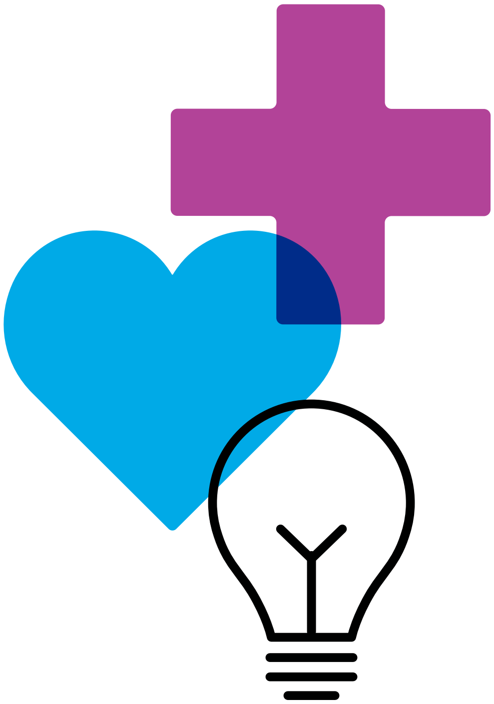

Patient-Centered Outcomes Research And Reproductive Health

A Report on the Planned Parenthood PCOR & Reproductive Health Summit

July 2016

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Research

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I. Introduction

Planned Parenthood is a national network of reproductive health care providers dedicated to delivering high-quality, affordable health care to women, men, and teens. Our 57 unique, locally governed affiliates nationwide operate over 650 health centers, which reflect the diverse needs of their communities. Together we serve over two million people each year across the United States to prevent unintended pregnancies through birth control, reduce the spread of sexually transmitted infections through testing and treatment, and screen for cervical and other cancers. About half of our health centers also offer patient-centered abortion care.

Inherent in the Planned Parenthood mission is a respect for each individual's right to make informed, independent decisions about their health – a principle that is also central to patient-centered outcomes research (PCOR). Everyone experiences reproductive health needs at some point in their lives, and reproductive health directly intersects with many other health priorities identified by the Patient-Centered Outcomes Research Institute (PCORI). Despite this clear alignment, reproductive health organizations have not been engaged in PCOR as a community, and there is an opportunity for enhanced focus on reproductive health in PCORI-funded research studies.

To address this gap, PCORI awarded Planned Parenthood Federation of America (PPFA) a Eugene Washington Engagement Award to:

- convene a group of stakeholders to explore the promise of PCOR for advancing reproductive health;
- increase participant awareness of emerging practices in patient engagement in reproductive health research and identify potentially unique challenges and solutions; and
- disseminate research priorities for PCOR in reproductive health to encourage more patient-centered reproductive health research.

In October 2015, PPFA convened 45 stakeholders for a two-day PCOR & Reproductive Health Summit to build capacity for increased patient engagement in reproductive health research. Summit participants represented 32 organizations and multiple stakeholder communities including: clinicians; researchers (PCORI awardees and others); PCORI representatives; patient and consumer advocates; and stakeholders from funding, health care, and policy organizations. Attendees had a range of professional backgrounds.

The purpose of this report is to describe our work to accomplish the project objectives, including introducing key PCOR concepts as they relate to reproductive health; describing what has been funded in reproductive health PCOR; demonstrating areas where more PCOR is needed; highlighting emerging practices in PCOR and reproductive health; and identifying potential next steps.

II. What is PCOR?

Patient-Centered Outcomes Research (PCOR) is an approach to research grounded in meaningful stakeholder engagement and specific methodological standards. There are many related concepts and terms, which may be understood and defined differently across disciplines, organizations, and researchers. Below, we define key concepts as we have come to understand them. It is our hope that this will provide those readers new to PCOR with basic working definitions to be used in future research efforts.

To understand PCOR, it is first helpful to understand the concept of **Comparative Effectiveness Research (or "CER").** CER is a type of research that aims to give people the information they need to make health care decisions by providing scientific evidence on the *effectiveness*, benefits, and harms of different treatment options and comparing these options in a real-world setting.[1]

Patient-Centered Outcomes Research (PCOR) likewise seeks to help people and their caregivers communicate, and give them the information they need to make health care decisions.[2] The hallmarks of PCOR are meaningful engagement of patients or other stakeholders, and answering research questions that matter to those who are most affected.

To understand how CER and PCOR are related, AcademyHealth – a leading health services research organization – has described PCOR as CER that:

1. engages patients and stakeholders in the research process;
2. investigates questions that matter to patients; and
3. helps people make informed health and care decisions.

CER and PCOR can both be used to study treatment approaches when the efficacy of the treatment or intervention is not known. These new treatments should be compared to existing treatments, which may include a placebo or "treatment as usual."

Some researchers have pointed out similarities between PCOR and **Community-Based Participatory Research (CBPR)**, an approach to research in which community members represent their communities and are engaged to help improve health and well-being, eliminate inequities in health, and use research to create social change.[3] In contrast, PCOR asks that researchers engage stakeholders in a guided way, based on the study context, to make sure that we engage people who could potentially benefit from the research. PCOR strives to improve people's health, give them the information they need to make their health care decisions, and create a way for patient, consumer, and caregiver voices to be heard. PCOR is generally used to answer questions for clinical decision-making and is focused within the health care system; on the other hand, CBPR often looks at larger influences in society or community needs to better understand health or other issues.

Patient and stakeholder engagement is one of the distinguishing factors of the PCOR methodology and represents a shift from doing research on people to doing research with them, involving patients throughout the research process. As the PCORI saying goes, it is "research done differently." PCORI defines patients as individuals who have or have had the condition under study.[4] Given that "reproductive health" is not a specific disease or condition but rather a group of needs or conditions that people may experience differently throughout their lives, we expand the definition of "patients" to include anyone who has reproductive health needs, whether they have sought medical care or could potentially seek care. Patients are critical stakeholders to engage in PCOR; however, there are additional stakeholder groups that could be included depending on the focus of the research.

Stakeholders include any group that has a stake in the health care system or people's health including: patients and consumers, caregivers and family members of patients, clinicians, representatives of health facilities or systems, purchasers, payers, industry representatives, researchers, and policy makers.[5] In reality, people are often members of more than one stakeholder group (for example a clinician who is also a patient). However, it is important to consider whether one person can actually represent multiple groups at the same time (for example, could the clinician who is also a patient truly speak from the patient perspective alone or would the clinician role necessarily influence their opinion?).

Also important to PCOR is that research should focus on **patient-centered outcomes**. This means that the outcomes should matter to patients, and should address questions from the patients' perspective, such as:

- Given my personal characteristics, conditions and preferences, what should I expect will happen to me?
- What are my options and what are the benefits and harms of those options?
- What can I do to improve the outcomes that are most important to me?
- How can the healthcare system improve my chances of achieving the outcomes I prefer?[6]

If a potential research study will not likely be able to produce evidence to answer these types of questions, it is worth considering whether the outcomes are indeed patient-centered. Engaging patients or other stakeholders in the process of identifying research questions and outcomes of interest can help to address this.

Research can engage patients and other stakeholders throughout the research process, from the identification of research questions through the interpretation and dissemination of results. Table 1 gives examples of patient engagement at different stages of research.

Table 1. Patient engagement throughout the research process

Research Stage	Example
Defining research question(s)	Patient partners are recruited to join the study team and help to generate and select the research question
Study design	Patient partners help to design study methods and define key outcomes
Data collection	Patient partners conduct interviews with study subjects
Data analysis	Patients partners are trained and participate in coding interview transcripts
Results interpretation and write-up	Patient partners help to identify key themes and assist in preparation of a study report
Dissemination of findings	Patient partners help to develop dissemination strategy and disseminate the findings to their networks

III. What types of research have been funded in this area?

To begin to identify areas for patient-centered reproductive health research, we searched funding and grants databases to find relevant current or previously funded studies. We included reproductive health research studies that were funded between January 2010 and June 2015 and focused on patient-centered outcomes or explicitly engaged patients in the research process. We reviewed relevant projects funded by the Patient-Centered Outcomes Research Institute (PCORI) and the Agency for Healthcare Research & Quality (AHRQ) and those listed on Clinicaltrials.gov and the National Institutes for Health (NIH) Research Portfolio Online Reporting Tool.

Our initial searches returned 897 projects. Upon reviewing for relevance, we identified 38 research projects, focused on sexually transmitted infections (10); prostate cancer (9); contraceptive use and method decision support (6); gynecological cancers (4); pregnancy-related topics (4); sexual health in the transgender community (2); uterine fibroids (2), which is one of PCORI's selected topics for targeted funding; navigating reproductive health preventive services (1); and intimate partner violence and reproductive coercion (1).

We conducted a similar search to identify any reproductive health-related research publications during the same period that focused on patient-centered outcomes or engaged patients in the research process. Of the 1,418 publications identified and reviewed, seven were considered relevant and focused on fertility care (4), contraceptive decision-making (1), managing blood glucose levels during and just after pregnancy (1), and intimate partner violence and HIV infection (1). The searches for funded and published reproductive health research helped us to understand the PCOR and reproductive health landscape and identify potential gaps and areas of ongoing investigation. The results also highlighted significant opportunities for more research in this arena.

IV. Where is PCOR needed in reproductive health?

One goal of this project was to develop and disseminate potential research priorities in order to encourage more patient-centered reproductive health research. We drew upon the PCORI methodology for *Generation and Prioritization of Topics for Funding Announcements*, which aims to identify "research questions that matter to patients, caregivers, clinicians, and other health care stakeholders but have not been answered reliably by previous studies."

> **"…evidence-based contraceptive counseling techniques…"**
>
> **(Clinician)**

Clinician and researcher voices

We started by gathering topics from the Society of Family Planning research priorities,[7] sought input from reproductive health researchers, scanned the PCORI Topic Database, and conducted a stakeholder survey of Planned Parenthood clinicians and researchers who work directly with patients. For the latter, we sent a voluntary, web-based survey to a Planned Parenthood network of clinicians, clinical administrators, and researchers. Over 100 respondents suggested topic areas for future patient-centered research in reproductive health.

Prioritizing research topics

Combining all of the topics gathered from reproductive health researchers, relevant topics from the PCORI Topic Database, and Planned Parenthood clinicians and researchers generated a list of 466 potential research questions. While we initially intended to narrow this list of topics by adapting PCORI's methodology for assessing and prioritizing topics, we soon realized that this approach would be challenging because of the breadth of reproductive health topics and the depth of background required to apply PCORI's criteria. After assessing each topic for relevance to patients and considering whether comparative effectiveness research would indeed be important, implementable, and fill an evidence gap, we found that we still had 75 topics on the list (the criteria that are used to evaluate each research topic can be found here). Rather than attempt to prioritize within those topics, we decided that providing the full topic lists from our stakeholders directly to researchers would be the most helpful so that they could decide which questions to pursue based on their own interests, expertise, and knowledge of existing research.

> **"Self pain assessment tool to aid decision making for medical vs. surgical abortion"**
>
> **(Clinician)**

Nonetheless, the PCORI methodology for Generation and Prioritization of Topics[8] may be helpful for researchers to use when considering whether or not to study a potential research topic. The criteria can help researchers to consider whether a potential research topic is patient-centered and the likelihood of putting findings into practice. We also encourage researchers to adapt the structure of the PCORI research topic brief template as a useful tool for considering a topic's fit for PCOR and CER. Patients and stakeholders can be engaged as part of the research team at this early stage to provide their perspectives as researchers consider these questions.

Patient and consumer voices

Two main principles guided our patient engagement plan – to use an open-ended approach to find out what matters to patients and to reach a broad sample of patients or potential patients, beyond just Planned Parenthood patients. We designed a brief survey to invite patients and consumers to tell us which reproductive health research topics matter most to them and what they would like researchers to study. The survey was based on the methods used by the James Lind Alliance Priority Setting Partnership.

We first provided the following broad definition: Sexual and reproductive health care deals with sexual pleasure and function, birth control, menstrual and period issues, sexually transmitted diseases (STDs), vaginal infections (like yeast infections), pregnancy, abortion, cancer screenings, or anything else. We then asked people to answer: **"What matters most to YOU about your sexual and reproductive health?"** Then, after giving some examples of research questions, we asked people to provide one or two questions for researchers to study, using the prompt: **"What do YOU want researchers to study?"** Finally, we asked respondents about their gender, age, and whether or not they had seen a health care provider in the last year.

Women and men ages 18–44 were recruited using Facebook and Instagram ads and the Planned Parenthood website. Additionally, we included the first question (What matters most to you?) on an existing in-clinic patient questionnaire. A total of 1,658 people completed the survey through Facebook ads (displayed for 10 days), Instagram ads (displayed for 3 days), the Planned Parenthood website (displayed for 16 days), and an in-clinic questionnaire (fielded over a three-month period).

Most respondents were recruited from the Facebook survey (58%), identified as female (91%), and had seen a health care provider in the last year (90%). Almost half of respondents were age 18–24 (46%) and one quarter were 25–29 (24%).

For the open-ended questions – "What matters most to you about your sexual and reproductive health" and "What do you think researchers should study?" – two researchers reviewed and coded each question for common themes and topics.

Table 2. Patient and Consumer Survey Respondents (N=1,658)

Respondent characteristic	Percent (N)*
Recruitment source	
Facebook	58% (963)
Instagram	1% (17)
Planned Parenthood website	17% (276)
In-clinic survey	24% (402)
Gender	
Female	91% (1,511)
Male	8% (124)
Transgender	1% (11)
Other	1% (10)
Age	
18–24	46% (762)
25–29	24% (403)
30–34	16% (264)
35–39	8% (134)
40–44	6% (95)
Seen health care provider in last year?	
Yes	90% (1,496)
No	9% (148)
Unsure	1% (10)

*Percentages may add to more than 100% due to rounding.

The top 10 most common codes for the question, ***"What matters most to you about your sexual and reproductive health"*** are listed below in Table 3 in order of frequency, with the most common listed first, along with examples of responses.

Table 3. What matters most to you about your sexual and reproductive health?

Top 10 most common codes	Example responses
birth control/contraception	*"I need to make sure that my birth control is what works for me and is effective."* (female, 20)
staying healthy	*"Staying safe and healthy."* (female, 18)
sexually transmitted infections	*"Prevention of STD and be sure that if contracted [the] right test and treatment are done."* (male, 25)
safety	*"I would like a safe, reliable birth control with minimal side effects."* (female, 23)
autonomy/choice	*"Freedom to make MY own decisions and access to affordable options."* (female, 31)
affordability	*"Getting affordable health care."* (female, 42)
pregnancy prevention	*"My ability to take care of my family and having security knowing that I can prevent pregnancy when I want and also allow it when I want!"* (female, 25)
access to birth control	*"Birth control that is available at an affordable price, and access to abortion in case my birth control method fails."* (female, 20)
access to health care	*"Getting trans affirming health care."* (transgender, 21)
abortion	*"Access to safe and legal abortion."* (female, 23)

The top 10 most common codes for the question ***"What do you think researchers should study?"*** are listed in Table 4 in order of frequency, with the most common listed first.

Table 4. What do YOU think researchers should study?

Top 10 most common codes	**Example responses**
birth control/contraception	*"How do different methods of birth control affect future fertility?"* (female, 20)
male birth control	*"Non-invasive birth control for men."* (male, 28)
cancer	*"Most effective, accessible, and affordable ways to prevent reproductive cancers."* (female, 35)
sexually transmitted infections	*"How to find alternative methods and medications to minimize and treat [herpes] outbreaks and shedding?" (female, 34)*
sexual health	*"Sexual health after age 40."* (female, 44)
long-acting reversible contraception	*"Longer lasting birth control implants"* (female, 19)
pregnancy	"What are the short and long term effects of gestational diabetes to a woman's health after pregnancy?" (female, 42)
mental health	"The impact of birth control on mental health. Which types are best for people who suffer from depression/anxiety?" (female, 21)
fertility	"Does testosterone use decrease future fertility for trans men?" (transgender, 27)
abortion	"Safety and new methods of medication induced abortions." (female, 37)

Combining all of the topics gathered from reproductive health researchers, relevant topics from the PCORI Topic Database, Planned Parenthood clinicians and researchers, and patients, we created a list of 2,460 potential research questions to be shared broadly with reproductive health researchers and other stakeholders to inform future research, clinical practice, and dissemination efforts.

V. What are some emerging practices in PCOR and reproductive health?

PCORI has compiled numerous resources on patient engagement, including tools from the PCORI Methodology Standards, the PCORI Engagement Rubric, and sample engagement plans from funded research and methods portfolios. Below are PCORI's engagement principles, developed from the contributions of the PCORI Pilot Project Learning Network and AcademyHealth, and examples of patient engagement from four current PCORI research projects in reproductive health.

Lessons from selected PCORI award recipients in reproductive health

The PCOR & Reproductive Health Summit benefitted from the input and participation of four PCORI-funded researchers that were early adopters of PCOR in this area of study. Their PCOR projects are summarized in Table 5 below.

At the Summit, these researchers shared some of their experiences with stakeholder engagement and lessons learned from their PCORI-funded research studies.

Avenues for patient and stakeholder engagement. Stakeholders were engaged primarily through advisory groups or as members of the research team itself. They provided input through in-person meetings, teleconferences, and email consultations, and gave feedback throughout the research process, from designing the study to recruiting and retaining study participants.

Benefits to patient engagement. All researchers provided examples of the ways in which their projects benefited from patient engagement, including developing recruitment strategies (e.g., recruitment letters mailed to potential participants designed to look like invitations, not business letters); simplifying the project name and survey instrument language; and adapting the intervention and study design.

PCORI Pilot Project Learning Network (PPPLN): Engagement Principles

The PCORI Pilot Project Learning Network (PPPLN) is a group of 50 unique research study teams that work together in order to facilitate shared learning; foster new collaborations; advance strategies for effective stakeholder engagement; support researchers in conducting, promoting, or using PCOR; and accelerate the dissemination and implementation of project insights and findings. The patient engagement methods used by the pilot projects contributed to PCORI's development of engagement principles:[9]

Reciprocal Relationships: The roles and decision-making ability of all research partners are determined collaboratively and clearly stated.

Co-learning: Stakeholder partners and researchers learn from each other. Patient and stakeholder partners learn about the research process as researchers learn about patient-centeredness and meaningful stakeholder engagement.

Partnerships: The time and contributions of stakeholder partners are valued and compensated. The research team is committed to diversity and demonstrates cultural competency.

Transparency, honesty, trust: Major decisions are made inclusively and information is shared readily with all research partners. Patients, other stakeholders, and researchers are committed to open and honest communication with one another.

Challenges identified. Common challenges of patient and stakeholder engagement included finding enough time, especially as much of the engagement is needed during the pre-study period; deciding who to engage; keeping people engaged between advisory group meetings; supporting patient partners; managing changing research timelines; and institutional flexibility in research policies and processes such as institutional review boards (IRBs).

Ensuring meaningful engagement. To ensure that patients felt comfortable providing input and voicing their opinions, researchers allowed patient groups to meet independently from other stakeholders, such as providers; hosted meetings at locations that were familiar to the patients; facilitated building rapport and comfort within the patient group; and allowed patients to run their own advisory group meetings.

Opportunities and challenges for PCOR in reproductive health

Building on lessons learned from the above ongoing research projects, Summit attendees brainstormed some additional considerations for conducting patient-centered outcomes research on reproductive health topics. Many challenges of conducting reproductive health PCOR may actually be opportunities. Additionally, much of what we think is unique to reproductive health may not be after all, and we can learn from researchers with experience in PCOR in other areas such as chronic disease and rare conditions.

Patient Population. Throughout the project we grappled with the challenge of defining who is a "patient" of reproductive health care because the needs are so broad. This was also identified as an opportunity as there is a large potential patient population to draw upon for research. Research on stigmatized services or among people who are experiencing stigma may be challenging, but people often want to share their reproductive health experiences.

Patient-centered outcomes. Reproductive health care is often influenced by larger cultural and societal patterns. Determining patient-centered outcomes and how to measure them may be challenging. Nonetheless, developing patient-centered outcomes research questions will allow us to research what matters to patients

Table 5. PCORI-funded research projects in reproductive health

Researcher	Research Study
Cynthia Chuang, MD Pennsylvania State University Hershey Medical Center	*The MyNewOptions Study* is a web-based randomized controlled trial to assess the impact of reproductive life planning on contraceptive use and continuation.
Christine Dehlendorf, MD, MS University of California, San Francisco	*Patient-centered support for contraceptive decision making* is a randomized controlled trial testing a new tablet-based tool designed to help women with their choice of a birth control method.
Tessa Madden, MD, MPH Washington University School of Medicine	*Implementation of Patient-Centered ConTraceptive Provision in Community Settings* (The IMPACCT Study) is designed to compare two different ways of providing contraception in community healthcare clinics.
Rachel Thompson, PhD Dartmouth College	*Right For Me: Birth control decisions made easier* is designed to compare a video-based intervention to paper-based contraceptive counseling tools.

to make the results relevant for making clinical decisions. Incorporating both patient and clinician experience may be beneficial towards generating relevant evidence to improve care delivery and health outcomes.

External factors. In addition to the external factors that generally challenge PCOR (e.g., IRB challenges to engaging patients) or facilitate PCOR (e.g., new data and technology solutions create more options for engagement), there may be additional considerations for reproductive health, such as navigating socially and politically charged issues. However, emphasizing the patient-centeredness of research may be an avenue to counter resistance toward further exploration and study of reproductive health issues.

VI. What's next?

Patient engagement. Engaging stakeholders in topic identification for PCOR and reproductive health using social media and our website has shown us that patients and consumers are willing to engage in reproductive health research, and that short surveys may be an efficient way to reach a broad audience. Furthermore, the experiences of the researchers discussed above demonstrate that more in-person, qualitative research may reveal different interests and priorities that are worth exploring, and provide opportunities for deeper understanding of interests and motivations.

As next steps, we plan to share lessons learned from this project and encourage researchers to explore innovative ways to engage patients. We will also consider new ways to engage patients, including exploring the creation of a panel of patients interested in engagement in research.

Disseminate project findings. We also commit to sharing the findings of our project, including the full list of suggested patient and stakeholder topic areas, emerging practices in PCOR and reproductive health, and resources for continued learning. We are distributing this report and an accompanying recorded webinar through professional listservs and through scientific journals and conferences. But we cannot do this alone! We will rely on all of our partners and collaborators in this effort to share these messages with your networks, friends, and families through email, Facebook, or even casual conversations.

Continued learning. Finally, much work still remains to fully explore the promise of PCOR in reproductive health. PCORI has developed detailed and rigorous methodological standards and these resources should continue to be explored and further applied to reproductive health. We will continue to work within our network of reproductive health researchers to learn from one another and build capacity to conduct reproductive health PCOR. Additionally, though we have a long list of research priorities from patients and other stakeholders, this is just the beginning, as there are no doubt many more areas to explore.

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