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A primary care-based interdisciplinary team approach to the treatment of chronic pain utilizing a pragmatic clinical trials framework

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ABSTRACT

Chronic pain affects at least 116 million adults in the USA and exacts a tremendous cost in suffering and lost productivity. While health systems offer specialized pain services, the primary care setting is where most patients seek and receive care for pain. Primary care-based treatment of chronic pain by interdisciplinary teams (including behavioral specialists, nurse case managers, physical therapists, and pharmacists) is one of the most effective approaches for improving outcomes and managing costs. To ensure robust integration of such services into sustainable health-care programs, evaluations must be conducted by researchers well versed in the methodologies of clinical trials, mixed methods and implementation research, bioinformatics, health services, and cost-effectiveness. Recent national health policy changes, in addition to the increasing recognition of the high prevalence and cost of chronic pain conditions, present a unique opportunity to shift the care paradigm for patients with chronic pain.

Implications

Practice: Treatment of chronic pain by interdisciplinary teams (including behavioral specialists, nurse case managers, physical therapists, and pharmacists) within the primary care setting best meets current health-care needs and promises one of the most effective approaches to care.

Policy: Recent health policy changes (increasing adoption of medical home model and electronic medical records) as well as the high prevalence and cost of chronic pain conditions may present a unique opportunity to shift the paradigm for care of chronic pain patients.

Research: Including researchers well versed in the methodologies of clinical trials, mixed methods and implementation research, bioinformatics, health services, and cost-effectiveness may best ensure robust integration of primary care-based interdisciplinary chronic pain treatment into sustainable health-care programs.

KEYWORDS

Chronic pain, Interdisciplinary/multidisciplinary teams, Primary care, Implementation, Research, Pragmatic clinical trials

It is becoming increasingly clear that pain is one of our most common and expensive public health problems [1]. Research shows that pain is the main reason patients seek medical care, and yet medical management of patients with chronic pain and complex problems remains fragmented, leading patients to seek a wide variety of primary and specialty care services in an effort to manage their pain and related conditions [1, 2]. Such fragmented care leads to poorer outcomes and significantly increases health-care costs as patients often receive unneeded diagnostic and medical procedures [2, 3].

Interdisciplinary pain management protocols, particularly those employing a biopsychosocial framework, have been among the most successful approaches in helping patients reduce symptoms and regain functioning [4–7]. Such protocols combine a variety of therapeutic modalities and rely on teams of physicians, behavioral specialists, nurse case managers, and physical therapists to help patients develop the skills to actively self-manage their condition [8–14]. However, while research has identified evidence-based interdisciplinary behavioral treatment approaches that are effective for patients with chronic pain, these interventions are rarely available in everyday practice settings [2] and will require a new care paradigm effected by changes in research, practice, and policy. Significantly, it is not enough to simply bring together treatment team members from different health-care disciplines. The treatment approach must be fully integrated across these disciplines to achieve the best results [15–17].

Finally, while interdisciplinary behavioral treatment programs have resulted in promising outcomes, they have generally not been conducted and evaluated in a manner to ensure robust integration into sustainable health-care programs. Specifically, this area of study

has had a clear need for pragmatic trials focused on broad and generalizable populations, flexibility in intervention implementation, and attention to the outcomes most meaningful to key stakeholders, including intervention costs and cost-effectiveness [18–20]. We review here the rationale for an interdisciplinary practice approach for the treatment of patients with chronic pain, and we detail the critical elements of a research and evaluation approach to maximize the feasibility of real-world implementation. We summarize the strengths and potential challenges of these approaches in Table 1.

CLINICAL CARE FOR PATIENTS WITH CHRONIC PAIN ON LONG-TERM OPIOID TREATMENT: THE SIGNIFICANCE OF THE PROBLEM AND PROMISE OF INTERDISCIPLINARY TREATMENT APPROACHES

Chronic pain is a widespread and growing problem–The prevalence of chronic pain continues to rise in the USA, causing widespread suffering; contributing to morbidity, mortality, and disability; and exacting significant economic and societal costs. It has been estimated that more than 116 million Americans–well over one-third of the US population and more than the number affected by heart disease, diabetes, and cancer combined–suffer from chronic pain [21]. A recent Institute of Medicine (IOM) report [1] projected the annual cost of chronic pain in the US to range from $560 to over $600 billion, including health-care costs ($261–300 billion) and lost productivity ($297–336 billion). Based on these stark numbers and the scope of suffering they represent, the IOM report identifies effective pain management as a "moral imperative." The report argues that pain should be considered a disease with a distinct pathology, and it calls for interdisciplinary treatment approaches–including those that address the overuse of opioid drugs.[1]

The use of opioids to treat chronic pain is rising–Prescription opioid use has increased dramatically in recent years [22]; since 1980, the proportion of patients with chronic noncancer pain who have been treated with prescription opioids has doubled [23]. This increase has been driven by a variety of factors, including the rising incidence of chronic noncancer pain (now affecting 15–30 % of all adults), acceptance of opioids as a standard pain treatment, and mounting pressure on physicians not to undertreat pain [22, 24–26]. Despite their ubiquitous use, however, there is a growing recognition that opioids carry significant risks, including misuse, overdose, addiction, and life-threatening interactions with other medications and alcohol [27–29]. A large percentage of patients (30–80 %) report unwanted side effects such as pruritus, nausea, constipation [30, 31], hyperalgesia [32], and cognitive impairment [33, 34]. Opioid-related morbidity [35] and mortality [36] have increased dramatically over the last two decades, as have the number of emergency department visits related to opioid medications [35, 37]. Risk appears to be elevated for individuals with past or current substance use disorders, who may be especially prone to abusing or becoming addicted to opioids [38, 39]. For all of these reasons, the use of opioids for long-term pain treatment remains controversial [40–43]. With concerns mounting over the widespread use of opioids for pain management [27, 44–48], providers are increasingly seeking strategies for incorporating nonpharmacological treatment options into care plans for their patients with chronic non-cancer-related pain.

Primary care physicians need guidance in treating and coordinating care for patients with chronic pain–While the needs of patients with chronic pain may be best served by interdisciplinary approaches to pain management, much of the responsibility for overseeing and coordinating care for these patients falls upon primary care providers (PCPs). PCPs are confronted daily with the fundamental challenge of alleviating pain-related suffering in their patients, often with little additional system support. An unfortunate consequence is that the prescribing of opioids is increasingly at the center of PCPs' approach in helping their patients manage pain. While practitioners are well aware of the risks and limitations of prescribing opioids as a monotherapy for pain, they often face the difficult task of relieving pain in the absence of readily available systematic, integrated, and interdisciplinary treatment options. These care management problems are exacerbated by the fact that the great majority of PCPs have neither the time nor the training in pain management to effectively balance these important responsibilities [49].

Interdisciplinary approaches to pain management have shown promise–At a time when primary care practice in the USA is trending toward the team-based medical home model, interdisciplinary teams are able to reduce the burden of care for patients with chronic pain by delivering evidence-based treatment and providing regular feedback to PCPs on these patients. Interdisciplinary pain management interventions have, in fact, been among the most successful approaches evaluated to date [4–7]. Interdisciplinary pain programs focus on integrating a variety of therapeutic modalities (e.g., physical and occupational therapies, psychological interventions, and medical services) to address the many clinical factors that can influence pain. Less common but increasingly relevant is the participation of a pharmacist. Research suggests that pharmacist-delivered educational interventions reduce adverse events and improve satisfaction for chronic pain patients [14], but the inclusion of pharmacists as members of interdisciplinary teams in the treatment of chronic pain has been largely unexplored.

An interdisciplinary approach primarily emphasizes pain management (rather than cure) and improved function (rather than pain relief) [50, 51]. Three decades of research has illuminated the therapeutic superiority of interdisciplinary pain treatment compared to less comprehensive therapies or single-

Table 1 | Strengths and potential challenges of interdisciplinary approaches to care and pragmatic framework for implementation/evaluation of a primary care-based behavioral intervention for the treatment of chronic pain

Feature	Strengths	Potential challenges
Interdisciplinary delivery of coordinated behavioral, physical, medical, and pharmacy services	• Optimizes health-care providers' concurrent attention to multifactorial contributors to chronic pain (e.g., lack of movement/deconditioning, pain catastrophizing/low pain self-efficacy, contributing comorbidities such as smoking, overweight, and sleep apnea) • Enables consistent messaging from multiple providers to patient regarding optimal behavior change strategies to improve functioning • Integrated, tailored behavioral treatments help patients with chronic pain improve functioning, as shown in controlled trials, reviews, and meta-analyses • Reduces burden on PCPs through interdisciplinary team management of behavioral, physical, medical, and pharmacy services for patients with chronic pain and regular feedback regarding patients' progress • Reduces both fragmentation and duplication of services with potential to achieve both time and cost savings • Consistent with movement toward the medical home care model and organization of services within coordinated care organizations • Patient-centered approach brings care options to patients in an integrated fashion, potentially resulting in higher patient satisfaction	• Current health plan compensation structure for health-care services/provider billing is often not well aligned with what is needed for team treatment, resulting in (1) potentially costly co-payments if patients are charged separately to see each of the providers on the interdisciplinary team and/or (2) inability of health-care providers to perform as a truly integrated team • Likely requires an up-front insurance/health plan investment in patient care that may not be readily reimbursed through traditional billing and gains (e.g., reduction in costly diagnostic and treatment procedures and emergency/urgent care services for pain), which may accrue over a longer time frame than that which would allow the insurer or health plan to realize a return on investment within regular business cycles • Requires team members to be both well versed in their own disciplines and sufficiently familiar with the concepts and approaches of their colleagues to be able to integrate the approaches in a seamless fashion. Members must be willing to blur roles when needed and present a unified approach to patient • Requires close teamwork and frequent communication among contributing providers and respect/appreciation for each team member's contribution—a more egalitarian structure than is found in many care organizations, in which ancillary disciplines (physical therapy, behavioral specialties, nurse care management) are subordinate to PCPs in care delivery and decision-making • To deliver services within the primary care setting, appropriate intervention space must be available to the team; means of coordinated charting also optimal but may be IT infrastructure or other barriers to implementation
Pragmatic trials framework for implementation/evaluation	• Intervention conducted in real-world settings with patients, providers, and features of health-care setting representative of those targeted for broader dissemination of findings	• Requires participation of researchers with a range of skills (expertise in clinical trials, health economics, medical informatics, qualitative research/community participatory research, health systems organization, applied biostatistics)

Table 1 | (Continued)

Feature	Strengths	Potential challenges
	• Use of outcomes and predictors readily available in health delivery systems where results applied (e.g., patient self-reported pain, use of opioid medications, use of ER/urgent care services) increases relevance to health-care providers, health plans, and insurers	• Limited range of preexisting clinical instruments collected at point of care, including restrictions in domains that can be assessed and a need for analytic methods that can manage irregularity of outcome data availability across participants
	• Lower implementation costs due to use of preexisting measures (often readily available in electronic medical record) and existing clinical intervention staff	• Participant adherence to intervention likely to be variable as no special strategies to maintain compliance with "prescribed" intervention are used in pragmatic trials
	• Emphasis on measurement of broader range of outcomes (e.g., includes provider and administrator satisfaction and impact of patient-level changes on use of health services) and process measures critical for sustained delivery including cost to health-care delivery system and implementation barriers	• Careful attention to training and supervision is likely important to enable less highly trained frontline clinical staff to successfully intervene with patients, many of whom have had multiple previous treatment failures and complex multimorbid difficulties. This approach is consistent with high-quality clinical care for these patients but not characteristic of most pragmatic clinical trials
	• Potential for rapid and robust integration into feasible, sustainable, real-world health-care programs	• Ethical and regulatory issues must be addressed to perform research in the health-care delivery setting

modality interventions [52–55]. It is important to note that many treatment approaches labeled as interdisciplinary still lead to fragmented pain care, as they frequently involve patients being seen sequentially by different health-care specialists, with variable coordination between these various elements of treatment. Furthermore, there is often a failure to distinguish between multidisciplinary and interdisciplinary approaches. True interdisciplinary teams integrate treatment approaches from separate disciplines into a consistent and coherent whole, with practitioners working in close collaboration and communicating frequently to optimize patient care. This process may entail some "blurring" of roles of the various professionals on the team [56, 57]. While an integrated, interdisciplinary approach promotes highly patient-centered care that may result in time and cost savings by reducing duplication of services, potential barriers stand in the way of implementation. These include readiness of those from different disciplines to approach patient care in this fashion, as well as the necessary structural supports from the health system, e.g., common scheduling, physical space, and the ability to bundle costs for services.

Self-care plays a central role in effective pain management–A growing consensus holds that a patient-centered, primary care-based approach to pain management will benefit the greatest number of patients and that a combination of medications and nondrug therapies within a biopsychosocial framework emphasizing self-management produces the best results [1, 58]. Provider-directed treatments (e.g., prescription pain medications, therapeutic injections, nerve blocks) have limited effectiveness in ameliorating persistent pain, and research suggests that successful management of chronic pain depends largely on patient activation. Indeed, helping patients develop the skills to self-manage their condition is at the heart of interdisciplinary pain management. Critical pain management tools include finding ways to remain active, developing coping skills (e.g., stress management), and treating concomitant conditions (e.g., depression). Research suggests that while patients recognize the importance of these self-management strategies, they need the support and validation of their health-care providers to initiate and maintain such steps [59, 60]. Researchers have also found that interventions have greater reach and are less burdensome to PCPs when diverse medical professionals are engaged in guiding patients' self-management. With nurse case managers and behavioral specialists increasingly recognized as central to primary care-based efforts to help patients manage a variety of conditions (e.g.,

arthritis, diabetes, cardiovascular disorders [61–64]), health organizations and policy makers are likely more receptive in adopting an interdisciplinary team model. Chronic pain could serve as an ideal treatment area for testing such a model, because patients with chronic pain are heavy users of health-care services and medical providers face significant challenges in treating them, including increasing concerns about opioid prescribing. These factors create a window of opportunity to partner closely with health-care delivery systems in identifying robust yet realistic alternative treatment approaches for working with such patients.

PRAGMATIC CLINICAL TRIALS AND IMPLEMENTATION METHODOLOGY: BRIDGING THE GAP BETWEEN CLINICAL RESEARCH AND PRACTICE

We have posited here that an interdisciplinary clinical treatment team approach may be best suited to meet the needs of patients who suffer from chronic pain and are on long-term opioid therapy. We believe that a similar diversity of expertise stands to benefit research efforts to implement and evaluate such efforts. The inclusion of researchers well versed in the methodologies of clinical trials, mixed methods and implementation research, bioinformatics, health services, and cost-effectiveness will help ensure that the design and research findings are well positioned for clinical adoption and to inform health-care policy. We briefly summarize these key domains below.

Pragmatic trials with cost-effectiveness analyses have higher implementation potential–In pragmatic clinical trials, researchers test an intervention in a real-world setting, thereby increasing the clinical relevance and applicability of their findings. This is a major distinction from traditional randomized clinical trials (RCTs), which are focused more on creating ideal study conditions than on conducting an intervention intended for a sustained real-world practice [65]. As a result, the characteristics that predict success in treatment efficacy trials often differ from those associated with success in disseminating a treatment into real-world settings [66–68]. If the goal is to test the real-world effectiveness of an intervention, then considering the broader implementation issues in the early stages of an intervention's development–as in a pragmatic trial–becomes much more important than creating a tightly controlled research environment. Many have argued that practical, rapid-cycle RCTs can better inform the implementation process without the long delays associated with other research efforts [65, 69].

In addition to the need for more pragmatic trials, there is a need for more naturalistic research designs [65] that incorporate both quantitative and qualitative methods [70]. Specifically, the setting in which an intervention is delivered is a key factor in understanding outcomes [18]. We suggest that rather than focusing exclusively on a single primary outcome, taking a multifaceted approach that emphasizes mixed methods, adaptive learning during the trial, and multiple outcomes will best address concerns of diverse stakeholders, thereby maximizing the chance that such an intervention is adopted and sustained in real-world practice settings.

We recognize that identifying costs and potential cost offsets of behavioral interventions are critical parts of dissemination into nonacademic settings [19]–especially in the present era of rapidly rising health-care costs. The willingness of decision makers to adopt effective interventions increasingly hinges on the estimated costs of implementation [19]. Therefore, quantitative outcome analyses should be accompanied by a formative and process evaluation of the experiences of patients, clinicians, and administrators in implementing the intervention, as well as cost estimates of the program, costs of implementation, and cost offsets in opioid and specialty pain service use. Table 1 lists a number of potential economic barriers in implementing an interdisciplinary model of care. Some of these are directly cost-related (e.g., proximity of return on investment), while others represent investment in infrastructure that is needed to support this model of care but which may conflict with the existing business infrastructure for charging and reimbursing for health-care services.

Practical robust implementation and sustainability model is a conceptual model for evaluating local practices in a larger context–The practical robust implementation and sustainability model (PRISM) [71] is presented in Fig. 1. PRISM considers how the external environment, intervention design, implementation infrastructure, and adopting organization (with particular emphasis on the health-care team) influence program implementation and success. PRISM is guided by the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework [65], which emphasizes public health measures of the effectiveness of research translation into practice. RE-AIM measures results along the following dimensions: reach (how well does the intervention function with diverse patient groups?), effectiveness (how effective is the intervention overall?), adoption (how widely is the intervention adopted by practice settings and clinicians?), implementation (how consistently is it implemented by various staff, and what are the facilitators of and barriers to implementation?), and maintenance (to what extent has the intervention been sustained?). These and other aspects of PRISM were derived from work in the diffusion of innovations [72–74], supported by social ecology theories and the PRECEDE/PROCEED model, which emphasizes the multifactorial (behavioral, environmental, social) contributors to complex health problems and the importance of active audience participation (in this case patients, providers, and health plan administrators) in identifying ways to mitigate such factors [75]. These methods are intended to identify,

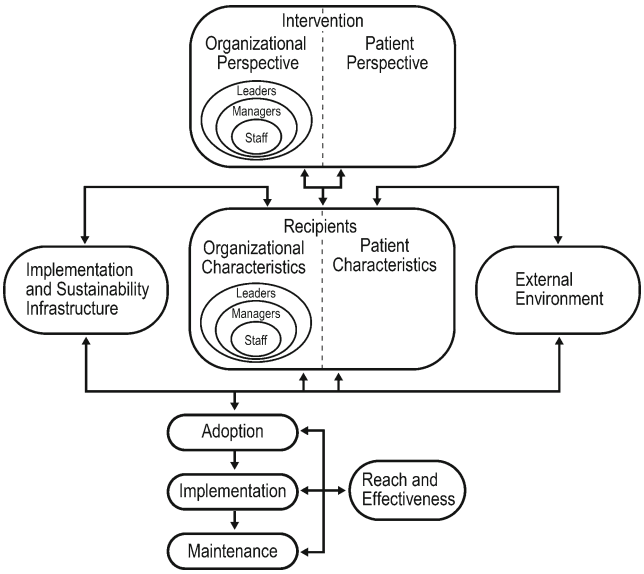

Fig 1 | The practical robust implementation and sustainability model (PRISM) [71]

document, and define key factors or "leverage points" [65] at multiple levels of influence. PRISM also borrows heavily from the chronic care model [76–79] to define critical intervention elements.

In the context of treating persistent pain, the PRISM model shows the importance of a broad treatment approach that considers the wide variety of health-care services that patients use to manage their condition. Because there are many stakeholders in the care of such patients and many perspectives among them, an effective and sustainable intervention is best ensured by the support and cooperation of those in the broader health-care environment. Of particular relevance here is the early and active partnership of "champion" PCPs to advise on how the intervention is structured and how the care delivery model might be refined (e.g., the format of the interdisciplinary team's feedback regarding patient functioning). Such partnerships ensure that the intervention approach integrates well into everyday practice and thus optimizes the engagement of already overwhelmed PCPs in the trenches of frontline clinical care.

Formative evaluation: a structured approach to implementation research–Formative evaluations provide structured methods for conducting implementation research protocols. Most formative evaluations are phased [80]: First, data collection focuses on key influences for success (degree of less-than-best practice, determinants of current practice, potential barriers and facilitators to change, and strategy feasibility, including perceived project utility). The second stage is a process- and implementation-focused evaluation. This phase begins during initial implementation and identifies influences that may not have been anticipated from the developmental analyses. Later phases of process and implementation evaluations provide information about the intervention necessary to continuously adapt and improve intervention processes and outcomes. Finally, an interpretive evaluation designed to illuminate the "black box" of implementation uses data from the previous parts of the evaluation, which are often combined with information from key stakeholders to understand what was really required to implement the intervention, how it affected the individuals concerned, whether it is perceived as successful or not, and whether stakeholders believe that it was "worth" the effort.

Electronic medical records are instrumental in pragmatic clinical trials–Some have touted health information technology as the key path in improving the health-care system [81], citing the ideal of a "learning health-care system" in which every patient encounter produces useful information that researchers and clinicians can learn from in near real time [82]. It is certainly true that health information technology tools are changing how care is delivered and creating new clinical research opportunities. The recently enacted Health Information Technology for Economic and Clinical Health (HITECH) [83] Act, part of the 2009 economic stimulus package, provides $27 billion over 10 years for the adoption of electronic medical records (EMRs) nationwide [83]. With large health-care systems having long used such integrated EMRs, the HITECH legislation makes these results broadly generalizable, as nearly all US health-care providers are likely to be using EMRs over the coming decade [84]. Thus, studies that leverage the EMRs to track patient participants and collect quantitative outcomes data are increasingly feasible. However, because EMR systems were not designed with research in mind, researchers who seek to utilize EMR data must ensure that their study team includes bioinformatics experts who can transform EMR data into a form usable by researchers.

PUTTING THE PIECES TOGETHER: A PRIMARY CARE-BASED INTERDISCIPLINARY TEAM APPROACH TO THE TREATMENT OF CHRONIC PAIN UTILIZING A PRAGMATIC CLINICAL TRIALS FRAMEWORK

We have highlighted here the importance of interdisciplinary teams in the clinical treatment of chronic pain, as well as in carrying out the research needed to evaluate the benefits of such care. Table 1 summarizes the strengths and the potential challenges of the proposed interdisciplinary team approach and the pragmatic trials framework for implementation and evaluation. Utilizing a diverse clinical team that includes physicians, behavioral specialists, physical therapists, nurse case managers, and pharmacists working in a closely coordinated fashion within the primary care setting would not only reduce the potential burden on often-overtaxed PCPs but would also better integrate services that are often delivered in a fragmented manner. Furthermore, because this model could be applied to multiple chronic diseases and conditions where pain is a feature, it has a broad potential impact. Finally, we have emphasized the benefits of using an interdisciplinary team to design and evaluate such programs. Including clinical trialists, qualitative and implementation researchers, bioinformaticists, health services researchers, and health economists will ensure a rigorous evaluation of the effectiveness of this clinical approach. A diverse interdisciplinary team will also ensure that sufficient attention is given to factors affecting implementation in everyday practice settings, as well as other outcomes of importance to health plan administrators and policy makers.

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