evaluating ongoing engagement. Its multi-inventory design also allows it to capture the perspectives of patients, managers, and organizational leaders.

- **Advantages:** The PPEET is available in English, French, Dutch, German, and Italian, enabling its use with a broader range of projects. In addition, the multipronged set of three questionnaires and the option for measuring either one-time or ongoing engagement make this a more nuanced and flexible tool.
- **Disadvantages:** Researchers have found that the participant component of this tool is more useful for short-term engagement activities, but has less utility for ongoing or longer-term engagement.[6]

Critical Outcomes of Research Engagement (CORE)[7]

- **Type:** Rubric/Assessment tool
- **Link:** https://pubmed.ncbi.nlm.nih.gov/31413988/
- **Description:** The CORE is designed to evaluate the impact that patient engagement has on how research is conducted and its outcomes. The CORE identifies 11 domains as critical to this assessment: Patient-centered; meaningful; team collaboration; understandable; rigorous; adaptable/integrity; legitimate; feasible; ethical and transparent; timely; and sustainable. Each of these domains has one or more assessment questions associated with it. It is critical to note here that no reportable measures are identified as part of the CORE, but this framework is still a useful tool for thinking about patient engagement.
- **Advantages:** CORE is one of few evaluation tools that examine the impact that engagement has on research outcomes rather than the quality of engagement itself.
- **Disadvantages:** The CORE identifies no reportable outcome measures, limiting its use in research.

Patient Engagement in Research Scale—22 item (PEIRS-22)[8]

- **Type:** Rubric/Assessment tool
- **Link:** https://pubmed.ncbi.nlm.nih.gov/33729634/
- **Description:** The PEIRS-22 is a validated measure of patient engagement in research that was originally developed as a 37-item inventory, and subsequently shortened in order to remove unnecessary items and items that were not well aligned with the constructs in question. The PEIRS-22 demonstrates good internal consistency, as well as structural and construct validity, and its shorter length means that respondent burden is minimized. The PEIRS-22 examines and provides scores for seven domains of engagement, and also produces an overall composite score. A list of the domains themselves and information on how to score and interpret the PEIRS-22 can be found in Chapter 8 of this handbook.

- **Advantages:** The PEIRS-22 is currently one of few well-validated measures for evaluating quality of engagement in a way that can be used in research.
- **Disadvantages:** It is not clear to what extent the modality of administration impacts score outcomes for the PEIRS-22. Simply put, more research is needed in this area. While this should certainly not preclude the use of this tool, as with any other inventory researchers should carefully consider how it is administered.

GRIPP2 Reporting Checklists[9] (Please see the corresponding entry under the Trainings section for additional GRIPP2 resources)

- **Type:** Rubric/Assessment tool
- **Link:** https://www.bmj.com/content/358/bmj.j3453
- **Description:** The Guidance for Reporting Involvement of Patients and Public (GRIPP) checklist was originally developed in order to provide a standard that researchers could use to ensure patient involvement was reported on in a consistent, transparent, and high-quality fashion. The GRIPP2 has subsequently been developed with the intent of developing international consensus on how to best report PPI in research.
- **Advantages:** The GRIPP2 checklist was developed with meaningful input from stakeholders in a wide variety of roles, including partners, researchers, and funders, and as such it reflects a range of important perspectives on the topic. In addition, these perspectives were sourced from an international pool of participants that included individuals from the United States, Australia, and Europe, thus improving the generalizability of the checklist. The GRIPP2 can be used proactively or retrospectively for planning or evaluation, respectively.
- **Disadvantages:** The research on how the GRIPP2 can be used across different study designs is still somewhat limited. In addition, while the GRIPP2 is quite functional, it is not highly prescriptive. While this is not a weakness per se, it may limit usability for individuals without more extensive research experience that would allow them to contextualize the tool.

For Everyone

The Family Engagement in Systems Assessment Toolkit (FESAT)[10]

- **Type:** Rubric/Assessment tool
- **Link:** https://familyvoices.org/familyengagementtoolkit/
- **Description:** The FESAT was developed by Family Voices based on an environmental scan and a series of key informant interviews that were conducted with the intent of identifying ways in which family partners can be supported in achieving meaningful engagement in health care systems research. Through analysis of these materials and interviews, researchers were able to identify four theoretical key domains for promoting and ensuring engagement that is both meaningful and sustainable: Representation, transparency, impact, and commitment. For each domain, specific criteria were proposed to help organizations meet this end. Based on these domains, Family Voices developed the FESAT with the goal of offering organizations conducting partnered work with a tool that they can use to assess how they are doing within each category.
- **Advantages:** The FESAT is a reasonable length and should be accessible to most users. It can also be used before, during, and after a project in order to help determine what should be done, how it is being done, and how it could be improved in the future.
- **Disadvantages:** It does not appear that the FESAT has been validated. While useful, it is difficult to know for sure if it is adequately measuring what it proposes to measure.

The National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem[11]

- **Type:** Rubric/Assessment tool
- **Link:** https://nationalhealthcouncil.org/additional-resources/patient-engagement-rubric/

- **Description:** While nominally designed for partners, this resource is also useful for researchers who intend to include patient partners in their research. It is intended for use in evaluating the quality and attributes of patient-centered research, as well as for providing guidance on meaningful engagement in research. This resource provides detailed rubrics on a range of relevant engagement domains, including patient partnership, transparency, meaningful outcomes, and timeliness. It also includes a glossary of relevant research terms, personal vignettes, and detailed backgrounds on each domain.
- **Advantages:** The domain-based structure of this rubric allows a high level of focus and detail. In addition, the rubric itself provides a great deal of useful background information.
- **Disadvantages:** This rubric is fairly long and very text heavy. It is not intended for use on its own and is not "scorable" in a quantifiable way.

Trainings

For Researchers

Developing our international PPI evidence base through high-quality reporting: The evolution and use of GRIPP2[12]
(Please see GRIPP2 Reporting Checklists under Rubrics and Assessment Tools for additional resources on the GRIPP2 checklist itself)

- **Type:** Training
- **Link:** https://training.cochrane.org/resource/developing-our-international-PPI-evidence-base-GRIPP2
- **Description:** This training offers an overview of the GRIPP2 reporting checklist, how it was developed, and how it has evolved to its current state. GRIPP2 stands for Guidance for Reporting Involvement of Patients and the Public, and represents the second iteration of a set of reporting guidelines for patient and public engagement in research. The GRIPP and subsequently the GRIPP2 were developed by the EQUATOR network in order to offer a comprehensive, meaningful system that researchers could use to ensure high-quality, transparent, and consistent reporting of this type of engagement. For more information on the GRIPP2, please see the entry in Rubrics and Assessment Tools, above.
- **Advantages:** This is a good tool for providing additional context for the GRIPP2 that may be useful for individuals intending to use it without the benefit of more extensive experience in this area.
- **Disadvantages:** This resource does not teach how to use the checklist and therefore is likely not particularly useful without additional information about that tool itself.

For Lived-Experience Partners

FYREworks[13]

- **Type:** Training
- **Link:** https://www.fyreworkstraining.com/
- **Description:** FYREworks was developed by the Patient-Centered Outcomes Research Center (PCORI) in conjunction with a group of youth, parents, researchers, and educators, with the goal of creating a more broadly accessible training to prepare youth, caregivers, and researchers to meaningfully participate in partnered research. FYREworks provides a good, comprehensive introduction to partnered research that is accessible to youth and adults alike. This training consists of a set of three online training units. Each unit is self-directed and consists of two to four modules.
- **Advantages:** FYREworks offers a fun format that is easy to use. While completion requires a two- to three-hour time commitment, the program can be broken up over time as needed, allowing users a degree of flexibility. FYREworks is free and self-paced. It is also accessible for younger team members and so may be particularly useful when working with youth partners. Upon completion, users receive a certificate indicating that they have finished, which may be useful for larger organizations or projects in which training verification is required.
- **Disadvantages:** This training is self-administered and offers no opportunity to interact with others. In addition, some of the medical content used may be discomfiting for some users. Finally, FYREworks also appears to have little available customer support, and it is only available in English.

PCORI Research Fundamentals[14]

- **Type:** Training
- **Link:** https://www.pcori.org/engagement/research-fundamentals
- **Description:** PCORI Research Fundamentals is a free training package designed for research partners who are new to partnered research. This program uses plain language and is divided into five modules, each based on a different phase of the research process.
- **Advantages:** A module-based system makes it easy to break up the training into manageable chunks. Content is fairly comprehensive, and the availability of transcripts can make completion faster and improves accessibility (which is already bolstered by the program's compatibility with screen readers). The self-guided structure means that trainees can "choose their own adventure" or focus on an area of particular need.
- **Disadvantages:** This training is fairly long, somewhat visually repetitive, and may be redundant for partners w/research experience.

For Everyone

Patient-Oriented Research Curriculum in Child Health (PORCCH)[15,16]

- **Type:** Training
- **Link:** https://porcch.ca/
- **Description:** PORCCH is a module-based program providing basic information for research partners on health research and research methodology, including foundational and practical info on successful engagement. An additional research ethics module is currently in production, and there are tentative plans for a Spanish-language version, although this is not confirmed. PORCCH is specifically focused on child health research, and we recommend this training for our lived-experience partners here at CYSHCN. This training may also be useful for researchers who are new to partnered work.
- **Advantages:** PORCCH uses clear terminology and good visual aids. The module-based structure allows focusing on particular areas if desired, and the program will soon include an ethics module and may eventually be available in Spanish.
- **Disadvantages:** This training could stand to be a little more engaging, as some users may find it boring or text heavy. As described above, it may also be useful for researchers who are new to partnered work, but is more focused on research partners.

Learning Together Simulations (Holland Bloorview)[17]

- **Type:** Training
- **Links:** Manual: https://hollandbloorview.ca/sites/default/files/2022-02/ChildBright-SimulationManual.pdf
  Access request: https://hollandbloorview.ca/access-simulations
- **Description:** This training involves a series of four short video simulations intended to be used with a facilitator guide to promote discussion and learning. This program intends to allow multidisciplinary teams to reflect on perspectives and approach to patient engagement in specific scenarios. Topic areas include: Finding a family partner; Partnering to set research objectives; Reviewing results; and Dissemination.
- **Advantages:** This is a free, scalable, relatively short activity that promotes discussion and can involve all team members. In addition, the simulation format allows participants to learn content and address their questions in a more nuanced fashion. Finally, the four topic areas cover the major phases of a partnered research project.
- **Disadvantages:** Successfully running these simulations requires a well-trained facilitator in order to be effective and is potentially time-intensive.

Family Engagement in Research Course (CanChild, McMaster University)[18]

- **Type:** Training
- **Link:** https://www.canchild.ca/en/research-in-practice/family-engagement-in-research-course
- **Description:** This 10-week (30-hour) online course is designed for both researchers and lived-experience partners who are interested in conducting research on child health. The course focuses on the importance of partnered research, how to conduct successful partnerships, and common barriers, as well as ethical issues present in this sort of work. The course also offers a range of useful tools and resources for evaluating and supporting partnered work.
- **Advantages:** This training appears more intensive than the other resources on this list. It also intends to integrate researchers and partners within the digital classroom, which may help to provide a more holistic perspective. Although the course costs money, scholarships are available for eligible applicants, and family partners are prioritized for this funding. Also, course completion comes with a certificate.
- **Disadvantages:** The 10-week time commitment may prove unrealistic for busy researchers and parents. In addition, the $500 cost could be prohibitive for individuals who cannot get a scholarship. Finally, the course is taught twice annually, and some interested parties may not be able to make this timing work with their schedules.

Guides

For Researchers

Strategy for Patient-Oriented Research (SPOR): Patient Engagement Framework[19]

- **Type:** Guide
- **Link:** https://cihr-irsc.gc.ca/e/documents/spor_framework-en.pdf
- **Description:** Describes the need for and benefits of patient-engaged research, along with outlining guiding principles and describing core areas of engagement. Includes a section on evaluation.
- **Advantages:** Relatively short. Includes an evaluation section, which is an important component of this work.
- **Disadvantages:** This document is from 2014 and may not be up to date with all recent research and standards. Cross-reference with more recent materials before use.

Methods of Patient & Public Engagement: A Guide[20]

- **Type:** Guide
- **Link:** https://static1.squarespace.com/static/5e57d5337fe0d104c77cca10/t/5ed808e613338b69dcb8f6df/1591216360358/20.05.20+PE+methods+of+Engagement+web.pdf
- **Description:** A guide for exploring options for participatory approaches and engagement methods at different stages of research/levels of engagement. The goal of this guide is to help research teams to explore different approaches/activities for engagement at different research stages. It is useful for looking at and deciding between different options for approaching meaningful engagement.
- **Advantages:** This guide does a good job of providing a range of options for engagement at different stages of the research process. It is very visually clear, with both color coding and numbering systems for organization.
- **Disadvantages:** The long, text-heavy format may be less suitable for some users or situations.

Recommendations on Patient Engagement Compensation[21]

- **Type:** Guide
- **Link:** http://cpn-rdc.ca/docs/default-source/default-document-library/pe-compensation-report_final.pdf?sfvrsn=b844aca9_2
- **Description:** A guide that outlines recommendations and policies for compensating partners. Its goal is to teach researchers best practice for how to properly compensate partners and plan budgets appropriately from the get-go. Serves as a useful road map for reducing financial barriers to participation and adequately recognizing contributions.
- **Advantages:** This guide covers a broad range of possible expenses and recommends specific compensation levels based on either unit of time or level of engagement. This resource also provides specific recommendations for working with indigenous elders.
- **Disadvantages:** Long and text heavy.

A Resource Toolkit for Engaging Patient and Families at the Planning Table[22]

- **Type:** Guide
- **Link:** https://www.albertahealthservices.ca/assets/info/pf/pe/if-pf-pe-engage-toolkit.pdf
- **Description:** This guide provides an overview of the components and types of successful family engagement, its value, levels of involvement, and evaluation, and also provides practical guidance in these areas.
- **Advantages:** Provides a detailed overview of all the components of successful engagement, from planning to recruitment, as well as reviewing common pitfalls and the means to avoid them.
- **Disadvantages:** Text heavy, long, and somewhat challenging to navigate. Provides a good overview but may be lacking in detail in certain areas.

Information for Researchers[23]

- **Type:** Guide
- **Link:** https://www.phc.ox.ac.uk/ppi/information-for-researchers
- **Description:** This provides an overarching overview of PPI: What it is, why it's important, and how to do it. It is intended as a reference document to guide researchers and should not be viewed as fully comprehensive. This guide covers topics from how to define research topics using public engagement, structuring the integration of PPI, recruiting partners, compensation, orientation/training of both staff and partners, a range of best practices, and working with "seldom-heard" groups. It also discusses some approaches to evaluation.
- **Advantages:** Covers a very wide range of topics and offers links to other resources for more information. It is also fairly well organized and easy to navigate.
- **Disadvantages:** Some organization-specific suggestions around compensation may not be applicable in other contexts. Very long and text heavy.

A Researcher's Guide to Patient and Public Involvement: A guide based on the experiences of health and medical researchers, patients, and members of the public[24]

- **Type:** Guide
- **Links:**
  - **Resource:** https://oxfordbrc.nihr.ac.uk/wp-content/uploads/2017/03/A-Researchers-Guide-to-PPI.pdf
  - **Background Research:**
    - Locock L, Boylan AM, Snow R & Staniszewska S. (2016). "The power of symbolic capital in patient and public involvement in health research." *Health Expectations*. DOI: 10.1111/hex.12519.[25]

- Crocker JC, Boylan AM, Bostock J & Locock L. (2016). "Is it worth it? Patient and public views on the impact of their involvement in health research and its assessment: a UK-based qualitative interview study." *Health Expectations.* DOI: 10.1111/hex.12479.[26]

- **Description:** A guide for researchers who are interested in PPI or have begun the process of conducting PPI research. Its intent is to provide the reader with an overview of PPI research, drawing upon two research projects on the experiences of patient/public partners and researchers. The guide provides information on the value of PPI, how it plays into different stages of research, reasons for involvement, and best practice in recruitment/training/compensation, as well as practical advice to help guide researchers. In addition, it addresses evaluation of PPI as well as common pitfalls.
- **Advantages:** Covers a large number of topic areas; includes sections specifically on DEI.
- **Disadvantages:** Text heavy and pretty long. Research based, but only from two studies, so generalizability/transferability may be somewhat limited.

Patient and Public Engagement in Health and Social Care Research[27]

- **Type:** Guide
- **Link:** https://www.rds-yh.nihr.ac.uk/wp-content/uploads/2015/01/RDS_PPI-Handbook_2014-v8-FINAL-11.pdf
- **Description:** Overview of a range of topics in partnered research. Topics include the value of partnered research, developing partnerships, planning effective partnerships, and how to involve partners in different phases of research. Also provides templates for a variety of these activities, including recruitment and role description. In addition, includes a glossary of common research jargon, as well as guidance on compensation and evaluation.
- **Advantages:** Provides useful templates, covers a wide range of topics, and is easy to navigate.
- **Disadvantages:** Long, text heavy. Templates may be limiting if not considered and adapted situationally. The broad scope of focus means that, although it covers a lot of ground, detail may be lacking in some areas.

Every Child Thrives: Doing Evaluation in Service of Racial Equity[28]

- **Type:** Guide
- **Link:** https://everychildthrives.com/doing-evaluation-in-service-of-racial-equity/
- **Description:** This series of three guides aims to provide detailed instruction on how to properly evaluate the impact of a program or change on the lives of children as well as their families in a manner that fully accounts for the priority and goal of racial equity in this process. The three guides cover the following subject matter:
  - Guide 1: Debunking myths
  - Guide 2: Diagnosing biases and systems
  - Guide 3: Deepening community engagement

  Across these three subject areas, Every Child Thrives aims to show how researchers and partners can incorporate the core values of self-reflection, learning, and racial equity into their work.
- **Advantages:**
  - The primary focus on racial equity is fairly unique among the resources listed here, and provides an incredibly important set of goals and values that should be integrated into all research. By helping research team members learn to take a critical lens to preconceived notions around race and racial equity, critically examine individual and systemic biases, and cultivate meaningful engagement with communities in the service of promoting equity, these guides will be an important reference tool for any evaluator.
  - Wordy, but well organized and reasonably accessible.
  - The iterative nature of the three guides means that they build upon each other to paint a cohesive picture of what they are aiming to achieve.

- **Disadvantages:**
  - While these resources are absolutely useful in a research context, they are focused on program evaluation rather than clinical research. As such, they may require some recontextualization depending on the situation in which they are applied.
  - As mentioned, these guides are quite long and may be less useful as a quick reference.

Resource Guide: Patient and Community Engagement in the Design and Implementation of Research Studies[29]

- **Type:** Guide
- **Link:** http://stmichaelshospitalresearch.ca/patient-and-community-engagement/resource-guide/
- **Description:** This resource actually contains three guides, each targeting researchers who have varying levels of experience with patient and community engagement in research (PCE). Each guide contains a range of useful additional resources.
  - **Level 1: Learn** This guide is targeted at scientists, trainees, and research staff who have little to no exposure to patient/community engagement in research. The guide introduces PCE and discusses:
    - The benefits of engagement
    - Frameworks for engagement
    - Historical context
    - The value of lived experience
    - Best practices
    - Capacity building
    - Power dynamics
    - Developing trust
  - **Level 2: Apply** This guide is intended for scientists, trainees, and research staff who have some knowledge and experience with PCE and want to learn more about implementing best practice in this area. Topic areas cover:
    - Providing meaningful partner support
    - Best practices for including people with lived experience
    - Understanding power sharing
    - Sharing budgeting/resources
    - Co-learning
    - Best practices in developing equitable teams
    - Anti-racist, equitable, socially accountable approaches to recruitment
  - **Level 3: Transform** **This guide is for scientists, trainees, and research staff with significant experience with PCE and seek to develop a deeper understanding of advancing these efforts, specifically through a diversity, equity, and inclusion (DEI) lens. Topic areas cover:**
    - Increasing the number of people with lived experience in leadership positions
    - Minimizing harm to communities
    - Gaining practical experience
- **Advantages:** These guides were developed with the direct involvement of patient and community partners. In addition, the multi-level approach allows for a broader range of consumers, as well as entry points for individuals or organizations with varying levels of experience doing partnered work.

- **Disadvantages:** This resource is not intended for non-research professionals. While it offers a comprehensive way for researchers to learn more about PPI that may also be useful for lived-experience partners, it is not directed at this audience. Given the benefits offered by this sort of multi-tiered structure, it is unfortunate that it was not developed with a broader audience in mind.

For Lived-Experience Partners

Partnering with Youth, Families & Patients in Research: A Standard of Compensation for Youth, Family, and Patient Partners[33]

- **Type:** Guide
- **Link:** https://cyshcnet.org/download-guides/
- **Description:** This is essentially similar content to the investigator version described above, with focus on the partner perspective. This guide intends to inform partners on what they should expect in terms of compensation and orientation, and also includes a glossary of commonly used research jargon. A Spanish language version is available for download via the link above.
- **Advantages:** This guide is fairly comprehensive, easy to read, and up to date. It provides information with the partner perspective in mind.
- **Disadvantages:** The formatting of this document may make it less useful as a quick reference guide.

For Everyone

UK Standards for Public Involvement: Better public involvement for better health and social care research[30]

- **Type:** Guide
- **Link:** https://sites.google.com/nihr.ac.uk/pi-standards/standards?pli=1
- **Description:** This guide outlines the United Kingdom's standards for public involvement in research. The document offers descriptions of six different standards: communications; governance; impact; working together; inclusive opportunities; and support and learning. For each standard, the guide offers reflection questions to help the reader determine if they are meeting the standard in question.
- **Advantages:** Accessible language, not text heavy, reasonable length.
- **Disadvantages:** This guide, while informative, does not offer much information on what to do if the reader finds themselves to not be up to standard. In addition, the guide is fairly broad, further limiting actionability. However, this may also be an advantage because it makes it more broadly applicable.

Evidence-Informed Practices and Strategies for Patient-Oriented Research (POR): A 'Menu' for Research Teams[31]

- **Type:** Guide
- **Link:** https://www.bcahsn.ca/sites/default/files/2021-06/POR%20Menu_20191004.pdf
- **Description:** This resource is designed for use by research teams who are in the process of moving toward POR. As its title suggests, it intends to offer a "menu" of evidence-based management strategies for doing this sort of partnered work. Ideally, it would be used by researchers in conjunction with incoming lived-experience partners to get conversations started about how to conduct patient-engaged work in productive, meaningful ways.
- **Advantages:** This guide is accessible to a range of experience levels, provides multiple management approaches/options, and is intended for collaborative use with the whole team.
- **Disadvantages:** While nominally intended for use by all team members, this tool is very much from the perspective of the professional researcher. While it may be accessible to lived-experience partners without research experience, it could feel exclusive based on that perspective.

Partnering with Youth, Families & Patients in Research: A Standard of Compensation for Investigators[32]

- **Type:** Guide
- **Link:** https://cyshcnet.org/download-guides/
- **Description:** This guide is designed as a practical tool for professional investigators to develop realistic and equitable budgets for patient-engaged research based on best practices in compensating lived-experience partners. The guide discusses different levels and types of engagement and how they should be compensated, as well as how to budget for research more generally with the needs of lived-experience partners in mind. Also provides example templates for planning engagement, and accounts for a wide range of potential expenses.
- **Advantages:** Well organized, detailed, easy to read, and up to date. There is a partner-specific version available as well.
- **Disadvantages:** Formatting makes it less useful as a quick reference guide.

Communication Tools

Everyday Words for Public Health Communication[34]

- **Type:** Communication Tool
- **Link:** https://tools.cdc.gov/ewapi/termsearch.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fhealthcommunication%2Feverydaywords%2Findex.html
- **Description:** Avoiding unnecessary jargon is key to ensuring that the non-research professionals on a research team are able to participate and contribute in a meaningful way. This handy website from the CDC allows users to search terms commonly used in public health and offers plain-language descriptions and alternatives. It also can work inversely, offering jargony versions of accessible language.

Plainlanguage.gov Checklist for Plain Language[35]

- **Type:** Communication Tool
- **Link:** https://www.plainlanguage.gov/resources/checklists/checklist/
- **Description:** Plainlanguage.gov offers a useful checklist for ensuring that your content is accessible to your intended audience. This tool provides a list of suggestions for ensuring writing is in plain language, along with links to additional information on each item.

Other Resources

Project Management Body of Knowledge (PMBOK)[36]

- **Link:** https://www.pmi.org/pmbok-guide-standards/foundational/pmbok/about
- **Description:** PMBOK is an invaluable tool for anyone managing a project. The information contained therein represents "good practice for most projects most of the time." This guide is designed with flexibility in mind, and its goal is to allow a project manager to select and tailor the best approach to their unique needs. The 7th edition of PMBOK was recently released, and so even researchers familiar with this guide may benefit from revisiting it. There is a cost for purchasing PMBOK.

PCORI Engagement Tool and Resource Repository[37]

- **Link:** https://www.pcori.org/engagement/engagement-resources/Engagement-Tool-Resource-Repository
- **Description:** Along with its module-based "Research Fundamentals" training described earlier in this chapter, the Patient-Centered Outcomes Research Institute (PCORI) also maintains a database of engagement resources that may be of interest to researchers or partners with lived experience. While some of these resources are included in this chapter, others are not, and so we recommend exploring this database if you are not able to find what you are looking for here.

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Appendix B

Case Studies

CASE STUDY #1

Family Engagement in the Collaborative Improvement and Innovation Network on Children with Medical Complexity (CMC CoIIN)

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Mary Jo Paladino, MSA, Project Coordinator, Family Voices
Meg Comeau, MHA, Principal Investigator, BU

Launched in 2017, the Collaborative Improvement and Innovation Network on Children with Medical Complexity (CMC CoIIN), a five-year project funded by the Maternal and Child Health Bureau, has created transformational family partnership few members report having experienced previously. The CMC CoIIN's goals were to improve quality of life for CMC, the well-being of their families, and cost-effectiveness of their care. Each of the 10 participating state teams included health care leaders and health care providers, family-led organizations, family and Title V leaders, and Medicaid representatives, among others.

Below, we outline a few key overall strategies we employed to drive progress in family partnership for all aspects of the CMC CoIIN project.

Strategy #1: Multi-level power sharing for multi-level projects.

The CMC CoIIN leadership and participating state teams ensured power sharing with families at all levels of system transformation efforts—on the leadership, network, and state team levels. The leadership team, partnered with Family Voices National, used multipronged strategies grounded in the three core values of equity, accountability, and transparency to advance family partnership. This translated to an operational culture of valuing varied types of expertise to learn from each other, ensuring a flattened hierarchy, and focusing on tangible action driven by lived expertise.

On the leadership level, in addition to Family Voices as fundamental partners, we ensured robust representation of family colleagues on the National Advisory Committee. Family partnership and family colleague voices were centered in all our technical assistance and training curricula from the very beginning (e.g., topics, panels, speakers, priorities), and all were commensurately compensated for their time and expertise. For every breakout group in annual state team learning sessions, we invited family colleagues as co-facilitators. Notably, while not her primary role, Principal Investigator Meg Comeau is parent to an adult child with medical complexity.

On the network level, one key strategy was a regular affinity group call hosted by Family Voices staff for family colleagues across the CoIIN, to cross-share operational strategies, problem-solve together, and provide TA/training and mentorship for each other. Family colleagues were invited alongside fellow team members for network-level workgroups that developed to identify outcome measures, add telehealth measures during COVID, and plan the annual state team learning session. We also required that a family leader colleague be among the capped number of team members to attend annual state team learning sessions. Our CMC & COVID-19 Extension for Community Healthcare Outcomes (ECHO) series, hosted in partnership with the American Academy of Pediatrics, was one of the first to engage family colleagues at every level: on the faculty, as guest co-presenters, and as active participants. Lastly, for dissemination opportunities, we asked family colleagues to co-present with state team members.

On the team level, all 10 state teams were required to engage family colleagues as core members for their quality improvement projects, and were paid accordingly. Family colleagues additionally had options to act as advisory members, interviewers, and more. The CMC CoIIN was among the first to implement the Family Voices Family Engagement in Systems Assessment Tool® (FESAT) consensus-driven action plan process as a requirement for all state teams to complete at least twice. The FESAT helped drive further tangible progress in family partnership on the state team level. Multiple teams chose to complete it a third time.

Strategy #2: Select meaningful outcomes driven by lived experience.

HRSA's visionary leadership and guidance led to two of the three goals outlined in the original NOFO being focused on child quality of life (QoL) and family well-being (FWB). These are unusual outcomes for health care to directly work to impact, yet key outcomes that matter deeply in day-to-day living for families of CMC. HRSA has remained steadfast in valuing these goals as equal in necessity to that of increasing the cost-effectiveness of care. The objectives to reach these goals were: increased access to a medical home, development of a shared plan of care, improved family engagement on the clinical level, and reducing unmet need. By intentionally involving families of CMC in measurement development, we could ensure we were measuring equitable and anti-ableist outcomes that really matter to them and their children, and by extension, their health care providers.

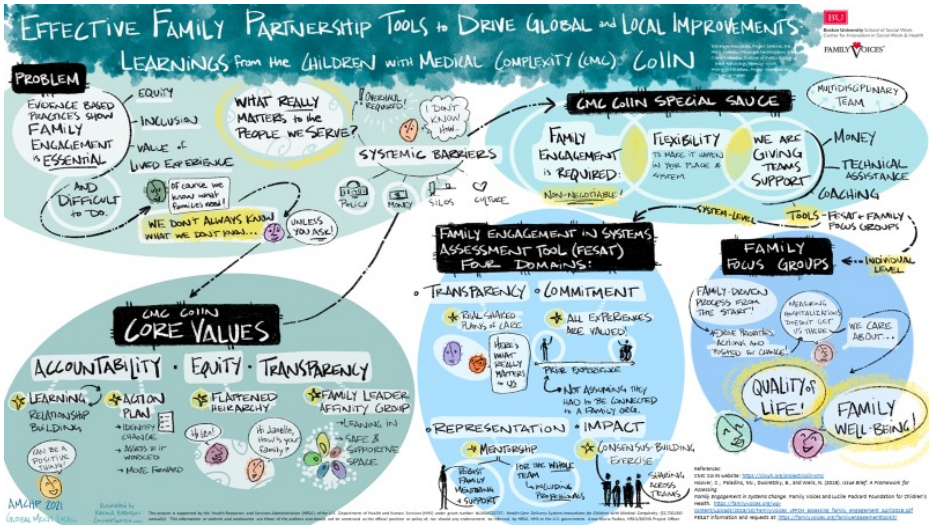
We assembled a workgroup composed of leading experts in the field of care for CMC, including family colleagues, evaluators, and quality improvement specialists, to design and test a quantitative self-report survey of families of CMC enrolled in each state teams' cohort. The domains of measurement were composed of the two family-facing project goals (QoL and well-being) and the four objectives. By intentionally involving families of CMC in measurement development, we could ensure we were measuring equitable and anti-ableist outcomes that really matter to them and their children, and by extension, their health care providers.

Through this project, HRSA has encouraged each state team to innovate and collaborate at new levels not previously possible in any formalized manner for CMC. To be able to figure out how to design interventions that could actually impact child QoL and FWB, state teams were compelled to partner with families in new and profound ways. The focus on these holistic outcomes led to a shift in teams' models of care to meet families' broader needs and priorities; a realization of the limitations of current measures; and a focus in quality improvement efforts on cross-sector collaboration and referral pathways to family-led organizations.

Strategy #3: Collect lived-experience data.

As the family survey measures were finalized in concert with all CoIIN stakeholders, it became clear—particularly among the collaborative's family leaders—that some measures were woefully inadequate to capture lived experience of families of CMC. In particular, a deeper dive was critical into "difficult topics," namely CMC quality of life and family well-being, given that the constellation of factors impacting these domains are unique and wide-ranging for families. CMC CoIIN leadership convened a Focus Group Work Group (FGWG) to identify how best to probe for CMC quality of life and family well-being in depth. Recognizing the importance of family partnership, the CMC CoIIN asked our Family Voices partner to chair the FGWG. In addition, the CMC CoIIN requested that each state team provide one family colleague to participate in the FGWG and offered an optional second state team representative position that could be filled by another family leader or any other interested state team member.

Once the FGWG developed the guide, family colleagues within each state team were supported by the leadership team to conduct focus groups at two annual site consultation visits. A summary of highlights from the group discussion was shared after each visit with each individual state team project as a complement to the quantitative data, to better inform their quality improvement efforts around non-medical needs to improve CMC quality of life and family well-being. In addition, aggregate qualitative analysis was conducted and shared. Analytic comparisons of change over time for subsequent groups were also included. Lived-experience data became even more critical after the onset of COVID, which happened in the project's third year. We developed infographics to share publicly of deidentified aggregate findings from the first round of focus groups in 2019 and second round focusing on COVID and telehealth in 2020/2021.



CASE STUDY #2

The Greening of Detroit

Charlene Shelton | Clarissa Hoover

In 1989 a nonprofit called The Greening of Detroit (TGD) sought to bring back trees in areas of the city where trees had been neglected or cut down. Environmentalists know that trees provide many functional benefits from cooling of neighborhoods to cleaner air, and they provide beauty and increase property values. By 2014, the organization received enough funding to plant more than 1,000 new trees per year. Surely the residents of the communities that were targeted would be excited and grateful to receive free trees for their homes. Not so much.

Residents understood very well the benefit of having trees, yet a quarter of the people approached declined the offer of free trees. Why would they decline an offer for not only free trees, but also having someone come and do the planting? It turns out that the nonprofit didn't know or understand the lived experiences of the residents of the targeted neighborhoods. These were communities of color that had been targeted historically for different reasons: Trees had been cut down following a 1967 race-based "rebellion." Residents believed the trees were cut so that they could be surveilled by helicopter by law enforcement. The city of Detroit, which was spraying DDT on the trees, said it was because the trees were dying of Dutch elm disease. Either way, the lived experience of the residents engendered mistrust of the city and of the TGD tree planters and staff, so they said "no."

Some Obvious Problems

The first problem we see is that no one talked to the residents to tell them what TGD was thinking about and getting the community's input about the *idea*. If TGD had talked the idea through with residents, they might have heard the narrative that was prevalent in the community and could have discussed how to work within the narrative to engender trust. A second problem involved bringing in people from outside that did not represent the community in any way—the residents were Black and the volunteers were white with no ties to Detroit.

The third problem was that TGD minimized the importance of community outreach by having only one person doing the outreach and not involving residents in the planning and execution of the scheme. Residents were not asked about where to plant or what kinds of trees to plant. They were informed about how the program would roll out by means of door hangers. Community meetings were scheduled, but many residents did not or could not attend. Finally, a fourth problem involved the distribution of power. Detroit's population in 2014 was 83 percent African American and had the highest concentration of poverty of the top 25 metro areas in the U.S. Residents felt marginalized and disenfranchised because no one asked them what they did or did not want and why and did not think to trust them enough to involve them in the distribution of power.

The Solution

TGD made changes thanks to a report by Dorceta Taylor, an environmental sociologist at the University of Michigan, and a study they commissioned by Christine Carmichael at the University of Vermont. They increased the community engagement staff to four people who live in the city and outreach to residents. Together, they have worked to gain the trust of the community.

Strategy #1: Investigate unenthusiasm

We inherit power relationships from the social context surrounding our work. Unenthusiasm—refusing to participate in studies, not signing up for particular lines of work, or (as in this case) refusing an offer of free services—is often one of the clearest signs that you are associated with a threatening power dynamic.

Strategy #2: Recognize multiple perspectives

Even when our beliefs are based on facts or data, everything we believe is interpreted within our personal context. Our families teach us, our history books teach us, our newspapers teach us, even our scientific articles teach us a version of truth that is shaped by culture, bias, and the selective knowledge that comes from chronically overlooking alternative perspectives. The subtext behind this strategy is not "no matter how weird"; we are talking about the need to **recognize multiple perspectives no matter how humbling** it is when they teach you something that you didn't know.

Strategy #3: Adapt and advance.

OK, so mistakes were made. We can't change the past, and we don't want to get caught in the ego trap of trying to justify it. Take stock of the mistake, acknowledge it (which may engender trust), and go to plan B (C, D, E . . .).

If you are doing research working with lived-experience partners, this WILL happen to you. Again and again. The goal of lived-experience partnerships isn't to reach the point where you no longer get caught making mistakes, it's to reach the point where you feel grateful when it happens.

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CASE STUDY #3

The USPHS Study

Clarissa Hoover

This next example goes back 100 years, to a community-engaged research project that shaped the entire future of medical research in the U.S. This observational study by the U.S. Public Health Service (USPHS) focused on a Black community in Alabama. Study participants were offered free health care addressing all their health care needs, not just those relating to the study itself. In response to the segregated educational environment of the time, a highly respected local educational institute, founded by Booker T. Washington, was recruited as an institutional research partner and a highly respected USPHS nurse, Eunice Laurie, was selected to serve as the local coordinator of the study. Mrs. Laurie, a Black woman who was raised and trained in the area, remained the public face of the study in the community for 40 years.

Have you recognized it? We are talking about one of the most famous (and notorious) medical studies in American history, the "Tuskegee Study of Untreated Syphilis in the Negro Male." While the other case studies in this appendix focus on the positive impact of lived-experience partners, **for this case study we want to share an example that demonstrates why this guide is necessary**. For starters, the USPHS study is a classic example of **cooptation**. Ninety years after it started, 50 years after it was terminated, people still argue about what happened during this study, and when they do they call it "the Tuskegee study" rather than correctly attributing it to the U.S. governmental agency where it was conceived, planned, conducted, and written up.

Strategy #1: Pause before you react.

Some things you don't want to hear about the USPHS Syphilis Study:

- It wasn't caused by a research-design problem. It wasn't caused by an ethics problem. It was caused by a racism problem.
- It wasn't "all the way back in 1930," it didn't even start until 1932. It didn't end until 1972, and there were plenty of people at that time (including the USPHS and many scientists) who defended it or said it wasn't that big a deal.
- We aren't talking about the USPHS Syphilis Study because Black people want to talk about it; in fact, more than one has told us that we should leave it be. We are talking about it because we believe that the widespread conviction, among people of color and among white people, is that **white researchers can't handle talking about Tuskegee**. And that's a serious problem, particularly when it is used as an excuse not to work with Black lived-experience partners, or not to deliver services in Black communities.
- One popular version of "the Tuskegee Experiment" story, still actively in circulation, holds that the Tuskegee Airmen were deliberately infected with syphilis so that the progress of the disease could be studied. The Tuskegee Airmen were a group of Black World War II heroes who were trained at the Tuskegee Institute (as Tuskegee University was known at that time), and who were not at all connected with the USPHS Syphilis Study.
- If it's unfair to the current-day USPHS to take the heat for one of the worst research studies ever conducted in the U.S., surely it's much more unfair to leave it connected with the name of Tuskegee University and the town of Tuskegee, Alabama.

- The U.S. research community came to terms with the ethical implications of the USPHS Syphilis Study in 1979, but still struggles with the racial implications. Many modern-day medical researchers still believe that genetics are a major factor behind racial health inequities. They aren't. The fallback position is to focus on the influence of cultural behaviors. Nope, that's not it either. Genetics and cultural factors (such as diet) should be expected to have variable effects on health, and that's what research shows—sometimes they hurt, sometimes they help. Besides, our determinations of race in the U.S. are not based on either genetics or culture. I once had a friend who said, "I'm Black and my son is white, because I've got the hair and he doesn't." That's a good example of the kinds of things we know about someone when all we know is their race.

Did any of these statements make you angry? Do you have some things you wish you could say in reply? We sure hope so—we tried to cast as broad a net as possible! However, our goal is to avoid arguments, not cause them. Gut reactions and snap judgments aren't all bad—in a hospital or a war zone, they can save lives. That said, the part of our brain that produces rapid decisions isn't the smartest part of our brain. Taking the time to reflect before we react gives us the chance to listen, learn, and grow when we hear things that challenge us. If you remembered to do that all the way through the list above, well done! If not, take a second look at one of the statements that bothered you. You won't necessarily agree with it, but you may realize that what it says isn't quite what you thought it said.

Strategy #2: Meet people where they are

"Meet people where they are" can refer either to physical meetings (for example, to see students go to a school) or intellectual meetings. If lived-experience partners want to talk about the USPHS Syphilis Study, then having that conversation is part of meeting them where they are. If they want to talk about Henrietta Lacks, or a TV show about race and genetics that they saw a few years ago, or whatever, **the fact that they want to talk about it makes it relevant**. Other lived-experience partners or researchers may be able to learn some skills to help bring the conversation around to the implications for the current project. Try asking questions like "What made you think of that today?" and "What's the most important lesson we can learn from that?"; or making statements like "What I thought of when you said that was . . ."

> "I tried to accept them as they were, see, not as what I wanted them to be. ...And then when they find that you're interested in them, they welcome you."
>
> — Eunice Rivers

Strategy #3: The rule of rings

The rule of rings is a piece of patient lore that states "comfort in, complain out." For example, if a person is diagnosed with cancer, they are in the center ring. Everyone around them should focus on supporting them, not on leaning on them for support. That might seem too obvious to say, but our lived experience proves that it hasn't been said often enough. The doctor might lead into the diagnosis by saying, "You have no idea how hard it is for me to tell you this." The best friend might fret, "I can't believe how hard it is to get together with you these days." Close relations might ask endless questions about the diagnosis, trying to finesse a statement that things aren't actually as bad as they sound.

The rule of rings goes on to say that the next ring is the people who are closest to the patient, such as people who live with them. The ring after that would be other people who love them. And so on. Anyone who is part of the situation should give a little thought to their own position compared to other people around them. Who should they focus on comforting, and who can they expect to comfort them if they complain?

In lived-experience partnerships, we think of the rule of rings as it was originally intended, but there are some other implications, too. For example, if a lived-experience partner shares a story about a traumatic experience, other people in the room shouldn't lean on them for help through how upsetting that story is. Also, when the topic is the USPHS Syphilis Study, white people shouldn't turn to Black people for emotional support. This may require developing a special set of phrases that communicate how much something has affected you while offering comfort at the same time. For example, "I've learned a lot from you even though I can't imagine what that was like." Or, "I really appreciate your willingness to talk about this."

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CASE STUDY #4

Planning Prevents Ethical Issues

Amanda Doherty-Kirby

A commentary by Vanderhout et al. shares an example of a project with family partner co-investigators and family advisors where there is clear planning to prevent ethical issues. While these efforts were mostly directed at preventing ethical issues with the engagement of the family advisors, many of these strategies can also be applied with less experienced lived-experience partners on the research team. This work, which included an evidence review, a Delphi study, and a workshop to develop consensus-based core outcome sets for two rare metabolic diseases had two patient co-investigators recruited at the grant application stage (but were already known in the rare disease community) who helped develop the study protocol, co-developed and carried out the patient engagement strategy, presented at conferences, and co-authored papers. The advisors provided input at key points during the study and were equipped to do so through training in the research process and the importance of their perspectives at the beginning of the study, given clear expectations of their advisory role, project timeline, anticipated time commitments, plan for remuneration, and recognition of the flexibility needed due to other commitments.

This training helped to build relationships and these relationships were maintained through newsletters written by parent co-researchers during periods of low study activity to highlight progress and new developments, show how feedback was used, and check on continuing interest, and for families and research team members to introduce themselves if desired. To reduce power imbalances at the workshop to reach consensus, written details about the process and results to date were sent to advisors and reviewed in person beforehand, seating was interspersed, the family role in and impact on the project was shared, and all were given equal time to share their suggestions for the three most important outcomes. The authors believe their approach to be transferable to other such studies.

Perhaps one of the most documented exemplars for lived-experience partners is the YouthCan IMPACT project, which included co-designing a community-based integrated youth service model for rapid delivery of mental health services and a multi-site randomized controlled trial comparing this model to the more standard hospital-based outpatient psychiatric services evaluating clinical and functional outcomes, user satisfaction, and cost-effectiveness.[35] The core research team consisted of principal investigators and youth, family, and community co-investigators. Core working groups (hospital, community, methods, and implementation science groups) also had youth (all groups) and family (community group only) representation and there were separate youth and family advisory groups for this project. This is consistent with the co-created McCain model for youth engagement, which allows for intense involvement by a small number of youth and less frequent engagement by more youth, allowing for the incorporation of a greater number of youth perspectives.[26]

This model was also used to guide family engagement for this project. Lived-experience partners were involved in all stages of the project (research design, grant writing, co-development of the service model, analysis, evaluation, implementation, dissemination). Contributions from lived-experience partners include envisioning and co-designing at the pre-funding stage, being grant co-applicants, project planning and oversight as core team members, reviewing and improving study procedures, training research staff, co-designing the integrated youth services model, co-developing the project website (http://youthcanimpact.com/) and co-disseminating the research through conferences, webinars, and publications. In addition, youth co-developed the model for engagement, were key in determining the primary outcome of functioning, as opposed to symptoms, which was what was originally considered

by the researchers, reviewed and co-selected all outcomes and measures, gave feedback on potential service components stressing the importance of peer support, reviewed and/or co-designed study materials, provided recommendations to make clinical spaces and study visit procedures youth-friendly, co-developed a list of mobile apps for youth, created youth-friendly postcards detailing available services, and determined the values that should guide the separate clinical and research teams.[37]

Research team members including lived-experience partners were interviewed to evaluate the startup of this project and data were also used to evaluate the impact of engagement with lived-experience partners. Key to the ability of lived-experience partners to have meaningful impact on the success of the project was involvement throughout the whole research process; building strong relationships based on transparency, honesty, and trust; a safe, inclusive, non-judgmental environment allowing for "open, honest, and respectful discussion"; accessible language; the commitment to co-design and shared decision making; and treating FYPs as equals.

There were still challenges with time and funding, schedules, the steep learning curve, navigating diverse perspectives, and continuity of youth in roles as some left and others were added to the team. Overall, lived-experience partners were seen to have great impact on YouthCan IMPACT's success. The last word in this section is left to one of the team members from the YouthCan IMPACT project: "Having the community representation and youth and family there really has been the biggest [. . .] but the best experience for me—and seeing really how we can integrate from the very beginning the youth and families and community into these large academic, scholarly research studies. It reshaped how I will do research, like, forever moving forward."

Glossary of Research Terms

Abstract
This is a brief summary of a research study and its results. It should tell you why the study was done, how the researchers went about it, and what they found.

Accessibility
The quality of being easy to approach, reach, enter, speak with, use, or understand; the quality of being suitable or adapted for use by people with disabilities.

Action Research
Action research is used to bring about improvement or practical change. A group of people who know about a problem work together to develop an idea about how it might be resolved. They then go and test this idea. The people who take part in the testing provide feedback on their experiences. They may also identify further actions that need to be researched and tested. This cycle of developing solutions and testing them is repeated until the problem has been solved. This is most similar to quality improvement (QI) and its academic cousin, QI research.

Adverse Event
An unfavorable outcome that occurs during or after a surgical or diagnostic procedure, or the use of a drug or other intervention, but is not necessarily caused by it.

Adverse Reaction (AR)
Any untoward and unintended response to a drug related to any dose administered.

Comment: All adverse events judged by the reporting investigator as having a reasonable causal relationship to a medicinal product would qualify as adverse reactions. The expression "reasonable causal relationship" means to convey, in general, that there is evidence or argument to suggest a causal relationship.

Advisory Group (Steering Group)
Many research projects have an advisory group (or steering group). The group helps to develop, support, advise, and monitor the project. The group often includes people who use services, caregivers, researchers, and other health and social care professionals who can provide relevant advice.

Analysis (Data Analysis)
Data analysis involves examining and processing research data, in order to answer the questions that the project is trying to address. It involves identifying patterns and drawing out the main themes, and is often done with special computer software.

Arm
Refers to a group of participants assigned to a particular treatment. In a randomized controlled trial, assignment to different arms is determined by the randomization procedure. Many controlled trials have two arms: a group of participants assigned to an experimental intervention (sometimes called the treatment arm) and a group of participants assigned to a control (the control arm). Trials may have more than two arms.

Attrition
The loss of participants during the course of a study.

Audit
An audit of health care involves carrying out a systematic assessment of how well that care is being delivered. Current policy and practice is compared with an agreed standard, so that any problem areas can be identified and improved. Later, the audit can be carried out again to check that the changes made have actually made a difference.

Basic Research
Basic research aims to improve knowledge and understanding, rather than finding a solution to a practical problem. It may involve work in a laboratory—to find a gene linked to a disease or to understand how cancer cells grow, for example. This kind of research can sometimes provide clues as to which avenues to explore to develop new treatments.

Bias
Bias in research is when the study outcome is influenced, intentionally or unintentionally. Bias may result from the research design, the influence of the researcher, or the influence of the study participants.

Blinding
The process of preventing those involved in a clinical trial from knowing which comparison group a participant belongs to. The risk of bias is minimized when fewer people know who is receiving the experimental intervention or the control intervention. Participants, caregivers, researchers, and analysts are all candidates for being blinded. Blinding of certain groups is not always possible, for example, surgeons in surgical trials

BP
Blood pressure

Caregiver
A caregiver is a relative, friend, or partner who provides (or intends to provide, or used to provide) a substantial amount of care to another person on a regular basis, but not necessarily through living with them.

Causal
If there is a causal relationship between two things, one thing is responsible for causing the other thing.

Clinical Guideline
A systematically developed statement for practitioners and participants about appropriate health care for specific clinical circumstances. The clinical guideline may be developed from existing studies, expert consensus, or a combination.

Clinical Research
Clinical research aims to find out the causes of human illness and how it can be treated or prevented. This type of research is based on examining and observing people with different conditions and sometimes comparing them with healthy people. It can also involve research on samples of blood or other tissues, or tests such as scans or X-rays. Clinical researchers will also sometimes analyze the information in patient records, or the data from health and lifestyle surveys.

Clinical Trial
Clinical trials are research studies involving people who use health care services, which often compare a new or different type of treatment with "standard care" (commonly accepted best treatment). They test whether the new or different treatment is safe, effective, and any better than what already exists. No matter how promising a new treatment may appear during tests in a laboratory, it must go through clinical trials before its benefits and risks can really be known.

Cluster Randomized Trial
A trial where clusters of individuals (e.g., clinics, families, geographical areas), rather than individuals themselves, are randomized to different groups. Cluster randomized trials are common in research about health care because they are often easier to implement and more meaningful than other study designs.

Co-Sponsor
Where two or more organizations share a significant interest in a study, they may elect to act as co-sponsors.

Cohort Study
An observational study in which a defined group of people (the cohort) is followed over time. The outcomes of people in subsets of this cohort are compared, to examine people who were exposed or not exposed (or exposed at different levels) to a particular intervention or other factor of interest. A prospective cohort study assembles participants and follows them into the future. A retrospective (or historical) cohort study identifies subjects from past records and follows them from the time of those records to the present.

Collaboration
Collaboration involves active, ongoing partnership with members of the public in the research process. For example, members of the public might take part in an advisory group for a research project, or collaborate with researchers to design, undertake, and/or disseminate the results of a research project.

Confidence Interval
A measure of the uncertainty around the main finding of a statistical analysis. Wider intervals indicate lower precision and narrow intervals indicate greater precision.

Confidentiality
Protecting the identity of a research participant. During a research project, the researchers must put protective measures into place, to ensure that all of the information collected about the participants is kept confidential. This means that the researchers must get the participants' written permission to look at their medical or other records. It also means that any information that might identify the participants cannot be used or passed on to others, without first getting the participants' consent. For example, when researchers publish the results of a project, they are not allowed to include people's names.

This confidentiality will only be broken in extreme circumstances: where it is essential for the person's care, treatment, or safety (where it is required by a court order, for example in a criminal investigation, or where it is necessary to protect the public).

Confounder
A factor that is associated with both an intervention and the outcome of interest that can change the apparent outcome of a study. For example, if people in the experimental group of a controlled trial are younger than those in the control group, it will be difficult to decide whether a lower risk of death in one group is due to the intervention or the difference in age. Age is then said to be a confounder, or a confounding variable. In experimental studies, randomization is used to minimize imbalances in confounding variables between experimental and control groups. Confounding is a major concern in non-randomized trials. In observational studies, confounding can be minimized by statistical analysis techniques.

Consultation
Consultation involves asking members of the public for their views about research, and then using those views to inform decision making. This consultation can be about any aspect of the research process—from identifying topics for research, through to thinking about the implications of the research findings. Having a better understanding of people's views should lead to better decisions.

Consumer
The term consumer is used to refer collectively to:

- people who use services
- caregivers
- organizations representing consumers' interests
- members of the public who are the potential recipients of services
- groups asking for research to promote good health or because they believe they have been exposed to potentially harmful circumstances, products, or services

Contamination
The unintended application of the intervention being evaluated to people in the control group; or unintended failure to apply the intervention to people assigned to the intervention group. For example, an experimental study that involves counseling by clinicians can be affected by contamination when clinicians inadvertently counsel patients in the control group, or fail to counsel those in the intervention group.

Control
A participant in the group that acts as a comparison for one or more experimental interventions. Controls may receive placebo, no treatment, standard treatment, or an active intervention, such as a standard drug.

Control Group/Arm
The groups being compared in the randomized trial. Also referred to as "study groups," "treatment groups," "the arms" of a trial, or by individual terms such as treatment and control groups.

Controlled Trial
A type of clinical trial in which observations made during the trial are compared to a standard (called the control). The control may be observations from a group of participants in the same trial or observations from outside the trial (for example, from an earlier trial, called a "historical control").

Cost-Effectiveness
A measure addressing the cost of achieving health benefits. To facilitate comparisons, health benefits can be quantified in several ways; one common measure is "QALYs" (Quality-Adjusted Life Years), which incorporate both extra life achieved and improvements in quality of life. Knowing the cost associated with each QALY gained can help decision makers assess whether the introduction of a treatment or service should be recommended.

Cost-Effectiveness Analysis
An economic analysis that describes the costs for some additional health gain (e.g., cost per additional stroke prevented).

CV
Curriculum Vitae. Similar to a résumé, but lists the scholarly products of the researcher, such as papers, grants, and presentations.

Data
Data are pieces of information collected through research. They can include written information, numbers, sounds, and pictures. Data are usually stored electronically, so that they can be analyzed, interpreted, and then communicated to others, for example in reports, graphs or diagrams. "Data" is plural. The singular is "datum."

Dependent Variable
A dependent variable is a variable whose value depends upon independent variables. The dependent variable is what is being measured in an experiment or evaluated in a mathematical equation. The dependent variable is sometimes called "the outcome variable."

Dissemination
Dissemination involves communicating the findings of a research project to a wide range of people who might find it useful. This can be done through:

- producing reports (often these are made available on the Internet)
- publishing articles in journals or newsletters
- issuing press releases
- giving talks at conferences

It is also important to give feedback about the findings of research to research participants.

Double Blind
A trial where neither the investigators nor the subjects included in the trial (healthy volunteers or patients) know which interventions/treatments have been assigned.

Effect Size
A generic term for the estimate of treatment effect for a study.

Efficacy
The extent to which an intervention produces a beneficial result under ideal conditions. This is as compared with effectiveness, which is the extent to which an intervention produces beneficial results under more typical "real-world" conditions.

Eligibility Criteria
The key standards that people who want to participate in a clinical study must meet, or the characteristics that they must have. These include inclusion criteria and exclusion criteria. For example, a study might only accept participants who are above or below certain ages.

Engagement
Engagement in research refers to active involvement between people who use services, caregivers, and researchers, rather than the use of people as participants in research (or as research "subjects"). Many people describe engagement as doing research with or by people who use services rather than to, about, or for them.

Enrollment
The act of admitting a participant into a trial. Participants should be enrolled only after study personnel have confirmed that all the eligibility criteria have been met and consent (if indicated) has been obtained. Formal enrollment must occur before randomized assignment in a randomized study.

Epidemiology
The study of population and community health, not just individuals.

Ethics
Ethics are a set of principles that guide researchers who are carrying out research with people. Ethical principles are designed to protect the safety, dignity, rights, and well-being of the people taking part. They include the requirement to ask each individual to give their informed consent to take part in a research project.

Evaluation
This involves assessing whether an intervention (for example a treatment, service, project, or program) is achieving its aims. A project can be evaluated as it goes along or at the end. An evaluation can measure how well the project is being carried out as well as its impact. The results of evaluations can help with decision making and planning.

Evaluative Research
Evaluative research seeks to assess or judge in some way, providing useful information about something, which cannot be gleaned by mere observation or investigation of relationships.

Evidence Base
An evidence base is a collection of all the research data currently available about a health or social care topic, such as how well a treatment or a service works. This evidence is used by health care professionals to make decisions about the services that they provide and what care or treatment to offer people who use services.

Evidence Synthesis
Evidence synthesis involves the development of techniques to combine multiple sources of quantitative and qualitative data to derive best evidence for use in health care.

Exclusion Criteria
Specific criteria that are defined within the study protocol that expressly exclude specific individuals from participating in a study, for example children in a study of adult conditions. The reasons for considering exclusion can range from safety issues, potential difficulties in management of particular participants, or the need to control variables within the study. Exclusion criteria must always be defended ethically to guard against discrimination.

Experimental Research
This type of research allows researchers to explore cause and effect, and almost always involves new drugs, diagnostic tests, or other treatments. For example, experimental research would be used to see whether a new drug is effective in reducing blood pressure. The research design (in this example, most likely a randomized control trial) will tell the researcher whether any reduction in blood pressure is definitely due to the drug.

Factorial Design
Factorial designs allow researchers to look at how multiple factors affect a dependent variable, both independently and together. Factorial design studies are named for the number of levels of the factors. A study with two factors that each have two levels, for example, is called a 2x2 factorial design. In a trial using a 2×2 factorial design, participants are allocated to one of four possible combinations. This type of study is usually carried out in circumstances where no interaction is likely.

Feasibility Studies
Feasibility studies are smaller studies that are done before a main study in order to answer the question "Can this study be done?" They are used to estimate important parameters that are needed to design the main study. They are often done in combination with acceptability studies, which answer the question "Will participants do this study?" For instance:

- willingness of participants to be randomized
- willingness of clinicians to recruit participants
- number of eligible patients, caregivers, or other appropriate participants
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure
- Follow-up rates, response rates to questionnaires, adherence/compliance rates, etc.
- availability of data needed or the usefulness and limitations of a particular database
- time needed to collect and analyze data

Focus Group
A focus group is a small group of people brought together to talk. The purpose is to listen and gather information. Focus groups (as opposed to individual interviews) take advantage of group dynamics and conversations between participants. It is a good way to find out how people feel or think about an issue, or to come up with possible solutions to problems.

Follow-Up
A process of periodic contact with participants enrolled in the trial for the purpose of administering the assigned intervention(s), modifying the course of intervention(s), observing the effects of the intervention(s), or for data collection.

Funder
Organization providing funding for a study (through agreements, grants, or donations to an authorized member of the employing and/or health care organization). The main funder remains responsible for securing value for money.

Generalizability
The extension of research findings and conclusions from a study conducted on a sample population to the population at large. The larger the sample population, the more one can generalize the results.

Gold Standard
The method, procedure, or measurement that is widely accepted as being the best available, against which new developments should be compared.

Grey Literature
Grey literature is material that is less formal than an article in a peer review journal or a chapter in a book. It is not typically indexed and harder to find in a systematic search, so it's not easily tracked down. It includes internal reports, committee minutes, conference papers, web pages, factsheets, newsletters, and campaigning material. However, grey literature may be made available on request and is increasingly available on the Internet.

Hypothesis
A hypothesis is an assumption, an idea that is proposed for the sake of argument so that it can be tested to see if it might be true. In the scientific method, the hypothesis is constructed before any applicable research has been done, apart from a basic background review.

Implementation
Implementation involves putting research findings into practice. This means using research findings to make appropriate decisions and changes to health care policy and practice.

Inclusion Criteria
Specific criteria that are defined within the study protocol that expressly include specific individuals to participate in a study—e.g., individuals within a certain age range, with a specific condition, etc.

Informed Consent (IC)
A process by which a subject voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the subject's decision to participate. A person gives informed consent to take part only if his/her decision is given freely after that person is informed of the nature, significance, implications, and risks of the study. Informed consent is needed for all experimental studies including clinical trials, but also for many observational studies.

Interaction
An interaction effect happens when one explanatory variable interacts with another explanatory variable on a response variable. This is opposed to the "main effect," which is the action of a single independent variable on the dependent variable.

For example, let's say you were studying the effects of a diet drink and a diet pill (the explanatory variables) on weight loss. The "main effects" would be the effect of a diet drink on weight loss, and the effect of the diet pill on weight loss. The interaction effect happens when the drink and pill are taken at the same time. It's possible the combination could speed up weight loss, or even slow it down.

Interim Analysis
Analysis comparing intervention groups at any time before the formal completion of a trial, usually before recruitment is complete. Often used with stopping rules so that a trial can be stopped if participants are being put at risk unnecessarily. Timing and frequency of interim analyses should be specified in the protocol.

Intervention
An intervention is something that aims to make a change and is tested through research. For example, giving a drug, providing a counselling service, improving the environment, or giving people information and training are all described as interventions.

Intervention Group
A group of participants in a study receiving a particular health care intervention.

Interview
In research, an interview is a conversation between a researcher and one or more people, where a researcher asks questions to obtain information from the person (or people) being interviewed.

Investigator
Researcher conducting the (clinical) study, those researchers leading the team are referred to as a PI (principal investigator).

IRB (Institutional Review Board)
Institutional review board, often called "human subjects committee." For organizations that conduct research, an IRB provides guidance and approval for research involving human subjects in order to comply with federal laws relating to protection of the rights and safety of subjects. All research involving human subjects at an organization is subject to IRB review and approval.

Journal
A journal is a regular publication in which researchers formally report the results of their research to people who share a similar interest or experience. Each journal usually specializes in one particular topic area. *The British Medical Journal* (BMJ), *Journal of the American Medical Association, Pediatrics*, and The Lancet are examples of journals. Manuscripts are usually reviewed by others in the field before the editors decide to publish (see "peer review").

Lay (Lay Person)
The term "lay" means non-professional. In research, it refers to the people who are neither academic researchers nor health care professionals. With the recent increase of patient and family engagement in the research process, lines between "professional" and "lay" participants are becoming increasingly blurred.

Lay (Non-Technical) Summary
A lay summary is a brief summary of a research project or a research proposal that has been written for members of the public, rather than researchers or professionals. It should be written in non-technical language, avoid the use of jargon, and explain any technical terms that have to be included.

Mentor
A mentor is an experienced person willing to share their experience, knowledge, and wisdom to help, guide, and support someone who is less experienced. Mentors act as teachers and advisors, and may become friends. A person who is newly engaged in research can ask for a mentor to help them adjust to their new role.

Meta-Analysis
A study that combines data and findings from multiple independent studies to draw conclusions about a research question. Well-done meta-analyses are often scientifically stronger than randomized controlled trials (RCTs).

Methodology
The term methodology describes how research is done. It will cover how information is collected and analyzed as well as why a particular method has been chosen.

Morbidity
Illness or harm.

Mortality
Death.

Multi-Site
A study conducted according to a single protocol but carried out at more than one site and by more than one investigator; one principal investigator oversees several local principal investigators.

Multi-Site Trial/Study
A trial conducted at several geographical sites. Trials are sometimes conducted among several collaborating institutions, rather than at a single institution—particularly when large numbers of participants are needed.

Null Hypothesis
A null hypothesis is a type of hypothesis used in statistics that proposes that there is no difference in outcomes from an experimental condition or observational situation. For example, the null hypothesis in a drug trial would be that use of the drug does not change the outcome it is expected to change. For statistical reasons, data that prove the null hypothesis to be false are needed in order to prove that there is a beneficial effect of an intervention.

Observational Study
A study in which the investigators do not seek to intervene, but simply observe the course of events. There is a greater risk of selection bias and confounding than in experimental studies. Observational studies are often less costly and quicker than experimental studies, and are frequently the first step leading to an experimental study.

Outcome
Research outcome is the end result of conducting research on a particular topic. It may be a list of statistics one ends up with after conducting a survey or it could be a conclusion (such as phonics is the best method for teaching reading based on research that collected pre- and post-1966 reading test results).

Outcome Measures
Outcome measures are measurements of the effects of a treatment or service. They might include physical measurements (measuring blood pressure, for example) or psychological measurements (measuring people's sense of well-being, for example). So if someone takes part in research, they may be asked questions, or they may be asked to have extra tests to assess how well the treatment or service has worked.

Output
The final stage of research is disseminating the findings to an appropriate audience. Dissemination can take many forms: a paper in a journal, conference paper or presentation, a formal report, or a dissertation/thesis for postgraduate study, web-based materials, and many others.

Participant
A participant is someone who takes part in a research project. Sometimes research participants are referred to as research "subjects."

Participation
Taking part in a research study, for example people being recruited to take part in a clinical trial or another kind of research study, joining in a focus group, or completing a questionnaire.

Participatory Research
This is a type of research where researchers and people who use services or caregivers are partners in a research project. The research addresses an issue of importance to service users or caregivers, who are engaged in the design and conduct of the research, and the way the findings are made available. The aim of the research is to improve people's lives. This isn't a research method—it's an approach to research, a philosophy.

Patient and Public Engagement
An active partnership between patients and/or the public and researchers in the research process, rather than the use of people as "subjects" of research. Patient and public engagement in research is often defined as doing research "with" or "by" people who use services rather than "to," "about," or "for" them. This would include, for example, engagement in the choice of research topics, assisting in the design, advising on the research project, or in carrying out the research.

Peer Interviewing
Peer interviewing is where people are interviewed by others who have a similar experience to them—their peers. For example, in a project to find out about children's experiences of after-school care, children with experience of using after-school care may act as peer interviewers, asking other children about their experience. Some researchers believe that this kind of interviewing enables people to talk more freely about their experience.

Peer Review
A reviewing process by experts in the same area of study used for checking the quality and importance of reports of research. An article submitted for publication in a peer-reviewed journal is typically reviewed by at least three other experts in the area, and their approval is usually required for the article's acceptance for publication in that journal. Peer reviewers might be members of the public, researchers, or other professionals. Peer review helps to check the quality of a report or research proposal.

Members of the public who act as peer reviewers may choose to comment on:

- whether the research addresses an important and relevant question
- the methods used by researchers
- the quality of public engagement in the research

Perspectives/User Perspectives
A user perspective is often what people with experience of using health or social services are asked to bring when they get involved in research. They are asked to provide ideas, comments, and suggestions based on the unique insight they have from their knowledge and experience of life with a health condition. They cannot be representative of everyone who uses a particular service, but they can offer their own perspective, and often that of other people.

PI
Principal investigator: The lead person at a single site designated as taking responsibility within the research team for the conduct of the study

Pilot Studies
A pilot study, pilot project, pilot test, or pilot experiment is a small-scale preliminary study conducted in order to evaluate feasibility, acceptability, time, cost, adverse events, and improve upon the study design prior to performance of a full-scale research project.

Placebo
A placebo is a fake or dummy treatment that is designed to be harmless and to have no effect. It allows researchers to test for the "placebo effect." The placebo effect is a psychological response where people feel better because they have received a treatment, and not because the treatment has a specific effect on their condition. By comparing people's responses to the placebo and to the treatment being tested, researchers can tell whether the treatment is having any real benefit.

Post Hoc Analysis
From Latin "after this," post hoc analysis consists of looking at the data after the experiment has concluded for patterns that were not specified when the study was initially designed.

Power (Statistical)
The probability of rejecting the null hypothesis when a specific alternative hypothesis is true. In clinical trials, power is the probability that a trial will detect, as statistically significant, an intervention effect of a specified size. Power is related to the number of participants in a study; the more participants, the higher the power. Ideally, we want a test to have high power, otherwise data that indicate a difference in outcomes may not be statistically significant, risking that a benefit of an intervention might be missed.

Pragmatic Trial
A trial that aims to test a treatment in a "real-life" situation, when many people may not receive all of the treatment, and may use other treatments as well.

Preclinical Study
Research using animals to find out if a drug, procedure, or treatment is likely to be useful. Preclinical studies take place before any testing in humans is done.

Primary Outcome
The outcome of greatest importance.

Primary Research (also called Primary Data Studies)
Experimental or observational studies that generate new data. This is in contrast to secondary data studies, where existing data about people are investigated to draw conclusions.

Probability
The chance or risk of something happening. Probability is used very frequently in statistics, to determine if there is a true relationship between experimental or observational conditions and outcomes.

Protocol/Research Protocol
A protocol is the plan for a piece of research. It usually includes information about:

- what question the research is asking and its importance/relevance
- the background and context of the research, including what other research has been done before
- how many people will be involved
- who can take part
- the research method, including the data to be collected and any interventions
- what will happen to the results and how they will be publicized

A protocol describes in great detail what the researchers will do during the research. Usually, it cannot be changed without going back to an IRB for approval.

Public Health Research
Public health is concerned with promoting good health, preventing disease, and protecting people from hazards, rather than treating illnesses. It covers topics like the control of infectious diseases, vaccinations, and helping people to adopt healthy lifestyles. It is more commonly observational (rather than experimental) research.

Public health research involves finding out new knowledge (or testing out existing ideas) to do with public health, so it might address questions about:

- the best ways to help people stop smoking
- how influenza spreads

Qualitative Research
Qualitative research is defined as studies that focus on why and how things happen and that do not use numerical data as their primary facts. Qualitative research is often done using interviews and focus groups, and is frequently the first step in gaining information about a new research topic. Qualitative research usually generates more questions than answers, and does not usually employ hypotheses or statistical analyses. An example of qualitative research is a project to determine why people want to stop smoking.

Quality Assurance (QA)
All those planned and systematic actions that are established to ensure that the trial is performed and the data is generated, documented (recorded), and reported in compliance with good clinical practice and any applicable regulatory requirement(s).

Quantitative Research
In quantitative research, researchers collect data in the form of numbers. So they measure things or count things. Quantitative research might ask a question like how many people visit their doctor each year, or what proportion of children have had an MMR vaccine, or whether a new drug lowers blood pressure more than the drugs that are usually used. Quantitative researchers use methods like surveys, observational studies, and clinical trials.

Questionnaire
A questionnaire is a prepared set of written questions used to obtain information from research participants. Questionnaires can be completed on paper, using a computer, or with an interviewer.

Randomization
There are two components to randomization: the generation of a random sequence, and its implementation, ideally in a way so that those entering participants into a study are not aware of the sequence.

Randomized Controlled Trial (RCT)
A controlled trial compares two groups of people: an experimental group who receive the new treatment and a control group, who receive the usual treatment or a placebo. The control group allows the researchers to see whether the treatment they are testing is any more or less effective than the usual or standard treatment.

In a randomized controlled trial, the decision about which group a person joins is random (that is, based on chance). A computer will decide rather than the researcher or the participant. Randomization ensures that the two groups are as similar as possible, except for the treatment they receive. This is important because it means that the researcher can be sure that any differences between the groups are only due to the treatment.

Reporting/Publication Bias
The publication or non-publication of research findings, depending on the nature and direction of the results

Research Methods or Techniques
Research methods are a particular way of studying something in order to discover new information about it or understand it better. For example, a focus group is a research method that's typically used to understand a consumer's reaction to a product or service.

Research Network
Research networks aim to bring together people who have an interest in research about a particular condition or group of people. Networks might be national or local. These networks encourage researchers to work together and improve the quality of research. For example, CYSHCNet supports research on health systems that impact children and youth with special health care needs and their families.

Research Partner
The term research partner is used to describe people who get actively engaged in research, to the extent that they are seen by their "professional" colleagues as a partner, rather than someone who might be consulted occasionally.

Partnership suggests that researchers and service users/caregivers have a relationship that involves mutual respect and equality.

Retrospective Study
A study in which the outcomes have occurred before the study commenced. Case-control studies and cohort studies can be retrospective, but randomized controlled trials never are. Secondary data studies are mostly retrospective studies, while primary data studies are usually prospective studies.

Reviewer
An individual with specific knowledge, experience, and skills in a field of practice who undertakes an independent review of a grant application or document for publication. The comments made by this independent "external reviewer" are used to inform the funding decision or the preparation of a written document. See "Peer review" above.

Sample Size
The number of participants in the trial. Sample size measures the number of individual samples measured or observations used in a survey or experiment. For example, if you test 100 samples of soil for evidence of acid rain, your sample size is 100. If an online survey returned 30,500 completed questionnaires, your sample size is 30,500. In statistics, sample size is generally represented by the variable "n."

Secondary Outcome
An outcome used to evaluate additional effects of an intervention deemed as being less important than the primary outcomes.

Setting
The research setting is the environment in which research is carried out. This could be a laboratory or a "real" setting, such as the subject's working environment if you are conducting research into people's working lives.

Source Documents
Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, subjects' diaries, pharmacy dispensing records, X-rays, etc.).

Statistically Significant
A result that is unlikely to have happened by chance.

Statistics and Statistical Analysis
The practice or science of collecting and analyzing numerical data, especially for the purpose of making inferences from a representative sample. Statistical analysis uses a set of mathematical rules to analyze quantitative data. It can help researchers decide what data means. For example, statistical analysis can assess whether any difference seen between two groups of people (for example between the groups of people in a clinical trial) is likely to be a reliable finding or simply due to chance.

Sub-Group Analysis
An analysis in which the intervention effect is evaluated in a defined subset of the participants in a trial, or in complementary subsets, such as sex or age.

Subject
An individual who participates in a clinical trial as either a recipient of the investigational product or a control.

Treatment
The process of intervening with the aim of enhancing health or life expectancy. Sometimes, and particularly in statistical texts, the word is used to cover all comparison groups, including placebo and no treatment arms of a controlled trial and even interventions designed to prevent bad outcomes in healthy people, rather than cure ill people.

Treatment Effect
An effect attributed to a treatment, which in a clinical trial is based on a comparison between active treatment and a placebo control or two or more treatment regimens.