

# Patient engagement in designing, conducting, and disseminating clinical pain research: IMMPACT recommended considerations

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## Abstract

In the traditional clinical research model, patients are typically involved only as participants. However, there has been a shift in recent years highlighting the value and contributions that patients bring as members of the research team, across the clinical research lifecycle. It is becoming increasingly evident that to develop research that is both meaningful to people who have the targeted condition and is feasible, there are important benefits of involving patients in the planning, conduct, and dissemination of research from its earliest stages. In fact, research funders and regulatory agencies are now explicitly encouraging, and sometimes requiring, that patients are engaged as partners in research. Although this approach has become commonplace in some fields of clinical research, it remains the exception in clinical pain research. As such, the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials convened a meeting with patient partners and international representatives from academia, patient advocacy groups, government regulatory agencies, research funding organizations, academic journals, and the biopharmaceutical industry to develop consensus recommendations for advancing patient engagement in all stages of clinical pain research in an effective and purposeful manner. This article summarizes the results of this meeting and offers considerations for meaningful and authentic engagement of patient partners in clinical pain research, including recommendations for representation, timing, continuous engagement, measurement, reporting, and research dissemination.

**Keywords:** Pain, Clinical trials, Patient engagement, Patient partners

## 1. Introduction

Clinicians and clinical researchers with relevant scientific expertise, whether in academia, industry, or healthcare organizations, are typically the ones who design clinical research studies, determine the various steps in the life cycle of the studies, and oversee their conduct. The patient's role in clinical research, historically, has been one of a study subject for researchers who have generated hypotheses to better understand their health condition and discover innovative and improved therapeutic approaches. Although it is logical to partner with the people who are directly or indirectly affected by the health condition to better understand its nature, symptoms, functional impact, and biopsychosocial determinants, traditional research structures have not naturally facilitated such partnerships.<sup>28,53,120</sup> An approach that has been developing over the past 30 years,<sup>22,25,48,51,80,115,130,131,177</sup> and has emerged in the past decade, is the engagement of patients, their caregivers, and individuals or communities who represent them, in the various components of clinical research. It is increasingly recognized that patient input and feedback in the design and conduct of research studies, as well as the dissemination of their findings, can be important for improving the patient-centeredness of studies to provide more meaningful findings.<sup>53,67,117,123,127</sup> This recognition

is reflected, perhaps most notably, by the increase in research funders who require investigators submitting applications for funding to incorporate patient engagement across the life cycle of their research studies.<sup>104,191</sup>

In different parts of the world and in different settings, the process of engaging patients and other relevant stakeholders in clinical research design and conduct has not followed a harmonized approach. This divergence is understandable because traditional mechanisms of allocating funding, resources, and time for clinical research have not taken this component into consideration. Adding to the complexity, the terminology that has been used to describe the process and the individuals involved have also been somewhat heterogeneous. For example, *patient and public involvement* is the more common term used in the United Kingdom<sup>10</sup> to describe the process and is typically referred to as *patient engagement* in North America.<sup>49,69</sup> With regard to individuals involved, terms such as *patients*, *patient partners*, *community partners*, *research partners*, *expert patients*, *citizens*, *public*, *end-users*, *consumers*, and *people with lived experience (PWLE)* are often used interchangeably in various settings. In addition, patient partners have been described as *stakeholders*, a term also used to describe other relevant representatives of these patients, such as their family

members, caregivers, advocates, and the important end-users of the data generated by these studies, such as clinicians, payers, and policymakers. The 2 terms primarily used at present are *patient partner* and *people with lived experience*.<sup>94</sup> In this article, we use the term “patient partner” to refer to patients who are representative of a study’s population of interest as well as their informal caregivers (like family members and friends) who are engaged as partners in the research. This terminology was recommended by the patient partners who are collaborators on this article. Although there may be a need to conduct equitable consensus building to identify the ideal term for consistent use, this is beyond the scope of this article.

In several therapeutic areas such as oncology,<sup>9,51</sup> neurology,<sup>36</sup> and infectious diseases (HIV in particular<sup>46</sup>), the need to incorporate patients as partners in research is already recognized,<sup>64,94</sup> and studies have been conducted to try to quantify the value of patient partner engagement in the added benefit, primarily with regard to time and money saved.<sup>112,123,163,166,171</sup> Although guidance exists on patient engagement as partners in research in these fields,<sup>9,33,36,44,46,48,51,68,73,82,94,96,105,112</sup> efforts to engage patients in pain research have not been well-orchestrated, and no current recommendations exist on how to most meaningfully engage patients as true partners in pain research. Although many of patient engagement practices are transferable across disciplines, pain research could benefit from specific guidance for several key reasons: (1) pain is a subjective experience, and considering individual voices can help us understand heterogeneity and similarities of experiences; (2) patient-centered outcomes and endpoints are particularly important because no objective biological markers for pain exist and clinical studies rely on patient self-report and patient-reported outcomes; (3) the gap between evidence and uptake in routine clinical care could be a function of limited consideration of patient preferences and perceived barriers to accessing pain care, among others; and (4) translational efforts for the

development of new therapeutics have had very low success rates.<sup>119,126</sup> In this article, we discuss considerations and present consensus recommendations for engaging patient partners in planning and conducting, as well as disseminating the findings of clinical pain research. Although many of the principles and recommendations we discuss may be relevant for basic and translational pain research as well, such a focus is outside the scope of this article.

## 2. Methods

The Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public–private partnership organized an Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) consensus meeting to discuss and develop recommendations for engaging patient partners in designing and conducting, as well as disseminating the findings of, clinical pain research. The IMMPACT meeting occurred on October 27 to 29, 2021 and informed the recommendations outlined in this article. Meeting participants were invited by the IMMPACT steering committee based on their expertise or experience involving clinical pain research and to represent stakeholders from patient organizations, public institutions, and industry. The committee attempted to identify the person(s) responsible for directing/executing patient engagement initiatives in national research organizations within and outside of the United States. Most of the published and publicly available models for patient engagement are from North America and Europe, and these reflected the geographical representation of the IMMPACT meeting participants. In addition, all members of the ACTTION management, steering, executive, and oversight committees were invited. The meeting included international representatives from academia, patient advocacy groups, government regulatory agencies, research funding organizations, academic journals, biopharmaceutical industry

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and, notably, PWLE of pain. Diverse academic disciplines were represented among attendees and coauthors, including anesthesiology, biostatistics, clinical trials, health and technology, neurobiology, neurology, pain medicine, pediatrics, pharmacy, psychiatry, psychology, rheumatology, social work, sociology, and surgery (a full list of meeting participants is available on the IMMPACT web site: <http://www.immpact.org/meetings/Immpact25/participants25.html>). Representatives who presented or participated in the majority of the 3-day meeting were invited to contribute as coauthors on this article; those who were unable to contribute as coauthors are listed in the Acknowledgement section.

Background lectures were presented by coauthors of this article (or other meeting participants—see Acknowledgement section) to facilitate discussion. Topics included: (1) Definitions, Historical Perspective & Best Practices on Patient Engagement in Research (C.G.), (2) Research Agency Funders Panel Discussion (R.K., C.V., D.A., R.B., K.C., K.K., R.K., and J.T.), (3) How to Identify, Locate and Incorporate Patients in the Planning of Clinical Pain Research (K.M. and G.G.), (4) Inclusion of Diverse, Disparate & Hard to Reach Populations (J.J.), (5) The “How Tos”: Incorporating Patient Partners in the Conduct of Clinical Pain Research (K.R.M. and L.L.), (6) Incorporating Patient Partners in the Dissemination/Implementation of Findings from Clinical Pain Research (C.C. and I.J.), (7) Special Considerations for Industry Pain Trials (D.L.), (8) Regulatory Agency Perspectives in Engaging Patient Partners and Other Stakeholders in the Planning & Conduct of Pain Clinical Trials (N.B., R.B., and A.C.), (9) Measuring Patient Engagement in the Planning, Conduct and Dissemination/Implementation of Clinical Pain Research (L.F.), and (10) and Journal Reporting on Patient (and Other Stakeholder) Engagement in the Planning and Conduct of Clinical Pain Research (F.K. and M.J.).

In addition, a narrative review of the available literature on patient engagement as partners in clinical trials was completed and presented at the meeting (S.H.),<sup>94</sup> along with preliminary findings from a systematic review on patient perspectives as participants in clinical pain trials (M.F.).<sup>63</sup> Presentations are available on the IMMPACT web site, <http://www.immpact.org/meetings/Immpact25/background25.html>.

During the meeting, attendees considered the advantages, challenges, and opportunities for patient engagement in clinical pain studies, as well as the content to include in the manuscript. The IMMPACT meeting was fully transcribed. (Transcripts are available on the IMMPACT web site: <http://www.immpact.org/static/meetings/Immpact25/Day1.pdf>; <http://www.immpact.org/static/meetings/Immpact25/Day2.pdf>; <http://www.immpact.org/static/meetings/Immpact25/Day3.pdf>.) The process to reach consensus was similar to that which is described in previous IMMPACT consensus articles.<sup>72,92</sup> After the meeting, the co-first authors drafted a consensus manuscript based on meeting presentations and analysis of the full meeting transcript to ensure that nothing was excluded from the manuscript. Iterative revisions to preliminary drafts of the manuscript were made until consensus was achieved among all coauthors, and any disagreements and conflicts of opinion were addressed via discussions. The patient partner coauthors participated as equal partners in every aspect of this process.

### 3. Benefits, challenges, and value associated with patient engagement

Once regarded as “subjects” who had research performed on them, patients are now contributing more frequently and more

formally across the spectrum of clinical research. This contribution includes helping to identify gaps in clinical care and disease management; set priorities for health research; design and plan research studies; select meaningful outcomes and endpoints; develop recruitment and retention strategies; address challenges in conduct; and disseminate and implement research findings.<sup>15,41,123,133,164</sup> Although approaches for participatory research (ie, research in direct collaboration with those affected by the issue being studied) started developing in the mid-1900s by Kurt Lewin and others,<sup>4</sup> possibly the most prominent model of this practice is community-based participatory research (CBPR)<sup>158</sup> that promotes the equitable involvement of community members, representatives, and researchers in all aspects of research process. This approach emphasizes that all partners equally contribute their unique expertise, and they share ownership, decision-making power, resources, credit, results, and knowledge. Community-based participatory research also implies that all participants are fully committed to producing outcomes usable to the public. This concept is different from the traditional model where scientists seek to answer questions or test hypotheses without input from PWLE, and this approach is likely to be particularly important when researchers are considering the effect of their results on communities from a broader perspective.

But why would researchers seek to engage patients as partners in research? Among numerous and diverse goals are to (1) ensure that clinical research reflects the needs and values of patients and other stakeholders; (2) improve the feasibility of conducting clinical studies; (3) improve the relevance of and encourage use of research results; (4) to expand the diversity, inclusion, and equity in clinical research; and (5) to inform practice and health policy. The level of patient engagement in research ranges from attendance or participation in focus groups to active consultation, collaboration, or shared leadership.<sup>5,27,85,123,164</sup> Research on the topic of patient engagement suggests that it influences a variety of study-related factors, including user orientation and acceptability, feasibility, study quality, relevance, and engagement quality and scope.<sup>67,94,123</sup> For example, patient partners can help identify potential barriers and facilitators to study participation and adherence. These can include helping to craft and review patient-centered and compelling language and the messaging used in advertising and marketing materials, as well as suggesting improvements, which may influence the efficiency of recruitment, avoidable protocol modifications, the ability to complete enrollment as planned, and importantly avoiding potentially stigmatizing and biased language.<sup>21,24,38,53,54,123,132,162</sup> In addition to directly informing study design and conduct, patient partners may be involved in setting research priorities and making policy decisions as well as participating in governance of research organizations and research networks.<sup>79,144</sup>

A review of 126 articles<sup>67</sup> describing research teams' experiences with patient engagement focused on their approaches to patient engagement, reported contributions by patients, and whether and how these contributions were measured. The primary study-related benefits of patient engagement were improvement in acceptability, feasibility and quality of the study, as well as the applicability of results. Hemphill et al<sup>91</sup> describe how engagement benefits all the different stakeholders involved in the study. Patients can benefit from an increase in knowledge and enthusiasm for research, professional development opportunities, acquisition of new skills, and making a positive difference in patient care. Communities benefit through increased trust with researchers and research capacity. Outside

of the study-specific advantages, researchers also benefit from a deeper understanding of real-world experiences and concerns of their study populations and a stronger commitment to patient partner engagement in the future. Some of the shared benefits and values associated with patient engagement are outlined in **Figure 1**.

Despite the benefits outlined above, active engagement of patients as partners in research can also be challenging. Institutions have not been traditionally structured to support such endeavors, neither are most pain researchers trained in effectively engaging patient partners in research. There is a need for careful consideration of infrastructure and resources, time, people and teams, and the balancing of views and priorities, which include differing perspectives and the potential for value conflicts.<sup>90,123</sup> As such, research teams are asked to bridge the gaps between, on one hand, the recognition of value that partnerships with patients bring and the increasing requirements from research funders to include patient partners in research, and on the other hand, the cost, the resources, and the training that are required for meaningful engagement.

#### 4. Models and frameworks of patient engagement

Several models to enable and promote patient engagement in research have been developed.<sup>94,128,129</sup> In the United States, some of the leading organizations in this domain are the Patient-Centered Outcomes Research Institute (PCORI), the Office of Research and Development of the U.S. Department of Veterans Affairs (VA), and the National Institutes of Health (NIH). Examples of their international counterparts are the National Institute for Health and Care Research (NIHR) and the Medical Research Council (MRC) in the United Kingdom and the Canadian Institutes of Health Research (CIHR). Representatives of all these organizations presented their perspectives at the 2021 IMMPACT meeting. Some of the approaches these organizations have taken to promote patient engagement are summarized below.

*The Patient-Centered Outcomes Research Institute* was authorized in 2010 with the purpose of assisting patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the way health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and synthesis of evidence. The main vehicle by which PCORI accomplishes its mission is the funding of comparative clinical effectiveness research (CER), particularly patient-centered outcomes research studies. Several examples of pain-specific projects that PCORI has funded include the Veterans Pain Care Organizational Improvement Comparative Effectiveness (VOICE) study (focused on managing pain while reducing opioid use in the U.S. Veteran population<sup>98</sup>), the Effective Management of Pain and Opioid-Free Ways to Enhance Relief (EMPOWER) study (focused on behavioral pain management approaches in patients who use opioids chronically<sup>42</sup>), the Learning About My Pain (LAMP) trial (evaluating literacy-adapted cognitive behavioral therapy and group pain education for chronic pain in low-income population<sup>176</sup>), and the Strategies to Assist with Management of Pain (STAMP) study (comparing cognitive behavioral therapy vs mindful meditation for chronic low back pain management<sup>62</sup>). In each of these CER research projects, active patient and stakeholder engagement has brought unique contributions.

*The Office of Research and Development of the US Department of Veterans Affairs* in 2015 launched a program for Veterans' engagement in VA research to help focus research on

useful and meaningful research questions, improve the relevance of primary endpoints in research studies, speed dissemination and uptake of research, and improve research communication. To support these missions, the Strengthening Excellence in Research through Veteran Engagement (SERVE) Toolkit has been published to support VA research centers and investigators in efforts to include Veterans and other partners in the development, implementation, and dissemination of research studies.<sup>97</sup> Specifically for pain, the VA has established a Veteran Engagement Panel for Pain/Opioid Consortium of Research, which provides feedback on pain-related research proposals, including on acceptability of proposed interventions, recruitment strategies, and communications.

*The HEAL (Helping to End Addiction Long Term) Initiative* of the NIH, launched in 2018, has focused on improving prevention and treatment strategies for opioid misuse and addiction and improving pain management. The HEAL Initiative committed to partner with patients and established priorities to enhance stakeholder engagement and diversity efforts. One of the specific steps has been to allocate research funding to enhance patient and community engagement and inclusion, beyond patient recruitment and retention efforts alone. The HEAL established the Community Partner Committee, consisting of patients, advocates, liaisons, and family members, to provide input on key issues faced by patients affected by pain and substance abuse.<sup>89</sup>

*The Canadian Institutes of Health Research* is the major federal agency responsible for funding health and medical research in Canada. The CIHR's Strategy for Patient Oriented Research (SPOR) is the result of extensive engagement with patients and caregivers, researchers and their institutions, health professionals, policy makers, charities, and the private sector.<sup>172</sup> The SPOR aims to change the culture of health care in Canada, to build capacity for patient-oriented research, through training and career development opportunities that support the creation and application of patient-oriented research by both researchers and health care providers. The SPOR funds 5 collaborative research networks in the area of chronic disease, including the Chronic Pain Network, a collaboration of national stakeholders supporting innovative research to better chronic pain management.<sup>34</sup>

*The National Institute for Health and Care Research*, the largest health research funder in the United Kingdom, found in 2006, has set up a standard expectation for public and patient involvement in its activities and research. The NIHR states that public involvement can improve the quality and relevance of research, as well as serving the broader democratic principles of citizenship, accountability, and transparency. The NIHR operates using standard sets of recommendations for public involvement.<sup>130</sup> These include *creating inclusive opportunities* (to reach people and groups according to research needs), *working together* (in a way where contributions are valued and mutually respectful relationships are built and sustained), *offering support and learning* (to build confidence and skills for public involvement in research), *involving public in governance* (including research management, regulation, and decision making), *communicating in plain language*, and *producing impact* (by identifying and sharing the difference that public involvement makes to research).

*The Medical Research Council (MRC)*, which is part of the United Kingdom Research and Innovation (UKRI), also deploys multiple programs for public engagement and funds specific programs to encourage such engagement in research. One of the specific pain-focused programs that UKRI has established in partnership with Versus Arthritis and Eli Lilly, called Advanced

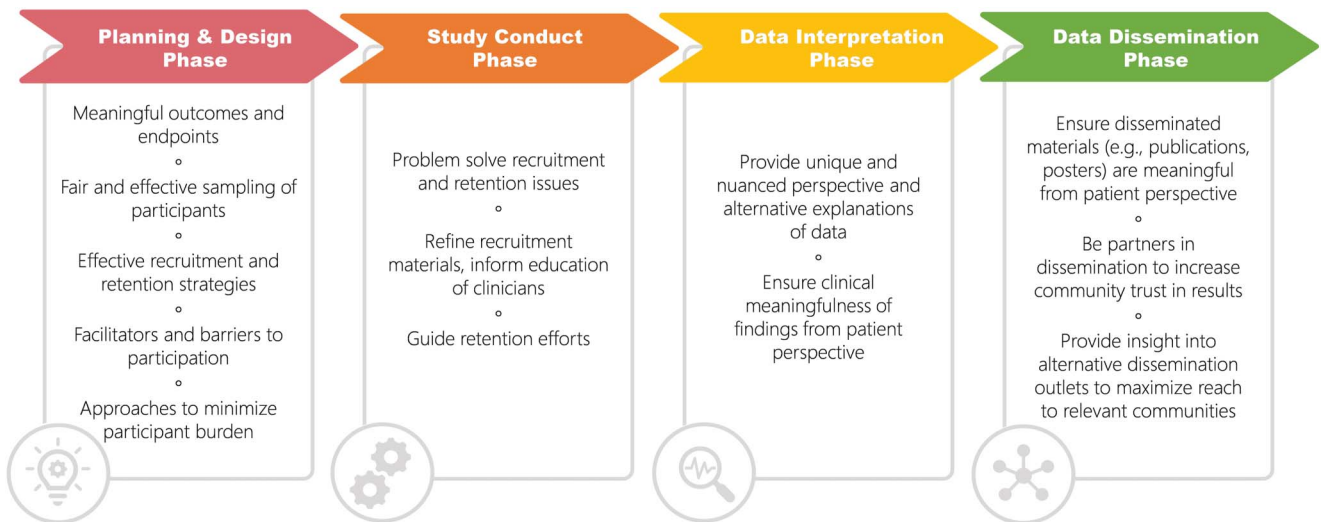


Figure 1. Shared benefits and values associated with patient engagement.

Pain Discovery Platform (APDP), is funding multidisciplinary consortia to unravel the complexity of pain and reveal potential new treatment approaches for a wide spectrum of painful clinical conditions. These consortia involve people with lived experience of pain as partners.

**5. Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials recommended considerations**

Currently, there are no formal guidelines for best practices specific to patient engagement for pain research.<sup>94</sup> Through an analysis of the information presented during the IMMPACT meeting, we aim to offer consensus considerations on the implementation of core principles of patient engagement to optimally fit individual pain studies. We recognize that the approaches for meaningful patient engagement, as well as the outcomes of such engagement, are likely to vary depending on the study type, nature of the research question, and context. For example, the process of patient engagement in designing and conducting a small Phase I study of a novel analgesic in healthy volunteers will likely differ from the analogous process for a large multicenter comparative efficacy trial in patients with chronic pain. Regardless of the specific context, this process should not be viewed as an administrative requirement that can be simply “checked off.” The goal, rather, is to move the field of clinical pain research toward more meaningful and impactful science, with patients being at its center. There is no one-size-fits-all method; instead, it is a process of dynamically applying core principles of meaningful patient engagement in a context-specific and value-specific manner.<sup>109</sup>

The overall considerations are outlined in **Table 1**, and sections 6, 7, and 8 of this article provide detailed steps for approaching patient engagement, measuring and reporting it, as well as highlight the views and perspectives of different stakeholders.

**6. Approaching patient engagement**

**6.1. How to start**

Patient engagement should be active, purposeful, and authentic, rather than passive or symbolic, and should occur throughout the entire lifecycle of the research process, from the development of research priorities to dissemination and utilization of findings.<sup>94</sup>

Involving patient partners in the very beginning of the strategic planning phase can help set the agenda of the research program (see section 6.1. for specific suggestions on how to support these initial steps).

Meaningful engagement is an ongoing process that begins with researchers actively engaging with community members, getting to know them, and understanding their needs and assets.<sup>44</sup> Identifying a community health worker or engagement specialist who has the pulse of the community and is integrated within the community itself can aid greatly in this process. Chiefly, inclusion of marginalized, minoritized, and other hard-to-reach (or “hardly-reached”<sup>167</sup>), seldom-heard populations should be prioritized.<sup>74</sup> As such, researchers should aim to build reciprocal, mutually beneficial relationships with marginalized communities. It takes time for researchers to build and sustain trusting and meaningful, bidirectional, and ongoing relationships rather than “parachuting in and then out.”<sup>101,107,116,170</sup> Engagement specialists or leaders, as well as potential patient partners, may be identified by attending community events (eg, health fairs, fundraisers). It may also be feasible to partner with organizations rather than a specific individual, including places of worship, community clinics, senior centers, community associations, charitable organizations, advocacy groups, and academic institutions. Another avenue for becoming more familiar with the community is to conduct community events.<sup>44</sup>

For clinical pain research specifically, researchers should consider hosting conferences that highlight the pain perspective and invite community members, as well as researchers, to these conferences. Such workshops or conferences can be an initial step to learn about patient perspectives on their participation in the different stages of research and to develop a plan to actively foster this engagement.

One example of the conference approach can be found in rheumatology research. Since 2002, Outcomes Measures in Rheumatology Clinical Trials (OMERACT) has included patient partners in their conferences, and each OMERACT working group is expected to involve patients in all aspects of the group work, including completing the prework before meetings. An evaluation of the OMERACT conferences suggested that their engagement with patients has significantly influenced outcomes research in rheumatology, including broadening the research agenda, identifying and integrating outcomes relevant to the patients, and improving patient-reported instruments.<sup>48</sup> An

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example of success of OMERACT conferences is the development of the “OMERACT Filter 2.0” that refers to an explicit working process through which stakeholders can reach consensus agreement to develop core outcome measurement sets.<sup>11,16,103,179</sup>

To organize events that incorporate the experience and insight of patients, organizations like Patients Included have provided self-accreditation guidance for authentically and safely including patients in medical and technology conferences.<sup>141</sup> Criteria for organizing inclusive events focus around the following: (1) active participation of patients and caregivers with relevant experience in the designing and planning of the event; (2) patient participation in both the delivery of the event and as audience members; (3) covering the travel and accommodation expenses for patients and caregivers participating in the delivery of the program; and (4) accommodating for disability requirements and allowing virtual participation to access pertinent content.

Attending or conducting conferences also allows for an opportunity to cultivate relationships between researchers and patients for future research endeavors. For example, the International Association for the Study of Pain (IASP) established the Global Alliance of Partners for Pain Advocacy (GAPPA) Task Force in 2018, with a mission to bring together patient advocates, patient organizations, scientists, clinicians, healthcare providers, and policymakers to create better outcomes in the awareness, understanding, research, teaching, assessment, and management of pain. Such initiatives can allow PWLE to contribute to pain research in various ways, for example, co-creation with PWLE to support equitable musculoskeletal health care<sup>12</sup> and active participation in the Scientific Program Committee for IASP’s World Congress on Pain.

## 6.2. Ongoing involvement

Ideally, research groups should set a process for identifying and including patients as integral partners in their research programs. Once patient partners have been identified and engaged as formal collaborators, ongoing involvement must be thoughtfully facilitated. The most basic, yet impactful, recommendations for facilitating meaningful engagement are clear descriptions of

responsibilities and expectations co-created with patient partners, adequate compensation, adequate training, and genuine camaraderie between researchers and patient partners.<sup>94</sup> Fair compensation is important for equal opportunity patient engagement and an effective way to demonstrate respect for patient partners’ expertise, experience, time, and skills.<sup>152</sup> The compensation can be financial or nonmonetary, but needs to be structured to promote equity, respect patient vulnerability, and remove potential cost barriers to participation. To facilitate the fair compensation of patient partners, some organizations have developed publicly available policies and guidelines for assigning financial value to patient expertise.<sup>65,143,152</sup> As a pain-specific example, the Solutions for Kids in Pain network outlines opportunities for engagement and expectations for patient partners, as well as a straightforward rubric,<sup>168</sup> for suggested compensation based on activity, commitment, responsibility, and scope.

To promote ongoing involvement, it is important to establish a shared vision of goals, roles, and expectations among all members of the research team<sup>14,59,66,110</sup> and to periodically revisit them to maintain an ongoing dialogue. At the end of a project, it is helpful to have a qualitative understanding through conversation about what was achieved and how, what the vision was for working together, and whether it was met. It is important to close the feedback loop at the end of a project by explicitly recognizing the contributions of partners to the project and discussing expectations of any continued involvement or collaboration.

## 6.3. Research dissemination

The main mechanism of disseminating the findings of scientific research remains publication of research articles in peer-reviewed journals and presentation at scientific conferences.<sup>57,102,156</sup> However, it is becoming increasingly evident that adoption and implementation of new best practices is often delayed by many years.<sup>30,102,178,189</sup> This is true of pain research in particular,<sup>30</sup> at least partially because of limited dissemination approaches, including via channels that reach the public and policymakers. Patient partners can have an important role in

**Table 1**

### IMMPACT–recommended considerations for authentic and meaningful patient engagement in clinical pain research.

|   |
|---|
| <p><b>How to start</b></p> <ul style="list-style-type: none"> <li>Develop authentic relationships to foster mutual trust with communities of interest</li> <li>Leverage community outreach groups (that may already be formed)</li> <li>Engage patients with the targeted pain condition(s) under study</li> <li>Provide fair financial compensation and ensure proper accessibility/disability accommodations</li> <li>Educate patient partners about clinical pain research (including principles such as clinical equipoise, blinding, randomization, placebos, and comparators) and researchers about patient engagement</li> <li>Jointly establish clear goals, roles, and responsibilities</li> </ul> |
| <p><b>Continuous engagement</b></p> <ul style="list-style-type: none"> <li>Provide flexible opportunities for patient partners to attend meetings</li> <li>Revise roles and responsibilities as needed</li> <li>Recognize project milestones</li> <li>Provide opportunities for training (eg, data science, presentation skills)</li> <li>Include patient partners as authors on publications and, as relevant, include on policy papers</li> <li>Support conference attendance and opportunities for presentation/co-presentation</li> </ul>   |
| <p><b>Measuring &amp; reporting engagement</b></p> <ul style="list-style-type: none"> <li>Use tools to measure extent, quality, and experience of patient partner engagement (continuous measures can support continuous learning and improvements)</li> <li>Consider evaluating the effect of patient engagement on trial outcomes, efficiency metrics, and costs</li> <li>Report the patient partner engagement methodology and its impact/outcomes in scientific publications. At the minimum, provide details in methodology of the manuscripts or as an appendix. Consider separate manuscripts with the methodology and results of measured engagement.</li> </ul>                                    |

**Table 2**  
**Examples of patient engagement measures.**

|                   | PPEET <sup>2</sup>  | REST-9 <sup>78</sup>  | PEIRS <sup>83</sup>   |
|-------------------|---|---|---|
| Respondents       | 3 questionnaires for (1) participants—those who participated in the engagement initiative; * (2) project—individuals in organization who requested or sponsored engagement component of the project; (3) organization—individuals who have a general awareness of how engagement works in the organization† | Nonacademic research partners   | Patient partners  |
| No. of items      | Participant questionnaire:<br>21 (one-time activity)<br>22 (ongoing/long-term)<br>Project questionnaire:<br>15 (planning)<br>16 (assessing engagement)<br>8 (assessing impact)<br>Organization questionnaire:<br>30 (annual or semiannual)  | 9 (end of project)  | 14 (procedural requirements); 4 (convenience); 4 (contributions); 5 (team environment and interaction); 3 (support); 3 (feel valued); 4 (benefits)                          |
| Example items     | Participants:<br>“I feel that my views were heard.”<br>Project:<br>“The engagement plan has clearly described strategies for communicating with participants.”<br>Organization:<br>“A commitment to PPE values and principles is found in key organizational documents.”                                    | “All partners assist in establishing roles and related responsibilities for the partnership.”<br>“The team builds on strengths and resources within the community or patient population.” | “I received sufficient explanation about the project.” “My preferences for meetings (such as time, duration, location, and format) were considered when planning meetings.” |
| Response options  | Level of agreement (strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree) + free text   | Quality: poor, fair, good, very good, excellent, not applicable<br>Quantity: never, rarely, sometimes, often, always, and not applicable  | Level of agreement (strongly disagree, disagree, neutral, agree, and strongly agree)  |
| Concepts measured | Level of engagement (based on “Communication and Supports for Participation,” “Sharing Your Views and Perspectives,” “Impacts and Influence of the Engagement,” and “Final Thoughts”)   | Level of engagement (based on ratings of quality and quantity of established engagement principles)   | Quality of engagement in research projects from a patient partner perspective   |
| Validation        | Content validity <sup>1,17</sup>  | Reliability and construct validity <sup>78</sup>  | Content, face, structural, and construct validity <sup>83,84</sup>  |

\* For example, citizens, community members, patient/family partner, and organization staff members.

† Board members, executive team, and managers. PPEET, Public and Patient Engagement Evaluation Tool; REST-9, Research Engagement Survey Tool; PEIRS, Patient Engagement in Research Scale.

facilitating public outreach, whether from their local communities or through other channels. Involving patients in dissemination activities, such as co-creating and co-presenting the work at conferences and other public speaking engagements, as well as sharing authorship can strengthen the clinical relevance of the disseminated materials. Richards et al. published considerations for conversations about authorship between researchers and patient partners, including guidance on determining team member contributions.<sup>153</sup> Additional dissemination activities can include partnering with patients on co-creating podcasts, engaging media outlets (including social media platforms and newsletters), and maintaining updated study web sites with plain language summaries of current or finished research projects.

**7. Measuring and reporting meaningful engagement**

“If you cannot measure it, you cannot improve it.”<sup>40</sup> Measurement of patient engagement is important to advance both the science and the practice of engagement.<sup>18,23</sup> A systematic review<sup>17</sup> of tools designed to evaluate the impact of patient engagement in research and health system decision making revealed 27 tools, including surveys, checklists, questionnaires, scales, and indices, the majority of which are targeted to evaluate a specific dimension of engagement and typically focus on process. The

main conclusion was that no gold standard tool exists to measure engagement across disciplines and different perspectives, and that the scientific rigor with which such evaluation tools are developed could be improved. The authors also note that the level of patient and public engagement in design and reporting of such tools needs to be improved.

In clinical pain research, the constructs of measures to gauge patient engagement success are not yet well defined. There is an opportunity to explore which patient engagement practices (and the approaches to measure them) from other settings are generalizable or transferable to pain research and which elements require unique development.

It is important to develop and validate tools that measure both the process of engagement (eg, Did patient partners believe that they were optimally engaged?; Did the patient engagement process support trust?; Were ideas treated with openness and respect?) and the engagement outcomes (eg, What was the impact of patient engagement on study conduct and results, on the partners engaged, and the relevance and use of health research?).<sup>17,18,24</sup> The majority of current measures are primarily focused on the engagement process<sup>6,84,122,183,184</sup> and few focus on outcomes.<sup>2,17,37,111</sup> Although it is important to continue to improve the engagement process itself, developing and validating measures for outcomes of patient engagement will be

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important for determining the value of patient engagement in clinical research, and for optimizing patient-centered clinical research practices.

Measuring and reporting patient engagement may not be a simple task. Various contexts and differing stakeholder questions regarding engagement exist—based on diverse priorities for measurement, including what is measured, how it is measured, and how the results are used. For example, patients may want to understand their impact on the research and the research team themselves, as well as whether they were supported and trained to best use their role and experiences (eg, avoiding jargon, using terms that are clear, and defining abbreviations). Researchers may ask how effectively they engage with patient partners and how it affects their research quality and outcomes. Policymakers may be interested in understanding whether the engagement is inclusive and how it may impact public health. Funding agencies may ask whether engagement leads to more efficient use of clinical research resources. It is critical to consider all the different perspectives, backgrounds, and values when measuring engagement. When possible, patient engagement should be measured at each stage of the research process, to understand the particular contribution to (1) conceptualization and design, (2) study conduct, and (3) dissemination and implementation.<sup>14,17</sup>

Proper validation of engagement measurement tools is also important. Only a few of the existing measures report their psychometric properties,<sup>1,17,83</sup> many of which focus on face validity.<sup>6,17,23,122,184</sup> Demonstrating the content and other forms of validity is also important for determining the accuracy and reliability of the measurement tools.

One measure that has undergone extensive validation is the Research Engagement Survey Tool (REST),<sup>76,78</sup> which offers the ability to compare partner engagement across and within studies over time. The REST assesses quality and quantity of engagement through the lens of 8 principles that were selected through a Delphi process to reach consensus among stakeholder and academic experts<sup>77</sup>: (1) Focus on community perspectives and determinants of health; (2) Partner input is vital; (3) Partnership sustainability to meet goals and objectives; (4) Foster co-learning, capacity building, and co-benefit for all partners; (5) Build on strengths and resources within the community or patient population; (6) Facilitate collaborative, equitable partnerships; (7) Involve all partners in the dissemination process; and (8) Build and maintain trust in the partnership. **Table 2** highlights the components of 3 recently validated measures based on a systematic review<sup>17</sup> and a more recent review of the literature.

## 8. Additional stakeholders' perspectives

### 8.1. Research funders

Multiple research funders now encourage (or require) funding applicants to engage patient partners in the development of their applications or engage patients as part of the research team in planning and executing the project. Some organizations, such as PCORI, VA, NIHR, and CIHR, require both such involvement and have specific budget categories to fund meaningful engagement and are interested in advancing the science of patient engagement in research, encouraging studies to examine different strategies to promote successful engagement. Other agencies and programs make recommendations and assign various levels of priority to the meaningful inclusion of patient and other stakeholder partners in grant proposals for conducting research studies. Specific to pain research, the NIH HEAL Initiative created

a workshop to educate potential applicants on principles and requirements for patient and other stakeholder engagement, recognizing the importance of this process to advance the Initiative's mission.<sup>140</sup> Recent HEAL funding opportunities explicitly encourage or require the involvement of patient partners and other stakeholders in applications and research projects.

However, there is currently a “*Catch-22*” situation because one of the most frequently reported barriers to early and meaningful patient engagement in research is cost.<sup>94</sup> Best practices dictate that engagement should begin at the outset of a project, with patient partners helping to design the study and formulate its goals. The majority of these decisions, however, are typically made before submitting the project for funding and, therefore, before it is known whether funding is available. Minimal or no funding before grant submission can limit the researchers' ability to build meaningful engagement. Currently, researchers as well as patient partners and stakeholders who value patient engagement often donate their time, talents, and insights in building those partnerships in the prefunding stages. A key question in this context is whether this process is fair, equitable, and ethical to the parties involved. If funding organizations want to prioritize meaningful patient engagement, they should consider novel or alternative methods for supporting engagement before grant submission, including providing additional time and funding to develop relationships with community members and request and incorporate feedback from patient partners at the earliest stages. For example, as an integrated learning health system, and as already acknowledged, the VA sponsors standing Veteran Engagement Panels<sup>108,185</sup> with members who are compensated for their involvement in identifying research priorities important to Veterans and serving as partners in the preparation of applications for funding. Another example is PCORI's Engagement Award Program,<sup>145</sup> which supports projects to build a community of patients and other stakeholders equipped to participate as partners in PCOR/CER and disseminate PCORI-funded study results. An example in the academic setting is the Patient and Public Involvement Fund set up by the University of Aberdeen<sup>138</sup> that is open to all researchers within the university to support early patient engagement activities. As other funders of clinical pain research move to require patient engagement as foundational for successful research grant funding, it is likely that more academic institutions and other entities will establish similar approaches.

### 8.2. Regulatory agencies and industry

Sponsors of clinical research, including drug (and to some extent device) companies, are driven to support patient engagement through the growing understanding that patients are increasingly informed and active. The regulatory and payer landscape also is now more demanding—with marketing approvals requiring the patient voice to be integrated in the drug development process. Both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) consider patients' voices as essential to the drug development and approval processes and have included patient and community representation on a variety of working groups and scientific advisory groups.<sup>29,61,139,142,157</sup> Both agencies, as well as regulatory agencies in countries such as Canada (Health Canada), Australia (Therapeutic Goods Administration), and the United Kingdom (Medicines and Healthcare Products Regulatory Agency) hold periodic meetings for engaging the public in the processes of drug (and device) approval, for enhancing patient-focused product development.<sup>60,93,106,124,139</sup>



Although the biopharmaceutical industry has viewed patient engagement as an imperative, there is no mandate to harmonize its operationalization, and individual drug and device companies have developed their own patient and public engagement processes and initiatives. To this end, one of the US initiatives that sought feedback from patient groups, industry, and academia to understand the barriers to engagement with patients is the Clinical Trials Transformation Initiative (CTTI), an FDA-sponsored, cross-industry and cross-sponsor collaboration anchored by Duke University.<sup>165</sup> Their findings illustrate where opportunities to engage with patients and advocacy groups exist across the research continuum. The European Patient's Academy on Therapeutic Innovation (EUPATI) has been providing education and training to industry and the public to increase the capacity and capability of patients and patient representatives to understand and meaningfully contribute to medicines research and development since 2012.<sup>186</sup> Another example is ACCELERATE, a multistakeholder platform of clinicians, researchers, regulators, patient advocates, and industry representatives, to catalyze patient-centric drug development for cancer.<sup>146</sup> Overall, both industry and regulatory agencies are making strides to meaningfully incorporate patient engagement in clinical research for patient-centered drug and device development. However, barriers such as funds and human resources, lack of consistent information and education for patient advocates, and lack of collaborative initiatives remain to be overcome.<sup>159</sup>

### 8.3. Journals and publishers

Journals seek to publish research that is rigorous, transparent, and impactful.<sup>7,19,113,125,148</sup> As discussed previously, meaningful patient and other stakeholder engagement can play a major role in improving all these aspects, particularly in pragmatic clinical trials.<sup>147,150</sup> As such, and as expected by some research funders and sponsors (eg, the Administration for Community Living<sup>3</sup> and PCORI<sup>188</sup>), patient partner involvement in research publications should be reported. Journals require that the methods and procedures in a study are transparent to allow the readers to understand what was done with enough detail to allow replication. Thus, if patient partners were involved in the research, the description of their role and the processes of their involvement must be clear and thorough. To enhance the likelihood that reviewers and readers can understand and assess efforts to engage patients as partners appropriately, it is necessary to educate reviewers and the pain research community at-large about the role of patient engagement. Thus, it is incumbent on the entire community to embrace opportunities for education in the service of building this research capacity. To remove barriers for patient partner authorship opportunities, it would be beneficial if journals eliminated the requirements for each author to have an academic affiliation.

It must be acknowledged that there are limitations to the reporting of PWLE and other stakeholder involvement in research articles because of word limits, which may hinder the ability to demonstrate the sophistication and breadth of stakeholder engagement in a study, as well as its full impact. Fortunately, there are a variety of alternative avenues for highlighting patient partner involvement in publications. For example, patient partner engagement can be included in the methods section or at a minimum in the Acknowledgements. Researchers can publish a review paper or a sister manuscript in a patient and public engagement-specific journal<sup>13,50,114,161</sup> on the purpose of the study, as well as why patient partner involvement is important to this area of research. A protocol paper may also be used to

describe how patient partners and other stakeholders influenced the way the study was designed, and how they will be involved in the planned research. There may be also opportunities to involve patient partners as reviewers or editors of such manuscripts. In the context of an interventional study, an intervention manual can be published that highlights stakeholder involvement in the development of the intervention. Lastly, a description of stakeholder involvement can also be submitted as supplemental material.

## 9. Remaining gaps and future research priorities

Even in therapeutic areas where patient engagement efforts have been the most advanced, the vast majority of studies do not routinely include patient partners nor report on their engagement in clinical research.<sup>94</sup> The situation is certainly true for pain research, where the culture of involving patient partners in clinical research design, conduct, reporting, and dissemination is currently the exception rather than the rule.<sup>94</sup> Interestingly, clinical trials focused on the development of new therapeutics for pain (and particularly new drug classes, outside of calcitonin gene-related peptide targeting for migraine<sup>31</sup>) have generally not resulted in new approved products in over a decade,<sup>56</sup> with some critiques on the selection of relevant patient population, study design, and clinically meaningful endpoints.<sup>43,55,99,174</sup> It is certainly possible, given the evidence for broad benefits of patient engagement, that increasing engagement in phase 1 to 3 trials of new pain therapeutics as a research priority may increase the probability of identifying safe and effective novel analgesic treatments. Additionally, while we have reported here suggestions for dissemination of research that involves patient engagement and considerations for reporting such engagement, recommendations for the implementation and uptake of such research have yet to be formally tested, particularly taking into account geographical, socioeconomic, and cultural differences that may require a more nuanced approach. Because the IMMPACT meeting did not include representation from all continents, or participants outside the United States, Canada, United Kingdom, France, and Germany, the generalizability of our recommendations outside of developed countries in North America and Europe may be limited.

### 9.1. Attaining patient-centeredness in pain research

To attain patient-centeredness, researchers can and should partner with patients to determine what kind of outcomes are worthwhile to focus on, what kind of relief in the intensity of their pain, or its interference with various functions patients are looking for, among many other items seminal to developing a meaningful clinical pain trial.<sup>175,180</sup> As a successful example, the patient-led recommendation of the OMERACT initiative to include *fatigue* as an outcome measure in arthritis trials has resulted in a change in key outcome measures in arthritis trials globally.<sup>48</sup> An additional set of metrics of patient-centricity is the acceptability, appropriateness, and feasibility of the interventions<sup>187</sup> and the likelihood of patient adherence to it. In an attempt to identify gaps in patient-centricity, researchers may find that the feedback differs based on the particular condition of focus and other factors such as comorbidities or social determinants of health that need to be considered. An effort to attain feedback from people who represent populations most affected by the condition of interest is likely to be particularly important. As a research priority, exploring and identifying best methods and practices of patient and stakeholder engagement that contribute to closing patient-

centricity gaps in pain research can lead to more useful and impactful pain trials.<sup>48</sup>

## 9.2. Diversity of research participants and partners

Arguably one of the important gaps in clinical research is the lack of diversity and adequate representation among research participants, as well as partner members of research teams.<sup>20,58,71,81,136,137,149,154</sup> Both are important for including diverse perspectives, and achieving a diverse patient partner team can help attain participant representation goals to improve external validity of clinical trials. There are several ways individuals involved in research at any level can improve diversity and empower the marginalized, hard-to-reach,<sup>160,181</sup> and hardly reached populations.<sup>32,167</sup> A primary barrier to recruiting diverse patient partners is that researchers tend to select groups who they have worked with before, allowing for only a narrow range of who are involved in the study. These steps often depend on the local relationships that have been established with patients, various stakeholders, and community partners. This is likely to result in selection bias (ie, patients who volunteer as research partners may be highly motivated and educated, and be strong communicators, but they might not best represent the population most affected by the condition). Researchers may also seek patient partners for a loosely defined good “fit,” thus limiting the necessary diversity of voices, and introducing bias in over-representing or underrepresenting diverse populations and opinions. Establishing a priori transparent criteria for the process of screening, interviewing, and selecting patient partner candidates can help minimize such bias. The researchers should recognize that these criteria might differ based on the study needs and scope. Therefore, pain researchers need to think about how to identify partners who can represent the interests of pain patients who are marginalized or disproportionately affected by the studied condition (eg, women, disabled people, people of color, and members of the LGBTQ+ community).<sup>100,173</sup> Current guidance on addressing this gap is lacking, but researchers should consider approaches to mitigate selection bias. The process of setting up transparent and fair criteria for engaging patient partners while attaining appropriate diversity and representation is a major gap.<sup>14,47,88,121,134,135,155,190</sup> Some initial efforts in this domain have occurred,<sup>14,39,47,95,118,151,155</sup> eg, using established patient engagement support units,<sup>95,169,182</sup> structured research educational programs for community members,<sup>35,75,87</sup> and volunteers most impacted by the disease/condition,<sup>26,45,52</sup> particularly in mental health research.<sup>95</sup> However, investigating and optimizing these efforts for pain research remains an important priority.

## 9.3. Consistent public messaging

Other gaps include the lack of public awareness around the need for and the impact of patient engagement in clinical research. Researchers, biopharmaceutical companies, and funding organizations all have a role in promoting the inclusion of patient partners. Major efforts by organizations and initiatives such as PCORI, CTTI, EUPATI, and NIHR INVOLVE are made for increasing awareness, but this approach has not become a standard in clinical research. As noted, there is also a lack of consistent terminology to describe patient engagement in research, which can be a barrier for the various stakeholders to understanding the goals, the process, and the outcomes of patient engagement. Variable terminology<sup>8,54,70,86,117</sup> contributes to a lack of consistency in process and outcome

measures.<sup>183</sup> PCORI has made a substantial effort in clarifying and consistently using terminology in their communication, but an international effort to improve the consistency of terminology related to patient engagement can further reduce these barriers.

## 9.4. Evidence on improved research outcomes with patient partner engagement

It is important to recognize that a key driver for wider adoption and implementation of patient engagement practices is likely to be the evidence of the added value of this approach. Given that this process requires time and resources—researchers, funders, companies, and the public—would want to see a consistent impact of patient engagement practices in clinical research on measures such as (1) patient-centeredness of studies, (2) duration and costs of studies, (3) transparency and credibility of research, (4) ability to lead to new drug/device approvals, (5) implementation of research findings, and (6) measurable advances in patient care and disease outcomes.

## 9.5. Additional questions

There are remaining questions for patient engagement in general, and for its role in pain research in particular, on (1) What defines successful engagement (and for whom)?; (2) How can we measure engagement and determine its impact?; (3) Under which conditions particular patient engagement approaches work best?; (4) How to optimize them in different contexts, settings, and communities, including low- and middle-income countries?; and (5) How can the model of patient engagement in research be incorporated in research training programs and degrees? Whether measures of engagement can be shared across disciplines or need to be refined for specific types of pain research [eg, across acuity (eg, acute vs chronic pain) and interventional approaches (eg, behavioral vs pharmacological vs neuromodulation therapies)] remains to be addressed.

In summary, improving the patient-centeredness of pain research is a critical component toward better understanding and treatment of pain conditions. We believe that incorporating and improving the practices of engaging patients as research partners can lead to improved, more transparent, and more meaningful clinical pain studies. In this article, we have outlined some of the issues and steps that may be taken to facilitate patient engagement.

## Conflict of interest statement

S.H. has received, in the past 3 years, research grants and contracts from the US National Institutes of Health, the US Department of Defense, and Patient-Centered Outcomes Research Institute and Eli Lilly and personal fees from Vertex Pharmaceuticals, Rafa Laboratories, and GW Pharma, outside the scope of submitted work. R.D.K. has received, in the past 3 years, research grants and contracts from the National Institutes of Health, Department of Veterans Affairs, and Patient-Centered Outcomes Research Institute and honoraria as a member of the Scientific Advisory Board for the Canadian Chronic Pain Centre of Excellence and as senior editor for the journal *Pain Medicine*. During the last 36 months, M.C.F. has received compensation for consultant work from ACTTION. I.G. reports personal fees from Adynxx, Biogen, Eupraxia, Novar-emed, and GW Research, outside the submitted work. J.V. has received consultancy fees from Casquar, Embody Orthopedics, and Vertex Pharmaceuticals, unrelated to this work. J.T.F.

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