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Opioid pharmacovigilance: A clinical-social history of the changes in opioid prescribing for patients with co-occurring chronic non-cancer pain and substance use

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ABSTRACT

There is growing concern among US-based clinicians, patients, policy makers, and in the media about the personal and community health risks associated with opioids. Perceptions about the efficacy and appropriateness of opioids for the management of chronic non-cancer pain (CNCP) have dramatically transformed in recent decades. Yet, there is very little social scientific research identifying the factors that have informed this transformation from the perspectives of prescribing clinicians. As part of an on-going ethnographic study of CNCP management among clinicians and their patients with co-occurring substance use, we interviewed 23 primary care clinicians who practice in safety-net clinical settings. In this paper, we describe the clinical and social influences informing three historic periods: (1) the escalation of opioid prescriptions for CNCP; (2) an interim period in which the efficacy of and risks associated with opioids were re-assessed; and (3) the current period of "opioid pharmacovigilance," characterized by the increased surveillance of opioid prescriptions. Clinicians reported that interpretations of the evidence-base in favor of and opposing opioid prescribing for CNCP evolved within a larger clinical-social context. Historically, pharmaceutical marketing efforts and clinicians' concerns about racialized healthcare disparities in pain treatment influenced opioid prescription decision-making. Clinicians emphasized how patients' medical complexity (e.g. multiple chronic health conditions) and structural vulnerability (e.g. poverty, community violence) impacted access to opioids within resource-limited healthcare settings. This clinical-social history of opioid prescribing practices helps to elucidate the ongoing challenges of CNCP treatment in the US healthcare safety net and lends needed specificity to the broader, nationwide conversation about opioids.

1. Introduction

Concerns about increases in the prescription, use, and misuse of opioid analgesics have garnered national attention in scientific, political, and media domains (Dowell et al., 2016; The White House, 2016; Newkirk, 2016). The number of opioid prescriptions increased dramatically between the late-1990s and mid-2000s (Manchikanti and Singh, 2008). The Centers for Disease Control (CDC) reported that by 2006, more unintentional overdoses were attributed to prescription opioids than to heroin and cocaine combined (CDC, 2011). Scientific evidence of a link between the increase in prescription opioids and a wide-spread overdose "epidemic" influenced a call for reform in the medical community, governmental regulatory bodies, and in the larger public domain (American Medical Association (AMA), 2016).

Chronic non-cancer pain (CNCP), defined as pain that persists for greater than three months not caused by a malignancy or associated with pain at the end of life (Trescot et al., 2008), affects approximately 25% of the United States (US) adult population and causes significant decrements in quality of life (Chou et al., 2009). CNCP interferes with a person's ability to perform activities of daily

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living, family life, and employment, and is associated with significant psychological stress (Gureje et al., 1998). The efficacy and appropriateness of prescription opioids for acute pain management are well documented (Carr and Goudas, 1999). However, the efficacy of chronic opioid therapy for CNCP is being re-evaluated due to a lack of evidence demonstrating functional improvements, significant side effects (e.g., endocrine and sleep disruption, opioid dependence, overdose, constipation, mental status changes) and community harm resulting from non-medical use of prescribed opioids (e.g., overdoses, violence, increased policing associated opioid misuse) (Ballantyne and Shin, 2008; Noble et al., 2010; Schrager et al., 2014).

The majority of Americans receive treatment for CNCP in primary care settings, not in pain specialty care clinics (Institute of Medicine (IOM), 2011). CNCP is a common condition among persons with co-occurring substance use disorders (Morasco et al., 2011). Safety net healthcare settings, defined by the Institute of Medicine (IOM) as those settings that "offer care to patients regardless of their ability to pay for services and [for which] a substantial share of their patients are uninsured, Medicaid, or other vulnerable patients," (Dunn et al., 2010) serve a disproportionate number of patients with co-occurring CNCP and substance use disorder, making them important clinical settings to study changes in opioid prescribing (Sullivan et al., 2008). Patients may be initiated on opioids in safety net emergency departments (ED), or use this venue to obtain opioids, leading to an active debate about the impact of ED opioid guidelines on safety net primary care (Barnett et al., 2017). CNCP patients with a history of substance use are more likely to be prescribed opioids, than patients without a history of substance use (Ives et al., 2006; Fishbain et al., 2008). Opioid analgesic misuse, defined as "the use of any drug in a manner other than how it is indicated or prescribed", and aberrant behaviors including diverting prescriptions for non-medical use, altering the route of administration, or forging prescriptions, are more common among individuals with a history of substance use and mental health disorders (Turk et al., 2008).

This paper explores the phenomenon of opioid prescribing for CNCP from the perspective of primary care clinicians (clinicians) who treat CNCP patients with a history of substance use (past or current). Although many studies have described the social and health consequences of opioid-associated overdose morbidity and mortality, little research has offered contextual information about the opioid prescribing of clinicians. An in-depth understanding of the educational, clinical, and social factors that contribute to opioid prescribing can improve responses to the unintended consequences of current opioid prescription practices. We describe the recent clinical-social history of opioid prescribing by examining factors that influence clinicians' opioid treatment decision-making processes. We elaborate on the potential unintended consequences of "opioid pharmacovigilance," the emergent climate of increased restriction on opioid prescriptions.

2. Theoretical orientation and historical context

Historically informed, social medicine studies of diabetes, sickle cell anemia, schizophrenia, cancer, and HIV/AIDS reveal how scientific, cultural, and social influences coalesce to inform clinical decision-making (Montoya, 2011; Rouse, 2009; Metzl, 2009; Jain, 2013; Epstein, 1998; Farmer, 1992). Clinicians' responses to a given disease are embedded within a larger social milieu (Stonington and Holmes, 2006). The need to "do something" - to respond to suffering - is felt by both clinicians and patients. Multiple factors influence how these responses might be enacted in clinical settings. In day-to-day decision-making about appropriate treatment, the expertise of an individual clinician, current scientific evidence, and social and political forces play important roles (Knight, 2015; Holmes, 2013).

Medical anthropologists have long been engaged in a critical examination of the phenomena of pain. Much of this early work addressed the impact of structural factors (e.g., disability claims, insurance status) on a chronic pain diagnosis, described the phenomenological experience of pain from the patients' perspectives, and explored miscommunication between patients and clinicians about chronic pain's etiology and validity (Good et al., 1992). More recent anthropological investigations (Greenhalgh, 2001; Buchbinder, 2015; Crowley Matoka and True, 2012) are focused on the diagnosis and treatment of pain within diverse clinical specialties and settings, and describe cultural norms and expectations about opioid prescriptions and clinicians' "anxiously ambivalent responses to pain and pain medications." (Crowley Matoka and True, 2012: 689) Historical examinations of the emergence of pain medicine (Baszanger, 1998) and the rise in the number of specific opioid prescriptions (Wailoo, 2015) underscore the importance of social and political context.

Drawing from this more recent turn toward the experiences of clinicians and an examination of the construction of a "clinical culture" (Boutin-Foster et al., 2008), we investigated clinicians' perceptions about opioid prescribing for CNCP. Our analysis offers perspectives that were not well studied, including how clinicians reflected on the social and historical context of their education about pain management; grappled with a lack of scientific evidence for opioid efficacy; and assessed the potential positive and negative consequences of increased surveillance of opioid prescribing.

We triangulated our qualitative interview data with epidemiological findings about national opioids prescriptions, overdose morbidity and mortality, and substance abuse treatment enrollment data, and historical analyses of the US opioid epidemic to identify three historical periods in which clinical understandings about opioids for pain management and practices of opioid prescribing experienced significant transitions. The three recent historical periods in which this analysis is situated are:

(1) A period of increases in opioid prescriptions (1990s through mid/late 2000s). See Fig. 1.
(2) A "pendulum swing" toward increased scrutiny about the safety and the efficacy of chronic opioid therapy (mid-2000s to approximately 2011).
(3) Increased opioid prescription surveillance (opioid pharmacovigilance) in which national, state, and clinical-level polices are implemented to curtail opioid prescriptions for CNCP (2011- present).

"Pharmacovigilance" is "defined as a set of practices aimed at the detection, understanding, and assessment of the risks related to the use of drugs in a population" (Langlitz, 2009:395). According to World Health Organization (WHO), "the aims of [p]harmacovigiliance are to enhance patient care and patient safety in relation to the use of medicines, and to support public health programs by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines." (WHO, 2006:8) Pharmacovigilance is considered essential to the modern governance of pharmaceutical medications and modern medicine. We use the term "opioid pharmacovigilance" to describe the current focus on patient and public safety in relationship to opioid prescribing. We document clinicians' experiences with changing patterns of opioid prescribing to explore how medical education, clinical experiences, scientific evidence, concerns about individual versus community health, and prescription guidelines coalesce to affect clinicians' management of CNCP.