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Stakeholder Engagement in Pragmatic Clinical Trials: Emphasizing Relationships to Improve Pain Management Delivery and Outcomes

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Abstract

Background. The NIH-DOD-VA Pain Management Collaboratory (PMC) supports 11 pragmatic clinical trials (PCTs) on nonpharmacological approaches to management of pain and co-occurring conditions in U.S. military and veteran health organizations. The Stakeholder Engagement Work Group is supported by a separately funded Coordinating Center and was formed with the goal of developing respectful and productive partnerships that will maximize the ability to generate trustworthy, internally valid findings directly relevant to veterans and military service members with pain, front-line primary care clinicians and health care teams, and health system leaders. The Stakeholder Engagement Work Group provides a forum to promote success of the PCTs in which principal investigators and/or their designees discuss various stakeholder engagement strategies, address challenges, and share experiences. Herein, we communicate features of meaningful stakeholder engagement in the design and implementation of pain management pragmatic trials, across the PMC. Design. Our collective experiences suggest that an optimal stakeholder-engaged research project involves understanding the following: i) Who are research stakeholders in PMC trials? ii) How do investigators ensure that stakeholders represent the interests of a study's target treatment population, including individuals from underrepresented groups?, and iii) How can sustained stakeholder relationships help overcome implementation challenges over the course of a PCT? Summary. Our experiences outline the role of stakeholders in pain research and may inform future pragmatic trial researchers regarding methods to engage stakeholders effectively.

Key Words: pain management, pragmatic clinical trials, military health services, veterans health services, stakeholder participation, complementary therapies

Background and Rationale

The National Institutes of Health (NIH)-Department of Defense (DOD)-Department of Veterans Affairs (VA) Pain Management Collaboratory (PMC) is an innovative intergovernment agency partnership that supports development, implementation, and testing of 11 large-scale, pragmatic clinical trials (PCTs) evaluating nonpharmacological approaches to management of pain and common co-occurring conditions in military and veteran health systems [1]. An NIH-funded PMC Coordinating Center leads and manages an Operations Core and seven Work Groups (including the Stakeholder Engagement Work Group). There is also a Military Treatment Facility Engagement Committee comprised of PIs from DODfocused PCTs along with pain management leaders from military treatment facilities where the trials are to be enacted. PMC includes a Patient Resource Group organized and chaired by a veteran and comprised of a diverse group of servicemembers and veterans. Finally, an External Board comprised of senior leaders from VA and DOD and other healthcare and research organizations complement the expertise and experience of the Work Groups. This collaborative structure provides a forum for problem-solving and identification of best practices and guidance for addressing significant challenges related to design and implementation of pragmatic trials [1].

A stakeholder is "an individual or group who is responsible for or affected by health- and health-related decisions" [2, 3]. Research stakeholders, then, are individuals or groups who may be affected by a scientific study.

Although patients and healthcare providers are the stakeholder groups most often asked to participate in clinical research, in the context of a PCT there may be several others. These include family members; clinic staff; information technology personnel; healthcare administrators; institutional review boards and other oversight groups; insurers; funding agencies; healthcare policymakers; and other constituents. Understanding how various stakeholder groups view a research study is essential for many reasons: influencing the likelihood of funding, ensuring that study designs maximize generalizability, contributing to proper and timely completion of research, as well as easing subsequent adoption of trial findings into clinical practice. An important first step to engaging stakeholders within pragmatic research is to develop a vision for their specific roles and to define a process guiding how their input will be incorporated into a trial's design. For example, the Patient-Centered Outcomes Research Institute (PCORI) has developed an Engagement Rubric to guide stakeholder engagement throughout the research process, from the time a research study is conceived through dissemination of study findings or beyond [4].

Herein, we describe illustrative examples from ongoing PMC trials and highlight promising practices by answering the following key questions specific to pain management PCTs:

- Who are research stakeholders in the PMC trials?
- How do investigators ensure that stakeholders represent the interests of a study's target treatment population, including individuals from underrepresented groups?

 How can sustained stakeholder relationships help overcome implementation challenges over the course of a PCT?

Methods

The Stakeholder Engagement Work Group was formed with the goal of developing respectful and productive partnerships that will maximize the ability to generate trustworthy, internally valid findings directly relevant to veterans and military service members with pain, frontline primary care clinicians and health care teams, and health system leaders. The Stakeholder Engagement Work Group provides a forum within which the PCT Principal Investigators (PIs) and/or their designees can discuss various stakeholder engagement strategies, address challenges, and share experiences in engaging stakeholders to promote success of the projects. During monthly teleconferences, Work Group members share different perspectives and expertise to develop and enact a comprehensive, evidence-based, and stakeholderinformed approach to conducting PCTs. Although all PCT studies incorporated stakeholder perspectives, the scope of stakeholder input and engagement varied widely across studies. During the first 2 years of the PMC, Stakeholder Engagement Work Group leadership held weekly or biweekly conference calls with PCT PIs or their designees to identify systematic and site-specific obstacles, as well as determine how to address them. This manuscript summarizes the findings and results of these discussions.

Results

The necessity of good stakeholder engagement takes on special urgency given the heavy burden of pain among military and veteran populations, the complexity of pain in accordance with the biopsychosocial model, and the multimodal nature of various nonpharmacological interventions and models of care that integrate nonpharmacological approaches. Across the PMC, PCTs are engaging stakeholders in a range of ways. Some investigators conduct formal qualitative research and site visits about proposed interventions and treatment options, while others gather more informal reviews of study protocols, recruitment materials, and outreach to target populations. These efforts clearly require an adept balancing act between recognizing complexities of target interventions and research protocols with understanding the strengths and needs of study populations and key institutional members.

Who Are Research Stakeholders in the PMC Trials?

Among the 11 PMC trials, many stakeholder groups (Table 1) provide input to PMC research, including patients with pain (veterans and military service members and their dependents), clinicians (e.g., primary care

providers, physical therapists, and behavioral health providers), and VA and DOD facility and operational leadership (e.g., facility and clinical service directors or commanders, director of the VA Pain Program Office). Stakeholders also include research funders (e.g., DOD, VA, NIH); payers (e.g., Tricare, Centers for Medicare and Medicaid Services); physician organizations (e.g., the American Academy of Pain Medicine); patient organizations (the National Pain Organization, the Reflex Sympathetic Dystrophy Syndrome Association), service organizations (e.g., Veterans of Foreign Wars); and myriad other groups (e.g., automobile manufacturers sponsoring research on spine pain). Engaging policy makers is also critical for post-study implementation efforts that are shaped by policy decisions. Within the PMC PCTs, stakeholder groups play important roles in study design and conduct, recruitment of diverse research participants, and overcoming implementation challenges. An External Board that includes policy makers and leaders from inside and outside the VA and DOD offers additional input to enhance the impact of the PMC and may assist in dissemination and implementation of actionable findings and products.

Stakeholder roles in PCTs may include reviewing grant applications or study protocols, commenting on recruitment materials and procedures, pre-testing surveys and data-collection methods, providing input on the feasibility and acceptability of interventions, and identifying meaningful study outcomes [5-7]. PMC PCTs use a range of approaches to involve stakeholders in study design and conduct (Table 2). For example, the Cooperative Pain Education and Self-management: Expanding Treatment for Real-world Access PCT (PI A. Heapy) tapped into expertise and experience from an existing research network that focuses on increasing representation of women veterans in research, the VA Women's Health Practice-Based Research Network (WHPBRN), which provided site metrics and an introduction to site staff, as well as facilitated site selection for the trial. Another PCT team that is testing the effectiveness of six complementary and integrative health (CIH) therapy interventions in VA facilities (PIs S. Taylor and S. Zeliadt) consulted with clinical and research experts in CIH on how to define exposure to each of the six therapies (e.g., therapeutic dosing of yoga sessions or mindfulness instruction). In this PCT, veterans also provided extensive feedback on survey content and length. A third example is the Sequential Multiple Assignment Randomized Trial PCT (PIs J. Fritz and D. Rhon) that is assessing the value of adding mindfulness to nonresponders of initial physical therapy and a holistic health approach to self-management of pain (i.e., DOD's Move2Health initiative). Stakeholder input was vital in this trial due to integration and coordination across a variety of services (primary care, physical therapy, behavioral health, Army Wellness Centers and supporting activities) as well as due to variation across S16 Bastian et al.

 Table 1. PMC PCTs and Their Stakeholders.

PI (Funder)	Study Title	Pain Type	Study Description/ Intervention	Stakeholders
S. Hastings, S. George (NIH)	Improving Veteran Access to Integrated Management of Chronic Back Pain	LBP	Multimodal integrated care pathway (pain modulatory treatment, tailored behavioral treatment, and home-based activity) vs. coordinated-care pathway (coordinated use of existing VA and non-VA pain management resources with guidance of a pain	Patients: veterans research engagement group (veter- ans, caregivers, civilian care partners) Providers/staff: Physicians, nurses, PTs, social work- ers, psychologists
K. Seal, W. Becker (NIH)	Education to Promote Non- Pharmacological Strategies to Improve Pain, Functioning and Quality of Life in Veterans	Moderate to severe chronic pain	navigator) Two care delivery approaches: Intensive Whole Health team vs. less intensive primary care group edu- cation (i.e., modified form of CBT for chronic pain vs usual care)	Stakeholders vary across sites but include VA leadership, veteran participants, primary care providers, CIH providers (e.g., physical therapists, yoga instructors, psychologists, chiropractors'
C. Goertz, C. Long (NIH)	Chiropractic Care for Veterans: A Pragmatic Randomized Trial Addressing Dose Effects for cLBP	Chronic LBP	Phase 1: Low (1–5) vs High (8–12) visit-dose chiropractic care Phase 2: Chiropractic care pain management vs. usual care	Patients: VA patients Providers/staff: Chiropractors, VA CMs, PCPs
J. Fritz, D. Rhon (NIH)	SMART Stepped Care Management for Low Back Pain in Military Health Systems	Chronic LBP	Phase 1: PT vs. Move to Health Phase 2: Mindfulness vs. combined PT and Move to Health	TRICARE beneficiaries (service members, dependents, veterans), PCPs, PT, behavioral health providers, clinic and department chiefs, and policy makers
A. Heapy (NIH)	COoperative Pain Education and Self-management: Expanding Treatment for Realworld Access	Chronic MSD pain	Asynchronous IVR-based CBT for chronic pain (COPES) vs. synchronous CBT for chronic pain (in-person, VVC, telephone)	Veterans research engage- ment group, PCPs and behavioral health providers, CBT for chronic pain therapists (psychologists, social workers), VA Women's Health Practice-based re- search network site leads
M. Rosen, S. Martino (NIH)	Engaging Veterans Seeking Service-Connection Payments in Pain Treatment	Chronic MSD pain	Test effectiveness and cost- effectiveness of Screening, Brief Intervention and Referral to Treatment for Pain Management (engaging veterans in nonpharma- cological pain treat- ments) vs. usual care	Veterans research engage- ment group, WH-PBRN, PCPs, behav- ioral health providers, VISN1 Mental Health Clinical Trials Network, VISN1 Pain Council
S. Taylor, S. Zeliadt (VA) D. McGeary,	Assessing Pain, Patient Reported Outcomes and Complementary and Integrative Health	Chronic MSD pain Chronic MSD	Test the effectiveness of self-care CIH (yoga, tai-chi, meditation/mindful-ness), practitioner-delivered CIH (acupuncture, massage therapy, chiropractic care) vs. dual care (self-care + practitioner-delivered CIH), and examining CIH "nudges"	Veterans using CIH, VA CIH providers, nation- ally recognized CIH clin- ical and research experts, and the operational part- ner (OPCC&CT)

Table 1, continued

PI (Funder)	Study Title	Pain Type	Study Description/ Intervention	Stakeholders
J. Goodie (DOD)	Targeting Chronic Pain in Primary Care Settings Using Behavioral Health Consultants	pain and non-chronic MSD pain	Behavioral health consul- tant delivered care for chronic pain in primary care setting	Active duty military, veter- ans, beneficiaries, Harker Heights Clinic-Fort Hood Internal Behavioral Health Consultants, Defense Health Agency clinical staff, CMs
D. Burgess (DOD)	Testing Two Scalable, Veteran-Centric Mindfulness-Based Interventions for Chronic Musculoskeletal Pain: A Pragmatic, Multisite Trial	moderate to severe chronic pain	Mobile mindfulness-based intervention + group (pre-recorded modules, viewed in an online group setting and interspersed with discussions led by a facilitator) vs. mobile mindfulness-based intervention (pre-recorded modules, without the group component) vs. usual Care	Veterans with chronic pain, Veteran advocates for pain, women's health, and mindfulness; VA CIH providers (Whole Health), VA leaders in CIH (Whole Health), VA leaders in pain manage- ment, VA leaders in women's health, national pain advocates
B. Ilfeld (DOD)	Ultrasound Guided Percutaneous Peripheral Nerve Stimulation: A Non-Pharmacological Alternative for the Treatment of Postoperative Pain	Surgical patients with acute pain	Percutaneous peripheral nerve stimulation (a novel, non-pharmaco- logic analgesic technique) vs. sham/placebo	Patients undergoing certain types of ambulatory sur- gery, anesthesiologists, surgeons, recovery room nurses, hospital adminis- trators, CMs
S. Farrokhi, C. Dearth, E. Russell Esposito (DOD)	Resolving the Burden of Low Back Pain in Military Service Members and Veterans: A Multi-Site Pragmatic Clinical Trial	Acute and chronic LBP	Clinical practice guidelines adherence (education/au- dit/feedback model - in- tervention arm) vs. usual care (comparison arm)	Patients with LBP referred for PT, PTs, Program- specific staff,

Abbreviations: chronic low back pain, cLBP; clinic manager, CM; CBT, cognitive behavioral therapy; complementary and integrated health, CIH; Department of Defense, DOD; interactive voice response, IVR; low back pain, LBP; musculoskeletal disorder, MSD; primary care provider, PCP; PT, physical therapist; VA, Veterans Affairs; DOD healthcare, TRICARE; VA Office of Patient-Centered Care and Cultural Transformation, OPCC&CT; VA video connect, VVC; VA Women's Health Research Network, WH-PBRN; VA New England Healthcare System, VISN1.

geographically diverse facilities. Stakeholder input informed not only site selection, but also study design, coordination of optimal care across care-delivery methods used within the military health system, flow of treatment interventions, and feasibility of outcome measures.

How Do Investigators Ensure That Stakeholders Represent the Interests of a Study's Target Treatment Population, Including Individuals from Underrepresented Groups?

In qualitative studies conducted with patients and other stakeholders, investigators have found that identifying and engaging stakeholders with certain characteristics (i.e., confidence, motivation, intelligence, focus on helping others) may be more important for facilitating research than the training they receive to enact a stakeholder role [8, 9]. Within military and veteran healthcare settings, a large majority of patients and other stakeholders may be men, but experiences and insights

may vary considerably based upon branch and era of military service, rank, and nature of service (wartime or peacetime; deployed or not). Further, the principles of effective and equitable stakeholder engagement recognize the importance of offering an inclusive space to ensure that underrepresented voices are heard and that feedback into decision-making about the study is considered. Women, people of color, and members of the LGBTQ communities have variable representation within military and veteran populations; yet, they have specific preferences, needs, and concerns related to pain management and healthcare [10–12]. People with addiction, military sexual trauma, post-traumatic stress, and mental health problems have unique healthcare needs, and their input may provide important insights into the design of pain management studies [13–15].

PMC PCTs have used a range of strategies to ensure recruitment of diverse research participants that reflect the experience of chronic pain as well as expected target populations for the interventions being studied. The S18 Bastian et al.

Table 2. Stakeholder Engagement and Impact on Trial Design and Throughout the Course of Pragmatic Clinical Trials.

Principal Investigator	Stakeholder Group Engaged	Structural Elements
A. Heapy	• WH-PBRN	 Early protocol shared with each WH-PBRN site Stakeholders provided input as to how intervention would work, or not work, at their facilities Feedback used to select research sites based on logistical concerns such as number of potential women veteran participants and availability of staff to assist with recruitment
S. Taylor and S. Zeliadt	 Veteran stakeholders CIH providers PCPs	 Providers joined conference calls to provide input on key elements of study intervention Veterans and other stakeholders contributed to study design, CIH intervention components, and outcome measures CIH providers facilitated communication with facility leadership and other providers to minimize interference of trial protocol on clinical care
J. Fritz and D. Rohn	TRICARE beneficiariesPCPsPTs	Stakeholder feedback incorporated into recruitment plan and data-collection process
S. Hastings, S. George	• PTs	 Stakeholders reviewed and developed discipline-specific training materials, intervention pathways, and remote delivery of service plans Identified concern that full day training session not feasible for many staff
C. Goertz, C. Long	 Veteran stakeholders DCs Clinic directors Site PIs SCs 	 Feedback on study protocol, data collection, and training procedures from DCs and SCs Feedback on treatment scheduling protocols based on interviews with veteran stakeholders and clinician input Site PI, clinic directors, and DC input on staffing levels of DCs
M. Rosen, S. Martino	• PCPs	 Busy clinics allow little time for participation in face-to-face interviews Emailed 10-minute surveys for stakeholders to complete on the quality of communication and interactions among different workgroups in providing pain care services for veterans with musculoskeletal conditions.
A. Ilfeld	 Anesthesiologists, surgeons, recovery room nursing staff 	 Anesthesiologists reviewed the protocol and helped develop a clinical pathway to optimize intervention timing and efficiency Surgeons reviewed the protocol and helped develop outcome measures most appropriate for ambulatory surgical procedures Nursing staff identified possible surgical delays and helped develop protocols to avoid
S. Farrokhi, C. Dearth, E. Russell Esposito	PTs, PT clinic leadership	delays Challenge identified that multiple research studies were recruiting patients with chronic pain at same DOD sites Identified concern that full-day training session during weekdays could reduce patient access and interfere with clinical workflow Stakeholders actively participated in developing discipline-specific training materials
D. Burgess	Women Veterans and VA Leaders in women's health	 and training session structure to minimize interference of trial protocol on clinical care Facilitator-training module developed to address specific needs and experiences of women veterans Meditations recorded in both male and female voices Recruitment and course materials designed to avoid being potentially disturbing to women

Abbreviations: complementary and integrated health, CIH; Department of Defense, DOD; primary care provider, PCP; PT, physical therapist; DOD health-care, TRICARE; VA Women's Health Research Network, WH-PBRN, Doctor of chiropractic, DC; principal investigator, PI; study coordinator, SC; Veterans Affairs, VA.

Learning to Apply Mindfulness to Pain PCT (PI D. Burgess) has adapted mindfulness-based interventions to address preferences and needs of women veterans and is the first study, to our knowledge, that will be statistically powered to examine the effects of these nonpharmacological treatments on women veterans with chronic pain. This PCT team has engaged women veteran leaders, who also have experience in pain and mindfulness, as well as VHA leaders in women's health. These efforts led to a facilitator-training module that addresses specific needs and experiences of female veterans. All meditations have been recorded in both male and female voices, and language in recruitment and course materials has been

carefully chosen to avoid being potentially disturbing to women. One PCT that is testing the usefulness of behavioral consultants trained in considering the biopsychosocial model of chronic pain (PIs D. McGeary and J. Goodie) convened focus groups at the Harker Heights Clinic at Fort Hood, Texas, consisting of patients, DOD program leads, and clinicians to determine usability, perceived effectiveness, helpfulness, and barriers related to the intervention being studied. Another PCT comparing an intensive Whole Health (VA) pain management approach to traditional primary care (PIs K. Seal and W. Becker) sought input from stakeholders with chronic pain and substance use disorder to understand and

mitigate fear that the study intervention could interfere with access to opioid prescriptions. The pre-implementation phase of this PCT included a stakeholder engagement strategy known as Evidence-Based Quality Improvement (EBQI) meetings [16]. These EBQI meetings, conducted at each study enrollment site, also helped cultivate stakeholder buy-in and facilitated commitment of local resources (e.g., intervention staff, space, administrative support).

How Can Sustained Stakeholder Relationships Help Overcome Implementation Challenges over the Course of a PCT?

There are several examples of successful approaches PMC PCTs have used to enlist stakeholders to address implementation challenges in pragmatic research (Table 2). One PMC PCT (PIs S. George and S. Hastings) is examining the effectiveness of two different guidelineconcordant, clinical care pathways for veterans with low back pain, for the purposes of improving pain interference and physical function. The study PIs used the "7Ps" framework of engagement [17], resulting in modified intervention-training practices, effective ways to enhance participation, and innovative ideas for reducing time burden on participating clinical staff. The latter is a common dilemma across pragmatic research, since providers are typically not paid for work beyond patient care. The Screening, Brief Intervention, and Referral to Treatment for Pain Management (PIs M. Rosen and S. Martino) addressed this issue via surveys to capture anonymous feedback from busy primary care providers in lieu of time-consuming and less flexible face-to-face interviews [18]. This research team also conducted full-day site visits, with flexible schedules, at each of its eight sites. Doing so was convenient for stakeholders and also allowed the research team to understand patient needs more contextually.

Other challenges include those posed by constraints of existing systems. For example, during the pilot phase of the Veterans Response to Dose in Chiropractic Therapy Clinical Trial (PIs C. Goertz and C. Long), the study team discovered numerous differences in how doctors of chiropractic (DCs) were integrated into the four VA facilities serving as clinical sites in their study, as well as varprotocols for chiropractic care. Through communication, feedback on study protocols and procedures, and clinician training, this group adapted processes to ease scheduling, manage clinician availability, and streamline data collection so as not to interfere with the workflow and documentation requirements of clinicians who would be involved in the study.

Discussion

Despite the value of engaging stakeholders, logistical challenges can make it difficult. An oft-cited, genuine

challenge to gaining and incorporating stakeholder input is the tight timeline required for grant submissions. The two-phase process (NIH UG3/UH3 mechanism) used to fund PMC PCTs has loosened this restriction by enabling PCT teams to include stakeholder engagement within its 18-month planning phase. Another common obstacle across PCTs is that healthcare staff and providers are not paid for time beyond that applied to patient care. To facilitate allocation of their time, departmental and hospital leaders need help from PCT study teams to underscore the value of engaging patients as stakeholders. Logistics can also be complex: people with chronic pain may have trouble traveling to in-person meetings due to mobility limitations (e.g., being in a wheelchair) or lack of time, means, or stamina for travel. Nonetheless, all stakeholders should feel comfortable participating in whatever mode of gathering has been chosen by a PCT team (e.g., conference call, in-person meeting, town hall), and alternatives should be offered for those with communication or other barriers. During COVID-19 virtual communication has become more accepted and may improve access to stakeholder input.

The inherent characteristics and goals of pragmatic research pose both opportunities and challenges for successful stakeholder engagement in real-world health systems, but to be meaningful, engagement must be flexible and dynamic. For example, in many clinical settings-but especially in military and veteran healthcare facilities—staff and provider turnover is high, necessitating engagement of new stakeholders over the course of a study as well as maintaining stakeholders' interest throughout the course of a study [19]. Persistence is particularly relevant in military settings in which a promotion in rank may entail different responsibilities and priorities (e.g., taking a leadership course and taking on more administrative or leadership responsibilities). Military treatment facility commanders are routinely reassigned every two years, requiring PIs to reach out to new leadership on a regular basis. The Military Treatment Facility Engagement Committee meets monthly to assist in fostering sustained communication with pain management and other leaders at the military treatment facilities at which the trials are being enacted. These examples and other lessons learned in engaging stakeholders in the PMC trials may be used to address the implementation challenges of translation into practice.

Racial and ethnic minorities are often underrepresented in research studies, may have limited access to healthcare, and may experience worse chronic illness and pain – all of which can affect study recruitment and implementation of results [20]. Despite explicit efforts to engage individuals from underrepresented groups in PCTs, care disparities may persist due to the nature of pragmatic research being representative of routine clinical care and the effects of bias and other sociocultural factors inherent therein. For pain management studies, stakeholders should represent a range of experiences with pain, addiction, and interventions being studied,

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and it is often helpful for these groups to prereview recruitment strategies. Sharing early findings with underrepresented groups may help to develop best approaches to move findings rapidly into practice. Trust, which undergirds successful interactions with and among stakeholders, is a vital component of clinical research and can be built through frequent interactions with stakeholders in military and veteran health systems. For example, many PMC PCTs have benefited from discussions with race and gender diverse volunteers of the VA Connecticut Veteran Engagement Group, veterans assembled by the VA to promote patient-centered research and translate VA research findings into practice. The PMC Patient Resource Group, composed of individuals from traditionally underrepresented subgroups, also provides additional input and assistance. The recommendation for PCT researchers is to seek out diverse representation in all phases of stakeholder engagement.

In summary, the PMC is advancing pain management by promoting the development of nimbler and possibly more generalizable study designs in various ways: emphasizing the role of stakeholders in pragmatic research; fostering communication between departments, institutions and federal agencies that may prevent administrative redundancies and enhance recruitment; and by allowing adequate time during research planning phases to obtain and incorporate feedback from stakeholders. Looking ahead, we anticipate being able to answer two questions: i) What is the evidence that stakeholder engagement improves recruitment in trials? and ii) Does engaging stakeholders improve dissemination and implementation of positive findings across target treatment populations? The collective experience of the PMC suggests that successful input from a wide array of stakeholders will reap many rewards for both the research community and for the many people that deserve effective, non-addictive treatment for chronic pain and its companion challenges.

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