A Multicomponent Intervention to Improve Primary Care Provider Adherence to Chronic Opioid Therapy Guidelines and Reduce Opioid Misuse: A Cluster Randomized Controlled Trial Protocol ☆

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ABSTRACT

Background: Prescription opioid misuse is a significant public health problem as well as a patient safety concern. Primary care providers (PCPs) are the leading prescribers of opioids for chronic pain, yet few PCPs follow standard practice guidelines regarding assessment and monitoring. This cluster randomized controlled trial will determine whether four implementation strategies; nurse care management, use of a patient registry, academic detailing, and electronic tools, will increase PCP adherence to chronic opioid therapy guidelines and reduce opioid misuse among patients, relative to electronic tools alone. The implementation strategies and intervention content are based on the chronic care model.
Methods: We include 53 PCPs from three Boston-area community health centers and one urban safety-net hospital-based primary care practice who have at least four patients meeting the following inclusion criteria: 1) age ≥ 18; 2) one or more completed visits to the primary care practice in the past year; 3) long-term opioid treatment defined as three or more opioid prescriptions written at least 21 days apart within 6 months and 4) an inpatient or outpatient ICD-9-CM diagnosis for musculoskeletal or neuropathic pain. We consider PCPs to be study subjects, and obtained a waiver of informed consent for patients because the study is promoting an established standard of care. We enrolled participants (PCPs) from December 2012 through March 2015. PCPs were randomized to receive the intervention, which includes four components: 1) nurse care management, 2) use of a patient registry, 3) academic detailing, and 4) electronic tools, or a control condition, which includes only the use of the electronic tools. The intervention PCPs receive the services of a nurse-managed registry for planning individual patient care and conducting population-based care for patients receiving opioids for chronic pain. In academic detailing visits, trained co-investigators provide intervention PCPs with individualized education to change prescribing practice. Electronic tools, located on a web site external to the EMR, www.mytopcare.org, include validated instruments to assess patient status, and management resources to facilitate PCP adherence to suggested monitoring. Electronic tools are available to PCPs in both study arms. The primary outcomes are PCP adherence to chronic opioid therapy guidelines and patient opioid misuse. Secondary outcomes include measures of substance abuse, possible opioid diversion, and level of opioid risk among patients. We will follow PCPs and their estimated 1200 chronic pain patients for 1 year after study enrollment. To determine whether the intervention condition achieves greater adherence to guidelines and reduced opioid misuse after 1 year compared to the control condition, we will compare the baseline and follow-up measures of the individual patients, stratifying by intervention status and noting differences that are statistically significant at the p = 0.05 level. Analyses will be based on intent-to-treat.
Results: Randomization resulted in groups with similar baseline characteristics. The ages of PCPs are evenly distributed, with inclusion of both PCPs who have recently completed training and those who have been in practice for more than 20 years. Two-thirds of enrolled PCPs are women, and one-third are non-white.
Discussion: The study will determine the impact of this multicomponent intervention on improving PCP adherence to guidelines and reducing opioid misuse among patients.

1. Introduction

Prescription opioid misuse is a significant public health problem and a patient safety concern. Studies have shown alarming rises in opioid abuse, addiction, diversion, and unintentional overdoses over the last 15 years (Substance Abuse and Mental Health Services Administration,

2007). Primary care providers (PCPs) are the leading prescribers of opioids for chronic pain, yet few follow practice guidelines regarding assessment and monitoring (Ballantyne & Mao, 2003; Morasco, Duckart, & Dobscha, 2011; Starrels et al., 2011). Based on the best available evidence, clinical guidelines endorse universal assessment for opioid misuse risk and monitoring for subsequent harm (Chou et al., 2009; Gourlay, Heit, & Almahrezi, 2005). The guidelines suggest that monitoring strategies for all chronic pain patients on long-term opioid therapy should be implemented according to patient risk level for opioid misuse. Patient risk level should be identified through individual risk factors, such as substance use disorders or psychiatric diagnoses. Recommended monitoring strategies include a controlled substance agreement, urine drug testing, frequent PCP visits, pill counts (to ensure that a patient is not diverting or misusing medications), use of state prescription monitoring programs (PMPs) that provide data on individual pharmacy fills of controlled substances, and addressing aberrant opioid-taking behaviors (Passik & Kirsh, 2004). Given that evidence supports these individual components (Carter & Hall, 2008; Chou et al., 2009; Katz et al., 2010; Manchikanti et al., 2006; Wang & Christo, 2009), the goal of this study is to implement and test an enhancement to usual care to improve uptake of the monitoring strategies, thus addressing the pressing need for an effective clinical approach to the mounting problems of opioid misuse.

We based our intervention on the chronic care model (Fig. 1) (Bodenheimer, Wagner, & Grumbach, 2002). This model is designed to help practices improve patient outcomes by changing routine delivery of ambulatory care through six interrelated system changes (health care organization, clinical information systems, delivery system design, decision support, self-management support, and community resources) meant to make patient-centered, evidence-based care easier to accomplish. The aim of the model is to transform daily care for patients with chronic illnesses from acute and reactive to proactive, planned, and population-based. It is designed to accomplish these goals through effective team care and planned interactions; self-management support bolstered by use of community resources; integrated decision support; and patient registries and other supportive information technology (IT). These elements work together to strengthen the PCP–patient relationship and improve health outcomes.

Our intervention approach maps to the domains of the chronic care model (Table 1) and is fashioned to take advantage of the documented efficacy of the individual intervention elements (nurse care management, patient registry, academic detailing, and electronic tools) to change PCP practices and improve patient outcomes. Quality improvement interventions in community health centers which have included disease registries in the setting of the chronic care model, most notably in the Health Disparities Collaboratives of the Health Resources and Services Administration (HRSA), have shown improvement in processes of care for asthma and diabetes (Landon et al., 2007). Electronic tools (which map to the decision support domain of the chronic care model) such as on-screen, point-of-care computer reminders have been shown to achieve improvements in PCP behavior, medication prescribing, and test ordering (Shojania et al., 2009). Academic detailing (which maps to the clinical information systems domain of the chronic care model and includes feedback on PCP performance) has been shown to improve how health care professionals prescribe medications, which may affect hundreds of patients (O'Brien et al., 2007; Solomon et al., 2001). Nurse care management, which maps to the self-management support, delivery system design, and decision support domains of the chronic care model, has been shown to improve patient pain outcomes for patients with chronic non-cancer pain (Kroenke et al., 2009, 2014). In this study, both intervention and control PCPs receive electronic tools on an external web site (www.mytopcare.org) to facilitate guideline adherence. These tools include validated instruments to assess patient status and facilitate PCP adherence to suggested monitoring.

The intervention PCPs receive the services of a nurse-managed registry for planning individual patient care and conducting population-based care for patients receiving opioids for chronic pain. Finally, in academic detailing visits, trained co-investigators meet with intervention PCPs to provide them with individualized education (including audit and feedback) to change prescribing practice. We are unaware of studies that have implemented the combination of these approaches to improve management of patients with chronic pain on opioid therapy. We believe that this is a highly innovative approach to improving PCP adherence to guidelines and, potentially, to reducing patient risk for developing substance use disorders.
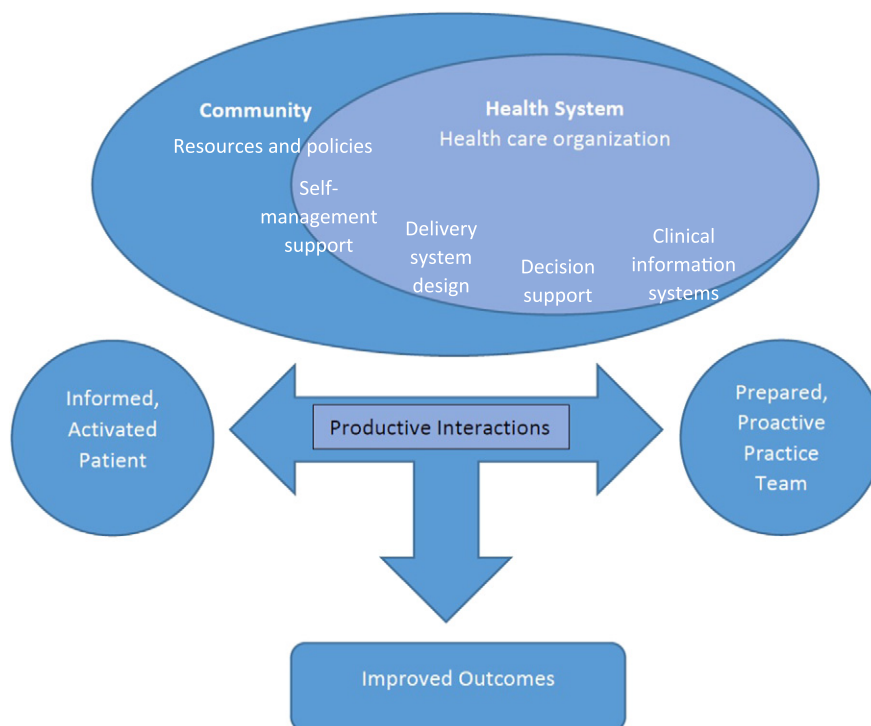

Fig. 1. Chronic care model.