ENGAGEMENT AWARD FINAL SUMMARY REPORT

Strategically Leverage Engage and Empower PCOR in Sleep

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To learn more about this project, visit www.pcori.org/EA-Parthasarathy004

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Project Methods and Key Findings

Methods

The goal of this project was to engage patients, scientists, and other stakeholders across the entire span of sleep research, from developing ideas, conducting research, to spreading the information and making changes to healthcare delivery that are patient-centered—patient-centered outcomes research (PCOR). Along with the Sleep Research Network (SRN; ~450 sleep researchers from 70 institutions within the United States) and Project Sleep (a nonprofit patient-advocacy group), the project team engaged and empowered patients and relevant stakeholders. The team conducted four in-person conferences over a two-year period (October 2016, June 2017, September 2017, and June 2018) and through sustained monthly activities in the PCOR working group of the SRN over the past two years.

Key Findings

The key project findings were as follows: there was a high level of interest in PCOR in the sleep and circadian rhythms arena from various patient-stakeholder groups; there were significant knowledge gaps regarding patient-centeredness and patient-stakeholder engagement, which the team addressed; there were identifiable areas of agreement and disagreement between various patient-stakeholder groups regarding PCOR research priorities in sleep and circadian sciences; there were challenges with engaging payors; a remarkable growth in PCOR funding from 2016 to 2018 (~$68 million in additional funding) was measured; the team successfully adopted people-centered language as official policy of the flagship journal in sleep medicine (SLEEP), which is the journal of the Sleep Research Society. In sum, there is a lot of interest in PCOR in the area of sleep and circadian sciences and this project contributed to identifying and addressing knowledge gaps by engaging various patients and stakeholder groups.
**Project Impacts on Patients and Other Stakeholders**

The project team influenced sleep researchers to incorporate patient-centeredness in their ongoing and future research studies by making them realize the importance of PCOR through presentations and working groups with patient partners and other stakeholders. The team created a centralized “sleep-specific” patient-stakeholder engagement resource that can enable both junior and established sleep researchers to develop and conduct PCOR. The team conducted national and international surveys of close to 2,700 patients and stakeholders in the domains of narcolepsy, insomnia, and sleep apnea to yield nonbinding guidance documents aimed at promoting the dissemination and implementation of emerging findings and methodologies as they related to PCOR/CER in sleep medicine.

There was a remarkable growth in PCOR funding in the area of sleep and circadian sciences during the duration of the team’s engagement award. The project team believes that it helped to raise awareness of PCOR in the sleep and circadian rhythms community of researchers and assisted them with better understanding the principles of patient-centeredness and patient-stakeholder engagement. The team accomplished such objectives by programming speakers with expertise in conducting PCOR as well as mock grant review panels at two of the team’s in-person meetings (June 2017 in Boston, Massachusetts, and June 2018 in Baltimore.

The following is a summary of the numbers related to the team’s engagement effort:

- First engagement meeting in Bethesda, Maryland (October 7, 2016) = 77 in-person attendees that included patients and various stakeholders.

- Second SLEEP2 engagement meeting in Boston, Massachusetts (June 3, 2017) = 76 in-person attendees that included patients and various stakeholders.

- Third SLEEP2 engagement meeting in Bethesda, Maryland (September 26, 2018) = 76 in-person attendees that included patients and various stakeholders.

- Fourth SLEEP2 engagement meeting in Bethesda, Maryland (June 2, 2018) = 58 in-
person attendees that included patients and various stakeholders.

- National survey regarding sleep apnea = 1,088 (916 patients with sleep apnea and 56 providers who treat patients with sleep apnea).

- National survey regarding insomnia = 448 (patients, providers, and researchers).

- International survey regarding narcolepsy = 1,170 (patients with narcolepsy, providers, and researchers).

- Newsletters reached an audience of over 500 sleep researchers and providers on eight occasions, disseminating the agenda and call regarding the meetings and programmed topics as well as outcomes of the meetings.

- Establishment of the MPSER (Multiple Patient Stakeholder Engagement Resource). This consists of 147 individuals who have agreed to serve on a “sleep-specific” multiple-patient stakeholder engagement resource based upon the patient-stakeholder group that they self-identified. The MPSER was developed over the course of the past two years as part of the SLEEP2 engagement award and they will continue to serve as a resource beyond the duration of the PCORI engagement award. Members of the MPSER self-identified as one of the “8 Ps”: principal investigators (researchers) (n=102); patients (n=17); providers (n=61); product makers (industry) (n=12); policy makers (n=8); public advocacy groups (n=11); purchasers (n=2); and payors (n=4). The MPSER serves as a centralized patient-stakeholder engagement resource for sleep researchers to develop, conduct, and effectively manage patient-stakeholder engagement in their PCOR-CER work. The deliverables that emanated from this SLEEP2 engagement award include: (a) A functioning patient-stakeholder engagement panel with representation of all the 8 Ps; (b) manual of procedures (MOP) and directory for the MPSER; (c) information regarding barriers for dissemination and implementation of PCOR findings in sleep.

- Additionally, presentations were made at the national SLEEP2018 meeting at a programmed symposium on patient-centeredness with over 200 attendees.
• Finally, the project team adopted changes to the policy of the flagship journal in the field of sleep and circadian rhythms, SLEEP, which has an estimated broad readership of over 20,000.

The team believes it has engaged and, to various degrees, influenced 23,192 individuals with its messaging regarding patient-centeredness as it pertains to sleep health and sleep disorders.

Project Accomplishments and Challenges

Accomplishments

First SLEEP2 Engagement Meeting: October 7, 2016 in Bethesda, Maryland

The project team successfully held and conducted the first of four SLEEP2 conferences in Bethesda, Maryland. The conference had Joe V. Selby, MD, MPH, as the keynote speaker and two patient plenary speakers from patient partners (Julie Flygare, JD, and Rebecca Fuoco, MPH). There were 77 attendees representing many patients and stakeholder groups who met on October 7, 2016. A patient engagement panel, mock grant review of PCORI grants, and plenary talks were successfully conducted. The team was able to disseminate preliminary patient-centered outcomes (PCO) and research priorities for sleep apnea that were derived from over 167 patients and stakeholders. The shift in attendees’ perceptions of important patient-centered outcomes and research priorities was measured by administering both pre- and post-meeting surveys. There was an outstanding array of speakers at this event. A networking blitz consisting of two- to three-minute introductory talks by many members from the centralized multiple patient-stakeholder engagement group (MPSER) was successful in introducing individuals to each other. At that time, over 36 members signed on to serve as members of the MPSER, and this deliverable was submitted to PCORI on November 30, 2016 as was originally proposed. Besides such a successful meeting, the team had conversations regarding future meeting content based upon suggestions from attendees as well as a review of study design for new research proposals that targeted PCOR in sleep and
Second SLEEP2 Engagement Meeting: June 3, 2017 in Boston, Massachusetts

The project team successfully held its second of four SLEEP2 conferences in Boston, Massachusetts. The agenda from this meeting is attached. There were several renowned speakers present at this conference. An expert in the science of narcolepsy, Emmanuel Mignot, MD, PhD, as well as Girardin Jean-Louis, PhD, a health disparities and sleep expert, served as the keynote speakers. Two patient partners (Julie Flygare, JD, and Rebecca Fuoco, MPH) also delivered plenary talks, with Fuoco showing some of the preliminary data from the narcolepsy survey. In the afternoon, individuals with narcolepsy shared their experiences with the audience, which was a dynamic session. Later, Narong Simakajornboon, MD, presented on recent research in narcolepsy and the PI of this project, Sairam Parthasarathy, MD, shared the results of the recent sleep apnea survey with the audience. During the workgroup sessions, the group split up into three smaller groups to discuss PCOs in the context of each of the sleep disorders that this project seeks to study (sleep apnea, narcolepsy, and insomnia). Finally, the event concluded with a networking blitz consisting of two-minute introductory talks by many members from the centralized multiple patient-stakeholder engagement group (MPSER). In total, there were 76 individuals in attendance.

Third SLEEP2 Engagement Meeting: September 26, 2018 in Bethesda, Maryland

The team successfully held its third SLEEP2 conference in Bethesda, Maryland, with a focus on insomnia. The agenda from this meeting is attached. The patient members of the PCOR working group of the Sleep Research Network (SRN) played an important role in determining the agenda. Several renowned speakers in insomnia presented at this conference. Experts in the science of insomnia, Dan Buysse, MD, and a clinical
psychologist with expertise in the area of cognitive behavioral therapy for insomnia (CBT-i). Rachel Manber, PhD, were our keynote speakers. Two members of the PCOR working group/organizing committee (Michael Grandner, PhD, MTR, and Sarah Honaker PhD, CBSM) also delivered a talk regarding the development of the insomnia survey that identifies patient-centered outcomes. Cody Havens, MPH, presented some of the preliminary data from the narcolepsy survey. Katie Stone, PhD, is an epidemiologist with over 25 years of experience in planning and directing large-scale multicenter cohort studies in sleep and circadian sciences in older adults, and she spoke about barriers and opportunities to developing more relevant patient-centered outcomes in insomnia. Finally, the event concluded with a networking blitz consisting of two-minute introductory talks by many members from the centralized multiple patient-stakeholder engagement group (MPSER). In total, there were 76 individuals in attendance.

Fourth SLEEP2 Engagement Meeting: June 2, 2018 in Bethesda, Maryland

The event had an outstanding panel of speakers with keynote from Laura Forsythe, PhD, MPH, Director of Evaluation and Analysis from PCORI, and this was followed by a forward-looking agenda of speakers addressing future engagement needs in the sleep arena. Julie Flygare, JD (patient lead of the main patient partner organization, Project Sleep), made an eloquent presentation of the patient perspective of sleep research. The event also included Azizi Seixas, PhD (New York University), discussing sleep health, Lisa Meltzer, PhD (National Jewish Health), discussing late school start for children that was aimed at improving their health and health-related quality of life, and Daniel Combs, MD (University of Arizona), discussing patient and caregiver perspectives of patient-centered management of pediatric sleep apnea. Additionally, Eric Zhou, PhD (Harvard Medical School), discussed the management of insomnia in black women. The meeting also had a mock grant review panel of grants that had been successful in obtaining funding from PCORI and other funding agencies. This section was programmed to improve the understanding of sleep researchers with regard to designing and competing
for patient-centered outcomes research. A networking blitz of two-minute presentations of ongoing PCOR as well as a program update by the project leader concluded the meeting.

Each meeting had a pre- and post-meeting attendee survey that allowed the team to seek information regarding future areas of interest besides assessment of their knowledge of PCOR and patient-centeredness as well as feedback regarding the meetings. Newsletters of the Sleep Research Network to the broad readership of over 500 members circulated the upcoming program as well as the summary of activities of each of the SLEEP2 engagement conferences.

Results from the sleep apnea survey were accepted for presentation at the June SLEEP2018 annual meeting and were presented by Cody Havens, MPH, at a major symposium. This was well received by the audience and awaits final publication in the journal SLEEP.

The project team has favorably impacted the journal policy of the major flagship journal in the sleep field (SLEEP) with a wide readership by advocating for adopting people-centered language as the journal policy. Such a change emanated from a passionate talk about people-centered language in medical journals espoused by Rebecca Fuoco of Project Sleep, which led the Deputy Editor of SLEEP in attendance at the PCORI engagement meeting to initiate a new change in journal policy. This request was later deliberated by the board of directors of the Sleep Research Society who own the journal SLEEP and the editorial board of the journal and enacted into policy. The original manuscript by the patient representative Rebecca Fuoco (of Project Sleep) entitled, “People-Centered Language Recommendations for Sleep Research Communication” and an accompanying editorial entitled, “Introducing People-Centered Language to SLEEP” by the project lead, Deputy Editor of SLEEP and patient lead of the main patient-partner for this engagement award (Julie Flygare, JD), was published in the flagship journal SLEEP in 2017. All articles published in this journal will be reviewed by the proof editor.
to ensure that people-centered language is incorporated in each and every article. The instructions to potential authors address this aspect for authors to be in compliance with the journal requirements for such language.

The results from the three patient surveys encompassing ~2,500 patients helped both identify and rank priority areas of patient-centered outcomes in sleep apnea, insomnia, and narcolepsy. Additionally, the team was able to identify shifts in ranking of patient-centeredness following the engagement efforts. Moreover, the team was able to identify new topical areas for PCOR in sleep and circadian sciences.

**Challenges**

Early challenges were related to having adequate representation from payors at the meetings and engagement efforts. Over the life of the project, the team has been able to make significant progress in overcoming this barrier by engaging and inviting payors to attend this meeting, asking readers of the team’s articles and presentations from payor groups (such as Anthem Blue Cross Blue Shield) to partner with the team on real-world implementation of patient-centered care delivery as well as future research initiatives.

**Project Stakeholders/Collaborators**

The patients and stakeholders have helped create the agenda for all of the four SLEEP2 conferences. They are part of the PCOR working group of Sleep Research Network (SRN) and, as part and parcel of such membership, enacted changes in how the network works as well as met monthly by phone to assist with upcoming meeting planning, speaker selection, design of surveys, review and analysis of such surveys, as well as creating action plans for addressing survey results. In particular, Flygare and Fuoco were instrumental in creating the narcolepsy survey from scratch and Adam Amdur of the American Sleep Apnea Association (ASAA) was instrumental in creating the survey for patients with sleep apnea. As such, the project involved a high-quality engagement based upon the scope, form, and frequency of patient and
stakeholder involvement throughout the two years of the engagement award. The team recognized before proposing this engagement award that there are four levels of progressively increasing engagement: information, consultation, collaboration, and stakeholder direction. Based upon the information provided above, the team adopted “stakeholder direction,” signifying that patients and patient advocates controlled parts of the project and had decision-making authority as voting members of the PCOR working group of the Sleep Research Network, which operated as the programming committee of the engagement conferences. Moreover, the team cross-coordinated with another PCORI Engagement Award for this initiative (namely, ASAA).

The project team’s engagement of patients and stakeholders has led to other initiatives in PCOR and patient-centered care initiatives. For example, the insomnia survey input that the team received from patients led to a competitive proposal to PCORI’s pragmatic trials application. Essentially, the survey informed the team as to the PCO knowledge gaps, comparators that patients prefer, and identified PCOs that the patients considered to be most important.

Another initiative has been the identification of important PCOs and the team’s efforts to engage a major payor (Anthem, Inc.), which emanated from the difficulties that were faced early in the engagement award. This has led to the team initiating a patient-centered approach to management of patients with sleep apnea. Anthem is interested in partnering with the team to implement patient-centered approaches to managing sleep apnea.

By engaging these diverse stakeholders, the project team has been successful in gaining a perspective on PCOs in sleep apnea, narcolepsy, and insomnia. This has helped to identify future research priorities that are patient-centered. This has given attendees lots of ideas for future research and helped them understand barriers for conducting patient-centered research as well. Two prior attendees of the SLEEP2 conference have successfully obtained PCORI funding. Tiffany Braley, MD, MS, of the University of Michigan attended the first PCORI-funded EAIN Engagement Conference (first SLEEP2 meeting in October 2016) and attended the PCORI mock grant panel. She has since secured a $3.5 million award from PCORI targeting fatigue in
patients with multiple sclerosis through a multiple-PI application along with Anna Kratz, PhD. The study is entitled, “A Randomized Controlled Trial of Telephone-Delivered Cognitive Behavioral Therapy, Modafinil, and Combination Therapy of Both Interventions for Fatigue in Multiple Sclerosis.” Moreover, Eric Zhou, PhD, an attendee of the very first SLEEP2 meeting in October 2016, has recently been awarded a $2.1 million PCORI contract that aims to reduce health disparities in black women with insomnia (along with Lynn Rosenberg, ScD, MS). Multiple other PCORI applications have been submitted by attendees of the SLEEP2 conferences. The most recent insomnia-themed SLEEP2 meeting (September 2017) has led a working group of researchers, providers, and patients to submit a large pragmatic trial application for a comparative effectiveness research study for the 2018 Cycle.

As of July 31, 2018, there are 44 PCORI-funded studies that included sleep and circadian sciences (totaling $186,326,707). This is an increase compared to the team’s last reporting of this measure in January 2017. There has been significant growth in PCORI-funded research in sleep and circadian sciences over the past two years. Moreover, as of July 2018, non-PCORI agencies supporting patient-centered outcomes research included:

- National Institutes of Health (N=256 / $70,749,275)
- Department of Defense (N=1 / $606,496)
- Department of US Veteran Affairs (N=19 / $3,913,231)
- Agency for Healthcare Research and Quality (N=14 / $3,142,362)

**Plans to Disseminate Findings from the Project**

The project team has already published four articles and abstracts. Additionally, manuscripts derived from the team’s surveys are being prepared for publication in major sleep journals. As noted above, one of the results that has already been implemented into practice is the change in journal policy for the flagship journal SLEEP, which has changed the way all articles are written to incorporate “people-centered” language.
**Additional Findings or Comments**

The PCORI SLEEP2 engagement award has helped the team bring patient-centered healthcare delivery and PCOR to the forefront in the sleep field. The team is immensely grateful for this opportunity.