

**Understanding Pain Specialists' Decision-Making on Prescription of  
Opioids for Chronic Non-Cancer Pain**

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**Thesis Declaration Form**

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

**Signature:**

**Name:** Bernice Lee

**Date:** 5<sup>th</sup> September 2019

## Overview

**Part 1** comprises a systematic review of the exploration of psychological variables in surveys on beliefs of physicians on opioids for chronic non-cancer pain. Fifteen papers met the study criteria and were reviewed. Psychological variables were studied in nine studies and are categorized into two themes – ‘confidence and comfort’ and ‘trust and ambivalence’. Evidence for the influence of psychological variables on decision-making on opioid prescribing is poor.

**Part 2** describes an empirical paper investigating the factors, including patients’ and physicians’ emotions, influencing the decision-making processes of pain specialists (N = 14) treating patients with chronic non-cancer pain using opioids. Thematic analysis yielded six themes: 1. Adhering to best practice; 2. Thorough understanding and application of expertise on opioids; 3. Paying attention to patient factors; 4. Maintaining doctor-patient relationship; 5. Clinicians’ emotions have little bearing on decisions; and 6. Recognising limitations of current prescribing climate. The findings suggest that both patients’ and clinicians’ emotions have some influence on clinicians’ decisions in the management of chronic pain.

**Part 3** is a critical appraisal that discusses the challenges encountered during the research process, examines the underlying assumptions and concludes with reflections on conducting qualitative research.

## **Impact Statement**

Findings from the literature review suggest that psychological factors that may affect physicians' attitudes and beliefs on opioids for treating chronic non-cancer pain are not well researched. In studies which investigated psychological factors, conclusions drawn on these factors' impact on decision-making in regard to opioid prescribing are questionable. Prevalent methods of surveying doctors' attitudes on opioid prescribing through self-report measures, e.g. surveys, are not ideal; instead, future research should aim to better understand what actually happens during clinical consultations, including through live or recorded observational methods.

Findings from both the literature review and the empirical paper indicate that drug and patient characteristics are frequently cited in considering the suitability of opioid treatments for patients with chronic non-cancer pain. Despite physicians' claims to be practicing evidence-based medicine by following clinical guidelines, various studies from a review of the literature have found that physicians reported prescribing opioids under pressure or when no alternative options were available even when opioids were not indicated. Such actions are concerning both in terms of potential harm to patients, as well as on a broader societal level, since over-prescribing of opioids increases the risks of misuse and death by drug overdose, and increases healthcare costs for little or no benefit. Further research is required to understand factors influencing practice of safe and unsafe prescribing.

The empirical project, a qualitative study of 14 experienced pain consultants, found that those sampled rarely prescribed or increased opioids in their clinical practice; they tended to recommend tapering or stopping them instead, in line with current

evidence that opioids do not demonstrate long-term benefits for patients with chronic non-cancer pain. It also identified both patients' (as appraised by physicians) and physicians' emotions with influence on physicians' decisions in the management of chronic pain. However, reliance on physicians' self-report has limitations for understanding the influence of emotions on clinical consultations and the patient-physician relationship, especially in the context of a prevalent medical culture that de-emphasises the role of emotions in medical practice. Particularly in the field of chronic pain, the therapeutic alliance has been identified as a key factor in influencing treatment outcomes (Matthias et al., 2014).

The results of this study have implications for how physicians approach consultations and reflect on their decision-making, recognising that emotions, both the patient's and their own, affect clinical decisions. Acknowledging patients' psychological and emotional distress, engaging in joint decision-making and developing mutual trust are essential to the patient-physician relationship. Furthermore, it is important for physicians to acknowledge how they feel in themselves, to recognise the potential influence of work and personal stressors on work performance, and to attend to how their emotions potentially influence the thought processes involved in decision-making. There is an urgent need for more openness (and safeness) for conversations about physicians' emotions and emotional wellbeing to occur. Medical education providers may want to consider their teaching of skills that build therapeutic alliance, and opportunities for reflective practice.

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**Part 1: Literature Review**

**A Systematic Review of Psychological Variables in Surveys on Physicians'**

**Beliefs toward Opioids for Chronic Non-Cancer Pain**

## Abstract

**Aims:** The systematic review aimed to explore the psychological variables in surveys on attitudes toward opioids for treating chronic non-cancer pain and to investigate the relationship between psychological variables and clinical decision-making.

**Method:** Three databases, PsycINFO, MEDLINE and EMBASE, were searched for articles published in peer-reviewed journals that surveyed physicians' attitudes and beliefs about opioids for treating chronic non-cancer pain.

**Results:** Fifteen articles were included in the review. Psychological variables in the surveys were extracted from nine studies and categorised. The findings showed two themes of psychological variables – Confidence and Comfort, and Trust and Ambivalence. Four studies which included data on prescribing practices showed that greater confidence in opioid prescribing and clinical skills was associated with greater satisfaction in prescribing and the belief that opioids were useful for patients with chronic pain. Lower trust toward patients was associated with lower prescribing frequency.

**Discussion:** Psychological variables are given little consideration in cross-sectional studies examining physicians' attitudes toward opioids for treating chronic non-cancer pain. The findings in the reviewed studies relating to the influence of psychological variables on clinical decision-making on opioid prescribing are questionable. Future research should further investigate psychological aspects in the patient-provider relationship on clinical decision-making and treatment outcomes.

## **Introduction**

### **Chronic Pain**

Chronic pain is defined as an unpleasant sensory and emotional experience that persists for more than three to six months (Bogduk & Merskey, 1994). Chronic pain is regarded by some as a disease in its own right and not merely as a symptom of other diseases (Niv & Devor, 2004). In the United Kingdom (UK), the most common causes of chronic pain are osteoarthritis and rheumatoid arthritis, and traumatic injury (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006). The economic and social costs of chronic pain can be substantial, presenting a burden that is as great as that imposed by health conditions prioritised as public health concerns (Breivik, Eisenberg, & O'Brien, 2013). In the United States (US), the total costs associated with chronic pain in adults are reported to exceed those estimated for heart diseases, cancer and diabetes (Gaskin & Richard, 2012). With an aging population and increasing prevalence rates of chronic pain in the UK and other developed countries (Fayaz, Croft, Langford, Donaldson, & Jones, 2016), there is a growing urgency to address issues around effective treatment and management of chronic pain, and of improving or maintaining quality of life and functioning.

### **Opioids for Treating Chronic Pain**

Opioids are routinely used in the treatment of acute and cancer pain, and their short-term use is, on the whole, recognised as an established and effective first-line treatment (Fields, 2011). In the 1990s to the early years of this millennium, the use of opioids became increasingly popular in treating chronic pain, in line with a healthcare ethos of improving the quality of life, e.g. achieving pain relief, regaining work and social functioning and improving mental wellbeing, for people living with chronic pain. Early guidelines recommended the use of opioid therapy for chronic pain in conjunction with a range of treatment modalities for appropriately selected

patients (Consensus Statement from the American Academy of Pain Medicine and the American Pain Society, 1998; Goucke, 2001; Kalso et al., 2003). Many studies were conducted to understand physicians' attitudes and beliefs about opioids (e.g. Turk & Okifuji, 1997; Onishi et al., 2017), including their knowledge and adherence to clinical guidelines (e.g. Allen, Asbridge, Macdougall, Furlan, & Tugalev, 2013) and to propose recommendations to improve the quality of care for patients with chronic non-cancer pain (e.g. Sullivan, Leigh, & Gaster, 2006).

In response to feedback from primary care physicians, there was a consequent move to develop and promote professional development programmes targeting opioid education so as to improve the treatment and management of chronic pain (e.g. Regunath et al., 2016). In some studies, the aims of education were to increase physicians' knowledge and comfort with prescribing strong opioids, but it is unclear whether education actually translates into good prescribing decisions, i.e. decisions that would effect improved management of chronic pain. For instance, a study by McCracken and colleagues (2012) using an educational intervention for GPs in relation to opioid guidelines showed that training was associated with increased knowledge of opioids for chronic pain and decreased concerns about adverse effects of opioids, but did not show significant changes in the frequency or reluctance to prescribe opioids. Furthermore, there is a lack of consensus as to the factors that constitute a good prescribing decision. If opioid interventions are made on the basis of each patient's needs, then the success of education should not be measured in increased or decreased percentages of opioid prescriptions to patients with chronic pain (Katzman et al., 2014). The study by Katzman and colleagues reported a decline in high-dose opioid prescriptions concurrent with an increase in low-dose opioid prescriptions (expressed as percentages of all opioid prescriptions over a period of

three years). This suggests that while opioid prescribing patterns may not necessarily have changed significantly, physicians are prescribing them more safely and perhaps as a consequence from an increasing awareness of the lack of efficacy of long-term use of opioids. What is needed is a more nuanced approach to defining and measuring the impact of education on actual prescribing practices, wherein prescriptions are made in accordance with the patient's needs, whether the clinical decision is to increase, decrease or stop opioids altogether.

### **The Opioids Debate**

The efficacy of long-term opioid use for chronic pain has been questioned (Ballantyne & Shin, 2008), with no strong indication of clear analgesic benefits. What has been well-documented are the common side effects on patients such as constipation, nausea and sleep disturbances (Kalso, Edwards, Moore, & McQuay, 2004). More worrying are the longer-term adverse effects of addiction, cognitive dysfunction, respiratory depression, sleep apnoea, endocrine dysfunction and/or hyperalgesia which have begun to surface in recent years following more detailed follow-up (Angst & Clark, 2006; Daniell, 2008; Furlan, Sandoval, Mailis-Gagnon, & Tunks, 2006). Other barriers to prescribing opioids include the lack of access to pain specialist resources, time constraints and regulatory barriers. The latter factor appears to be more relevant to physicians in the US than in the UK (Weisberg, Becker, Fiellin, & Stannard, 2014). Whereas physicians were once reluctant to prescribe opioids because of concerns regarding side effects, lack of knowledge of safe opioid prescribing and/or a misdirected understanding of the likelihood of consequences such as addiction and drug diversion, now it appears that those who err on the side of caution are likely to be considered as adhering to current best practice (Nuckols et al., 2014).

In primary care practice, physicians who tended to self-report higher reluctance to prescribe strong opioids also had higher levels of concerns about long-term commitment to prescribing strong opioids, patients misusing medication or developing physical dependence, and inadequate training in prescribing pain medications (Blake, Leighton, van der Walt, & Ravenscroft, 2015).

A study of UK general practitioners found that reluctance to prescribe opioids was associated with being female, more years in practice and less specialist training (McCracken, Velleman, & Eccleston, 2008). It is also somewhat concerning to note that prescribing practices have been found to be consistently correlated to clinicians' beliefs about opioids, and less so to sociodemographic or contextual variables (Hutchinson, Moreland, Williams, Weinman, & Horne, 2007) or to knowledge and practice of clinical guidelines for treating chronic pain. A study by Mordecai and colleagues (2018) showed that prescribing practices varied by region and socioeconomic status – higher opioid prescribing rates were located in the north of England, and in areas of greater social deprivation.

European primary care physicians find chronic pain challenging to treat, and were less confident in prescribing opioids for chronic pain compared to prescribing opioids for cancer pain (Johnson, Collett, & Castro-Lopes, 2013). Among those who reported high confidence in using strong opioids for chronic pain (23% of 1305 physicians), common reasons given for their confidence were the availability of treatments (unspecified) and experience, i.e. practitioners with fewer years of clinical practice ( $\leq 5$  years) reported greater confidence in prescribing compared to practitioners who had practiced for longer. Reasons for low confidence included concerns about addiction or abuse and adverse events. These findings are consistent with studies investigating reluctance to prescribe opioids; increased reluctance / low



confidence was associated with more years in clinical practice (McCracken et al., 2008) and concerns about drug misuse and dependence (Blake et al., 2015). This suggests that there may be a correlation between reluctance and confidence and subsequent impact on opioid prescribing.

Physicians also reported chronic dissatisfaction in treating chronic pain patients (Walker, Katon, Keegan, Gardner, & Sullivan, 1997). The patient characteristics most associated with physician frustration were patients' perceptions of greater lack of control over their illness, poor social support and ongoing preoccupation with their symptoms, thereby resulting in a state of increasing demands on the healthcare system that the physician may perceive as excessive.

### **The Role of Clinical Practice Guidelines**

Research in the past decade indicate that long-term use of opioids for treating chronic pain yields little benefit, and may in fact be detrimental to overall health. This has prompted the publishing of updated clinical guidelines (British Medical Association, 2017; Dowell, Haegerich, & Chou, 2016), detailing recommendations for the use of opioids for treating chronic pain. While the benefits of short-term opioid use are well documented, more evidence is required to justify decisions for prescribing opioids in the long term for chronic pain patients (Fields, 2011). Contrary to physicians' beliefs that the primary function of opioids is providing analgesic relief (Duensing et al., 2010), current guidelines recommend that opioid effectiveness is best evidenced by improved functioning rather than by pain relief (Kahan, Mailis-Gagnon, Wilson, & Srivastava, 2011). The systematic review by Dowell et al. (2016) highlights that contemporary clinical guidelines draw on evidence which is based on clinical observations and expert opinion, and is classed as low in quality under GRADE methodology (Guyatt et al., 2008). It should be noted that evidence and

recommendations from clinical guidelines, while useful as a tool to appraise the complexities of clinical decisions, are insufficient for every clinical decision that a provider needs to make (Reuben et al., 2015). Thus, effective decision-making requires a reliance on physicians' clinical judgment and experience, and an appreciation and careful application of the multiple aspects of treatment and management for chronic pain, particularly where opioids are concerned.

### **Measuring Physicians' Attitudes towards Opioids for Treating Chronic Pain**

There are several questionnaires and scales designed to measure attitudes and beliefs of physicians towards opioids for treating chronic pain. For instance, the Clinicians' Attitudes about Opioids Scale (CAOS; Wilson et al., 2013) is used to measure clinicians' beliefs in regards to perceived effectiveness of opioids, impediments and concerns about opioid use, differences between weak and strong opioids and the influence of medical education. Many more questionnaires exist that have not been psychometrically validated but were developed to investigate specific aims.

Some studies opt for a qualitative approach via semi-structured interviews. These seek to understand physicians' beliefs on a phenomenological level and to further describe complexities in decision-making that may not be captured through surveys which only have limited response options and little room for elaboration (e.g. Harle et al., 2015). The questions that are being asked and the specific variables under consideration, therefore, are important in understanding how physicians' beliefs about opioids influence the ways by which they make decisions and how they might approach what is often a difficult and emotion-laden subject with highly-distressed patients.

## **Decision-making in Opioid Prescribing**

Normative theories of medical decision-making such as expected utility theory (EUT; Pauker & Kassirer, 1975) and evidence-based medicine (Djulbegovic, Guyatt, & Ashcroft, 2009) operate on the assumption of how people ‘should’ make decisions, and that they are motivated to maximise utility and thus, behave accordingly. However, normative theories fail to account for contextual factors and individual differences.

Conversely, descriptive theories of rational decision-making explain how people actually make decisions; by accounting for the characteristics of the decision (e.g. high stakes versus low stakes situations), context (e.g. time pressure, cognitive load, social context) and individual differences (e.g. cultural background, professional background, decision-making styles). Therefore, decisions are context-sensitive, requiring adaptations to the problem at hand based on the considerations of any or all of the above factors exerting an influence on the decision-making process and outcome (Djulbegovic & Elqayam, 2017). The threshold model further explains practice variance; physicians act differently because of different ways of cognitively assessing disease probability or in weighing up the benefits and harms of medical interventions. Physicians who are more sensitive to harms than benefits would be said to have higher thresholds than an EUT analysis would prescribe (Djulbegovic, Hamm, Mayrhofer, Hozo, & van den Ende, 2015). These physicians are perhaps the ones who report greater reluctance to prescribe opioids for chronic pain, assuming all other factors being constant.

The literature on clinical decision-making is sparse (Hozo, Tsalatsanis, & Djulbegovic, 2016), but the authors suggest that clinicians and policy makers should pay close attention to the implications of applying different decision-making models

because the differences can be significant. Taken in conjunction with evidence showing that several years after the US opioid epidemic alarms were raised (Office of National Drug Control Policy, 2011), the crisis has shown little sign of abating; one area highlighted was a call to improve clinical decision-making in the hopes of making real change happen (Davis, Green, & Beletsky, 2017).

### **Aims**

This review seeks to answer two questions. Firstly, what psychological variables, if any, are surveyed in studies investigating the beliefs of physicians about opioids for chronic non-cancer pain. A majority of the studies on physicians' beliefs survey concerns relating to opioid effects and patient and physician factors. However, there might be other factors which relate less to medical or logistical characteristics but that involve specific psychological aspects of physicians' attitudes toward opioids. Psychological aspects may be defined as those which encompass mental states and processes such as motivation, perception, control and affect. For instance, perceived trustworthiness (by both patient and physician of the other) in the therapeutic encounter relate to a shared understanding of the problem and may promote better pain care (Buchman, Ho, & Illes, 2016). On the physician's part, the association of patient satisfaction with opioid therapy provision suggests that the culture of consumerism exerts a stronger effect compared to other variables such as evidence-based treatments (Wallace, Freburger, Darter, Jackman, & Carey, 2009). Other factors contributing to long-term prescribing include perceived (or actual) lack of alternative treatment options and a mutual lack of control, whereby GPs felt pressured to be helpful, usually by increasing opioid therapy (McCrorie et al., 2015).

Secondly, having identified the psychological variables in the survey questions posed to physicians, the second research question is concerned with how

these variables relate to physicians' actual decision-making in prescribing opioids. Of interest is how psychological factors might interact with or influence physicians' knowledge (and practice) of clinical practice guidelines, or relate to the reported reluctance of physicians in prescribing opioids, especially in a climate in which prescribing rates continue to increase (NHS Digital, 2017). Clarity on how and why physicians ascribe differing weights to medical and contextual factors to their decision-making, in reference to the threshold model, will be sought.

In summary, this study aims to review the literature on the surveys targeting beliefs of physicians on opioids for treating chronic non-cancer pain, and specifically of interest is the identification of the psychological variables in the survey questions. It also seeks to understand the relationship between these variables and decision-making regarding physicians' opioid prescribing.

The following research questions will be addressed:

1. What are the psychological variables that are explored in surveys on beliefs of physicians on opioids for chronic non-cancer pain?
2. What is the relationship between psychological variables and decision-making for opioid prescribing?

## **Method**

### **Search Strategy**

A systematic search of PsycINFO, EMBASE and MEDLINE was conducted from the earliest date until 19 February 2018. PsycINFO covers topics related to psychology and psychiatry while EMBASE and MEDLINE databases are good sources for identifying studies on health care interventions. The exact search terms included a combination of keywords (mp) and Medical Subject Heading (MeSH) terms. Some MeSH terms were exploded (exp) to include citations with more

specific MeSH subheadings. The search used the AND operator to combine the searches from concept A, B and C together. A final step included limiting the combination of concepts A, B and C to English language. The search terms used for each of the three databases are provided below.

### ***PsycINFO***

#### A. Opioids

Exp Opiates/ or exp ANALGESIC DRUGS/ AND (opioid\* or opiate\* or "opioid analgesic" or analgesi\*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

#### B. Chronic pain

Exp Chronic Pain/ AND ("chronic pain" or "chronic non cancer pain").mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

#### C. Physician attitudes

health personnel attitudes/ AND doctor.mp. or exp Physicians/

### ***EMBASE***

#### A. Opioids

analgesia/ or opiate/ AND (opioid\* or opiate\* or "opioid analgesi\*" or analgesi\*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word]

B. Chronic pain

chronic pain/ AND ("chronic pain" or "chronic non cancer pain").mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word]

C. Physician attitudes

health personnel attitude.mp. or health personnel attitude/

***MEDLINE***

A. Opioids

opiods.mp. or Analgesics, Opioid/

B. Chronic pain

Chronic Pain/ AND ("chronic pain" or "chronic non cancer pain").mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

C. Physician attitudes

health personnel attitude.mp. or "Attitude of Health Personnel"/

Three articles were sourced in the process of screening articles obtained from the database searches, by scanning the reference lists. Although these hand-searched articles did not show up in the database searches, they were included in the final shortlist of studies as they were found to provide relevance for the research question and also met inclusion criteria. The articles obtained by hand searching were two

quantitative studies (Hutchinson, Moreland, Williams, Weinman, & Horne, 2007; McCracken, Velleman, & Eccleston, 2008) and one qualitative study (McCrorie et al., 2015) conducted in the UK, and had been referenced in several shortlisted studies. For example, Hutchinson et al. (2007) was referenced in Allen et al. (2013), Lin, Alfandre, and Moore (2007) and Seamark, Seamark, Greaves, and Blake (2013). All titles and abstracts of all records from the database and hand searches were independently reviewed by the author. Following initial screening of titles and abstracts, 26 full-text records were considered for evaluation. Disagreements were discussed with an independent assessor until consensus was reached.

A final list of 15 records were included in the review.

### **Inclusion and Exclusion Criteria**

Articles were included if they used surveys which examined physicians' beliefs, attitudes and perceptions of the use of opioids for the treatment of chronic non-cancer pain (CNCP). The review included articles from peer-reviewed journals and Western healthcare settings. As defined in the database search strategy, only articles written in English were included in the review.

The review excluded articles which investigated patient-only and non-physician (e.g. clinical nurse specialists) attitudes, clinician attitudes towards opioid dependence, addiction or abuse, comorbid CNCP and substance misuse, and opinion articles. The review also excluded articles which examined clinician attitudes toward opioid treatment agreement and risk assessments for opioid use/misuse for CNCP.

### **Data Extraction**

Following article selection, demographic information on the sample population (i.e. age, gender, physician type), number of participants, type of study, and country were extracted from the papers. These are displayed in Table 1.



In addition, data relating to beliefs of clinicians toward opioids for treating CNCP were extracted from survey questionnaires. Data was collated and categorised (see Table 2). Some categories were referenced from the articles. For example, the study by Barry et al. (2010), which used grounded theory to analyse the data, categorised the findings into three themes – patient, clinician and logistical factors. Similarly, Keller and colleagues (2012) categorised physicians’ concerns about the use of opioids into four categories – patient, drug, system and physician factors. For the purpose of this review, psychological variables are defined as variables investigating mental states and processes such as motivation, perception, control and affect. Key words that were looked for included, but not limited to, ‘perception’, ‘confidence’, ‘concerns’, and ‘fears’. Particular attention was paid to survey items which would potentially be classified as psychological variables.

### **Quality Assessment**

The AXIS tool (Downes, Brennan, Williams, & Dean, 2016) is a critical appraisal tool for assessing the quality and risk of bias in cross-sectional studies. Twelve out of 15 of the articles in this review were cross-sectional studies. The AXIS tool comprises 20 yes/no/don’t know questions, which ask the rater to consider the quality of the study design and reporting and the possible biases in the study. The remaining three articles were assessed using a tool specifically for qualitative research; i.e. the CASP Qualitative Checklist (2018). The rater is asked to rate a series of 10 yes/no/can’t tell questions. Both appraisal tools do not use numerical scoring systems and hence, rely heavily on the subjective interpretation of the rater.

### **Data Synthesis**

All papers used either descriptive statistics or thematic analysis to report findings. Although the aims of the papers were broadly similar to each other, the

measures used were quite different, including measures that were not standardised, and so would not be appropriate for meta-analysis. Therefore, a narrative synthesis was used for this systematic review. Key information from the studies will be described followed by a discussion on the quality of evidence and the relationships between the studies. In relation to the research questions, the review will discuss the themes found across survey questionnaires in the identified studies included in this review, and interpret the collected evidence.

### **Results**

The PRISMA diagram (see Figure 1) illustrates the systematic process that resulted in 15 papers for review. From a total of 86 studies screened by titles and abstracts, 63 were excluded. A further three studies sourced by hand searching were included in the 26 studies that were read as full papers to assess their eligibility against the inclusion criteria. Of these, 11 records were excluded for the following reasons: sample included non-physicians (e.g. Jamison, Scanlan, Matthews, Jurcik, & Ross, 2016), survey questions did not target attitudes towards opioids (e.g. Sullivan et al., 2006) and not a primary study (Turk, 1996).

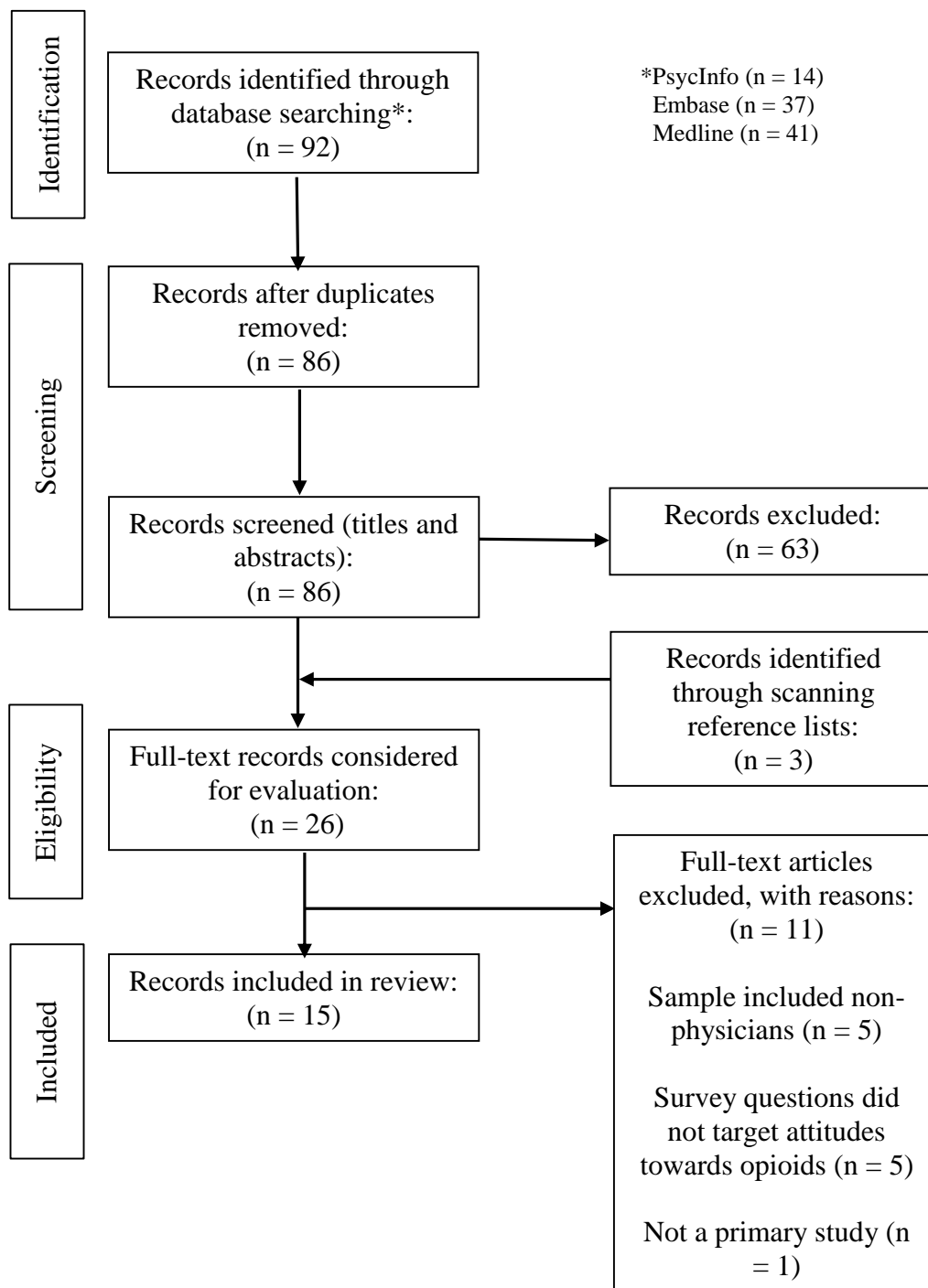


Figure 1: PRISMA Flow Diagram

### Characteristics of Studies

Table 1 presents the characteristics of the studies included in this review. Studies took place across three countries, with the majority of studies conducted in the US (n = 9), followed by the UK (n = 4) and Canada (n = 2). The studies sampled a range of physicians, with most sample populations consisting of family medicine or

general practitioners (GPs). One study sampled only academic family physicians (Macerollo, Mack, Oza, Bennett, & Wallace, 2014). Another study comprised internal medicine residents (Regunath et al., 2016). Five studies sampled more than one type of physician specialty. For example, 27.3% of the sample from Duensing et al. (2010) were pain specialists, the second largest group after general practice physicians (44.4%). Other studies included palliative care physicians (Morley-Forster, Clark, Speechley, & Moulin, 2003), geriatricians (Lin et al., 2007), infectious disease specialists (Barry et al., 2010) and psychiatrists (Barry et al., 2010; Duensing et al., 2010).

Survey methods varied across studies. In the cross-sectional studies, questionnaires were administered either online (n = 4), postal (n = 5), telephone (n = 1) and on-the-spot (n = 3). For the studies which used qualitative methods, one used semi-structured interviews (Barry et al., 2010), and two used both interviews and focus groups (McCrorie et al., 2015; Seamark et al., 2013). In the study by McCrorie et al. (2015), early interviews of patients informed the development of patient vignettes to facilitate discussions in the two focus groups comprising GPs only. Ongoing data collection and analysis allowed focus groups to subsequently inform later patient interviews (n = 6). All interviews and focus groups were conducted face-to-face. Data analysis methods included thematic analysis (McCrorie et al., 2015; Seamark et al., 2013) and grounded theory (Barry et al., 2010).

Only one study in this review obtained measures from participants twice (Regunath et al., 2016), i.e. pre-and-post intervention. This occurred in the context of an educational module which aimed to improve internal medicine residents' knowledge and confidence in prescribing opioids for CNCP.

Although no time limits were set on the database search strategy, studies that were included in the review were fairly recent; covering a period of 13 years between 2003 and 2016. Papers published early in this time frame tended to present arguments in favour of prescribing opioids for treating chronic pain whereas papers published more recently tended to take a cautious stance towards opioid prescription.

Table 1: Characteristics of Studies Included in the Review

Author, Country	Year	N	Age, Mean (SD)	Male (%)	Population	Type of survey
Allen et al., Canada	2013	710	Not reported	59% (based on 622 responses)	Family physicians	Online questionnaire
Barry et al., USA	2010	23	Not reported	45% (based on 20 responses)	Physicians <i>Internal medicine (50%)</i> <i>Infectious disease (20%)</i> <i>Addiction medicine (15%)</i> <i>Psychiatry (10%)</i> <i>Family medicine (5%)</i>	Semi-structured interview
Burgess et al., USA	2011	382	45.3 (12.2)	71.7%	Internal medicine physicians	Postal questionnaire
Duensing et al., USA	2010	275	Not reported	85.8%	Physicians <i>General practice (44.4%)</i> <i>Pain specialist (27.3%)</i> <i>Oncologist (6.2%)</i> <i>Neurologist (5.8%)</i> <i>Surgeon (5.5%)</i> <i>Rheumatologist (5.5%)</i> <i>Psychiatrist (5.5%)</i>	Online questionnaire
Hutchinson et. al., UK	2007	115	44 (10)	61.7%	GPs	Postal and on-the-spot questionnaires

Author, Country	Year	N	Age, Mean (SD)	Male (%)	Population	Type of survey
Keller et al., USA	2012	35	49.1 (11.1)	71%	Primary care physicians <i>Family medicine (69%)</i> <i>Internal medicine (11%)</i> <i>Paediatrics (3%)</i> <i>Other (11%)</i> <i>Missing (6%)</i>	Postal questionnaire
Lin et al., USA	2007	132	Not reported	43%	Physicians <i>Internal medicine (79%)</i> <i>Geriatricians (21%)</i>	Questionnaire
Macerollo et al., USA	2014	491	Not reported	56.8%	Academic family physicians	Online questionnaire
McCracken et al., UK	2008	414	Not reported	50.2%	GPs	Postal questionnaire
McCrorie et al., UK	2015	15 GPs 23 patients	Not reported	26.7%	GPs	Focus group Semi-structured interview
Morley-Forster et al., Canada	2003	70 30	Not reported	Not reported	Physicians <i>GPs</i> <i>Palliative care physicians</i>	Telephone interview
Regunath et al., USA	2016	45	29.8 (2.9)	66.7%	Internal medicine residents	Questionnaire
Seamark et al., UK	2013	22	Not reported	68%	GPs	Semi-structured interview; focus group
Turk et al., USA	2014	1535	Not reported	82.9%	Physicians	Online questionnaire
Wolfert et al., USA	2010	216	Not reported	Not reported	Physicians	Postal questionnaire

## Quality Assessment

All 15 papers were assessed using critical appraisal tools. The ratings are shown in Appendix A and Appendix B for cross-sectional and qualitative studies respectively, with accompanying notes. All papers had clear statements of the objectives of the study and used appropriate designs for their aims. The main weakness of most of the studies was the potential for responder bias (see Questions 7, 13 and 14 on AXIS tool). As most of the papers used purposive or convenience sampling with no possibility to gather information about non-responders, it was generally difficult to know if the characteristics of responders differed from that of non-responders systematically. Only one study (Lin et al., 2007) reported characteristics of non-responders. In their study, demographic data were accessible because the target sample comprised all the staff physicians in the hospital. All studies mentioned as a limitation the unrepresentativeness of the results given that it was difficult or impossible to collect data from non-respondents. In some studies with smaller sample sizes or low response rates, the limitation of the findings' generalisability was also discussed (e.g. Keller et al., 2012; Morley-Forster et al., 2003). Four studies (Allen et al., 2013; Duensing et al., 2010; Keller et al., 2012; Turk, Dansie, Wilson, Moskovitz, & Kim, 2014) used sampling frames which raise questions about their appropriateness to represent the target population being studied (Question 5 on AXIS tool). For example, three studies (Duensing et al., 2010; Keller et al., 2012; Turk et al., 2014) recruited participants from online networks which required membership subscriptions. Whether participant members differed from non-members needs to be considered in the interpretation of the studies' findings.

Another weakness found in four (Burgess, Dovidio, Phelan, & van Ryn, 2011; Keller et al., 2012; Regunath et al., 2016; Wolfert, Gilson, Dahl, & Cleary,



2010) out of the 12 cross-sectional studies was the use of questionnaires that had not been trialled, piloted or published previously (Question 9 on AXIS tool). In all three qualitative studies, there was no discussion on any critical examination by the researcher on their role, potential bias and influence during the research design and process (Question 6 on CASP checklist). The seven guidelines of Elliot, Fischer, and Rennie (1999) for qualitative studies include ‘owning one’s perspective’ and providing credibility checks. The former involves the researchers stating their theoretical orientations and biases to enable readers to evaluate the researchers’ interpretations of the data. The latter involves the use of several methods for checking the reliability of the results such as triangulation and testimonial validity. All three studies did not discuss researchers’ orientations; however, all conducted credibility checks by using analytic auditing, i.e. having multiple researchers check the results against the data. As is typical with qualitative studies, the sample sizes are generally small. Again, questions of generalisability are raised in the Discussion sections, as is the call for further research to build on or contribute to current findings.

### **Main Findings**

Twelve studies aimed to identify the factors influencing physicians prescribing of opioids for CNCP and beliefs about opioids (Allen et al., 2013; Barry et al., 2010; Duensing et al., 2010; Hutchinson et al., 2007; Keller et al., 2012; Lin et al., 2007; Macerollo et al., 2014; McCracken et al., 2008; McCrorie et al., 2015; Morley-Forster et al., 2003; Seamark et al., 2013; Turk et al., 2014). Three studies investigated physicians’ knowledge of opioids and clinical practice guidelines (Allen et al., 2013; Regunath et al., 2016; Wolfert et al., 2010). Seven studies described prescribing practices and/or volume of chronic patients seen by physicians (Allen et

al., 2013; Hutchinson et al., 2007; Macerollo et al., 2014; McCracken et al., 2008; Morley-Forster et al., 2003; Regunath et al., 2016; Wolfert et al., 2010). One study investigated the influence of political ideology on physicians' treatment decisions and attitudes toward patients with chronic pain (Burgess et al., 2011). All cross-sectional studies but one (Wolfert et al., 2010) used Likert scales for quantifying survey items.

While the specific aims of the studies varied from each other, the underlying theme was the investigation of physicians' perceptions of opioid treatment for chronic pain. The questions from surveys in each study were extracted – from either appendices or Results sections – and collated. Where survey questions were open-ended, for both quantitative and qualitative studies, the responses and themes were examined and included in the categorisation of factors influencing physicians' perceptions. Table 2 displays the collated factors. These are organised according to drug factors, patient factors, physician factors, other factors and psychological factors.

Drug factors included considerations such as side effects (e.g. nausea, constipation), long-term adverse effects (e.g. addiction, misuse) and efficacy and evidence base of strong opioids for chronic pain. Patient factors took into account patient behaviours (e.g. drug diversion, drug misuse) and immutable factors such as a history of substance abuse. Physician factors included physicians' knowledge and expertise (e.g. knowledge of opioids, dosages and clinical guidelines), immutable factors (e.g. gender), available resources (e.g. referrals to specialist care), and political ideology, e.g. degree of medical authoritarianism (see Burgess et al., 2011). Other factors relate to physicians' concerns with regulation and legislation, ease of access to drugs and access to other forms of support (e.g. addiction treatment settings

specialising in managing pain, see Barry et al., 2010). Psychological factors are described in the next section.

The majority of the studies surveyed physicians' beliefs about opioids in relation to long-term adverse effects (n = 12), patient behaviours (n = 12) and physicians' knowledge (n = 11). A substantial number of studies (n = 9) also included survey questions about regulatory concerns.

Table 2: Classification of Questionnaire Variables

Authors	Drug factors			Patient factors			Physician factors		
	Side effects	Long-term adverse effects	Efficacy and evidence base	Behaviours	Immutable factors, e.g. history of substance abuse	Knowledge / expertise	Immutable factors, e.g. gender	Resources	Political ideology
Allen et al. (2013)	•	•	•	•		•			
Barry et al. (2010)		•		•				•	
Burgess et al. (2011)									•
Duensing et al. (2010)	•	•	•	•		•			
Hutchinson et al. (2007)	•	•	•	•	•				
Keller et al. (2012)	•	•	•	•		•			
Lin et al. (2007)	•	•		•		•	•		
Macerollo et al. (2014)		•	•	•		•			
McCracken et al. (2008)	•	•	•	•		•	•		
McCrorie et al. (2015)						•		•	
Morley-Forster et al. (2003)	•	•		•				•	
Regunath et al. (2016)						•		•	
Seamark et al. (2013)	•	•		•	•	•			
Turk et al. (2014)		•	•	•	•	•		•	
Wolfert et al. (2010)		•		•	•	•			

Table 2 continued

Authors	Other factors			Psychological factors	
	Regulatory concerns	Access to drugs	Access to other support	Confidence, comfort	Trust, ambivalence
Allen et al. (2013)	•	•			
Barry et al. (2010)			•		•
Burgess et al. (2011)					•
Duensing et al. (2010)	•	•	•	•	
Hutchinson et al. (2007)					•
Keller et al. (2012)	•	•			
Lin et al. (2007)	•				
Macerollo et al. (2014)	•		•	•	
McCracken et al. (2008)	•			•	
McCrorie et al. (2015)			•		•
Morley-Forster et al. (2003)	•	•			
Regunath et al. (2016)			•	•	
Seamark et al. (2013)			•	•	
Turk et al. (2014)	•	•			
Wolfert et al. (2010)	•				

## **Research Question 1: Psychological Variables**

For the scope of this review, psychological variables are defined as variables investigating mental states and processes such as motivation, perception, control and affect. Key words included, but were not limited to, ‘perception’, ‘confidence’, ‘concerns’ and ‘fears’. In general, what emerged from examining the questionnaire items were two groups of psychological variables – firstly, physicians’ confidence and comfort levels in prescribing opioids, and secondly, trust (or lack of trust) toward patients and ambivalence toward patients and opioids.

Where questionnaires used the word ‘concern’ in items such as ‘concern about long-term adverse effects’ and asked participants to rate the importance of the factor affecting decisions to prescribe opioids or not, these were classified under the relevant heading, i.e. ‘drug factors: long-term adverse effects’, and not under the heading of ‘psychological variables’. Such items were considered to belong to the domain of medical factors rather than relating more to a specific psychological aspect or process. Psychological variables were extracted from nine studies and are described in the following sections.

**Confidence and Comfort.** Duensing et al. (2010) surveyed physicians’ comfort levels in prescribing opioids on three survey items (see Section III: attitudes towards pain treatment). Over 70% of respondents reported feeling comfortable with prescribing opioids for chronic pain and in using immediate-release and extended-release opioids. 45% of patients who were being treated for chronic pain were prescribed strong opioids.

Macerollo and colleagues (2014) examined the associations between physicians’ confidence in prescribing skills and comfort levels with prescribing with their beliefs and concerns about negative outcomes. Confidence and comfort were

measured using two items on a 4-point Likert scale – ‘I am confident in my clinical skills in prescribing opioids’ and ‘I am comfortable prescribing opioids for chronic pain’. Similar to the results in Duensing et al. (2010), a majority of physicians (76.2%) reported being ‘somewhat’ or ‘strongly’ comfortable in prescribing opioids. 88.4% of physicians reported confidence in their clinical skills.

McCracken et al. (2008) investigated the relationship between physicians’ patterns of prescribing with their attitudes and concerns towards strong opioids for chronic pain. The authors used a 15-item questionnaire to measure attitudes and beliefs in GPs about strong opioids, of which one item was ‘lack confidence to prescribe’. A majority of physicians (72.8%) indicated confidence in prescribing strong opioids.

Regunath et al. (2016) measured physicians’ attitudes, knowledge and confidence towards opioids before and after administering an educational module designed to increase knowledge about opioid prescribing. Two items on the questionnaire targeted confidence about opioid prescribing – ‘I have educated enough to help with confident prescription’ and ‘confident about opioid conversion’. The study demonstrated that the educational module was overall useful in increasing physicians’ perceived improvement in their knowledge and confidence in prescribing opioids for chronic pain. However, as data on prescribing practices were not obtained, it is unclear whether increased confidence translated to changes in prescribing practices and clinical decision-making.

Some respondents in the qualitative study by Seamark et al. (2013) reported that clinical experience over time and in palliative care facilitated confidence in prescribing opioids for chronic pain, whereas others were more reticent while reflecting on previous negative experiences with patients using opioids.

In all four cross-sectional studies, confidence among physicians was found to be generally high, i.e. more than 70% of respondents. The measure of confidence was in relation to physicians' knowledge of opioids, their application of clinical skills in opioid prescribing, and in prescribing strong opioids.

**Trust and Ambivalence.** Barry et al. (2010) used grounded theory to derive themes describing the barriers and facilitators to opioid therapy. Physicians expressed ambivalence and frustration in prescribing opioid analgesics particularly toward patients whom they felt were abusing opioids. They also perceived some patients' motivations as questionable. For example, physicians noted that some patients requested and used opioids for diversion and euphoric effect rather than for pain relief.

Burgess et al. (2011) investigated the influence of medical authoritarianism (MA), defined as "a measure of right-wing authoritarianism that is adapted to the clinical environment" (p. 1401), on the prescribing practices and attitudes of physicians. Previous research showed that physicians high on MA tended to be less tolerant of uncertainty (Jost, Glaser, Kruglanski, & Sulloway, 2003), preferred the biomedical model of medicine (compared to relationship-centred aspects of medicine) and displayed more negative attitudes toward members of stigmatised groups (Merrill, Laux, Lorimor, Thornby, & Vallbona, 1995). MA was measured using four items from the MA-Scale (Merrill et al., 1995). The researchers also administered a measure designed to assess physicians' perceptions of patients' trustworthiness and to observe how this might correlate to MA. The 8-item questionnaire included statements such as 'Patient is exaggerating his pain' and 'Patient can be trusted' that were rated on a 5-point scale.



Hutchinson et al. (2007) used factor analysis on items concerning appropriate prescribing and perceived risks of opioids. Factor 4 represented physicians' suspicion about patient requests for increased analgesics and included item statements such as 'increasing requests for analgesics usually indicate addiction to the analgesic'. Similar to Barry et al. (2010), patients' motivations for their requests for and use of opioids was an area of ambivalence for physicians, touching upon issues of trust in the transaction between physician and patient.

A thematic analysis of focus group discussions with GPs (McCrorie et al., 2015) to understand processes contributing to long-term opioid prescribing found that the theme of mutuality and trust in the patient-physician relationship facilitated a platform for physicians to suggest non-pharmacological approaches to pain management. Physicians acknowledged that consultations could be difficult when patients were resistant to suggestions of decreasing or stopping opioid treatment. Despite an awareness of the risks of escalating doses, physicians sometimes continued to prescribe opioids with the intention of building a trusting relationship so that patients would, they believed, be more receptive to alternative pain management options at a later time.

The theme of trust was particularly prominent across the four studies when patients requested opioids, or increased doses. Physicians expressed ambivalence when patients requested opioids; many had encountered patients who had used opioids for the wrong reasons and this in turn led to wariness toward patients. From the physicians' perspectives, trust was also important to help patients understand the rationale for decreasing or stopping opioids when the analgesics no longer worked and to encourage them to accept other treatment alternatives.

In summary, a review of the literature found that the psychological variables pertaining to physicians' attitudes toward opioids are 'confidence and comfort' and 'trust and ambivalence'. Five studies measured confidence levels, which were found to be generally high, i.e. more than 70% of respondents. Confidence was related to physicians' knowledge of opioids and application of clinical skills in opioid prescribing. Four studies investigated physicians' perception of trust toward patients; lower trust and higher ambivalence were experienced when physicians queried patients' motivations for opioid requests.

### **Research Question 2: Relationship between Psychological Variables and Clinical Decision-making**

This section discusses the studies from which psychological variables were extracted. Four studies (Burgess et al., 2011; Hutchinson et al., 2007; Macerollo et al., 2014; McCracken et al., 2008) included data on prescribing practices and decision-making as self-reported by physicians. Five studies (Barry et al., 2010; Duensing et al., 2010; McCrorie et al., 2015; Regunath et al., 2016; Seamark et al., 2013) did not have data on prescribing practices or discussed the impact of psychological variables on prescribing patterns.

In the study by Macerollo et al. (2014), 96.9% of respondents reported prescribing opioids in their current practice; of these, 66.2% prescribed opioids to five or more patients on their caseloads. Physicians who reported more confidence in their opioid prescribing skills were more likely to identify chronic pain management as high priority ( $\rho = -0.29, p = <0.001$ ) and found greater satisfaction in prescribing opioids ( $\rho = -0.28, p < 0.001$ ). Physicians who reported more comfort with prescribing were more likely to report satisfaction in prescribing opioids ( $\rho = 0.49, p$

< 0.001), that patients function better with opioids ( $\rho = 0.35, p < 0.001$ ) and that patients experience substantial pain relief with opioids ( $\rho = 0.27, p < 0.001$ ).

Predictably, McCracken et al. (2008) found that physicians' lack of confidence to prescribe opioids was associated with greater reluctance to prescribe ( $r = 0.28, P < 0.001$ ) and lower frequency of prescribing ( $r = -0.12, P < 0.05$ ) in their practice.

Contrary to the original hypothesis in Burgess et al. (2011), physicians high in MA were more likely to prescribe a stronger type or higher dose of opioid. MA was also positively correlated with perceptions of the patient as non-trustworthy ( $\beta = .24, t(352) = 4.95, p < .001$ ). The authors concluded that although physicians high in MA may experience more difficulty in establishing trusting relationships with chronic pain patients, they are more likely to adhere to the medical model and clinical guidelines and actively treat pain by prescribing opioids. Conversely, physicians low in MA, although likely to have better patient-physician relationships, may run the risk of undertreating pain because they are less likely to prescribe opioids.

74.5% of respondents in the study by Hutchinson et al. (2007) reported prescribing opioids for persistent pain. There were no statistical differences between prescribers and non-prescribers in their responses to statements relating to suspicion of requests for increased analgesics. However, among prescribers ( $n = 82$ ), fewer patients were prescribed opioids by physicians who reported greater suspicion (factor 4:  $r = 0.34, p = 0.002$ ).

In summary, the findings suggest that greater confidence in opioid prescribing and clinical skills was associated with greater satisfaction in prescribing and the belief that opioids were useful for patients with chronic pain. Lack of

confidence was associated with greater reluctance and lower frequency of prescribing. A lack of trust in patients produced mixed findings – Hutchinson et al. (2007) found that higher suspicion was associated with lower prescribing frequency. Conversely, while the links between prescribing practices and perceptions of patients as untrustworthy are not clear, it appears that although physicians high in MA tend to perceive patients as untrustworthy, they also tend to prescribe stronger opioids and at higher doses (Burgess et al., 2011).

Of the 15 studies that were reviewed, two psychological variables were found in nine studies. Four studies examined the associations between two psychological variables, i.e. confidence and trust, and prescribing patterns. The results show that that lower confidence was associated with greater reluctance and lower frequency of prescribing, while a lack of trust produced mixed findings in two studies.

### **Discussion**

The aim of this review was to explore physician psychological variables in questionnaires that survey physicians' attitudes and beliefs on opioids for chronic pain, and how these might be associated with clinical decision-making. A systematic review of the literature found 15 studies, of which nine included psychological variables as part of a series of survey questions designed to understand physicians' beliefs. Psychological variables were classified by the author into two groups – confidence in prescribing skills and knowledge of opioids and trust within the patient-physician relationship. Of the nine studies, four studies discussed the associations between psychological variables and prescribing patterns and/or decision-making.

From this review, it can be observed that psychological variables are paid little attention in the weighing up of different factors affecting clinical decision-

making. Judging from the prioritisation of survey questions (e.g. based on the number of questions asked in each domain), much of the research around the subject deals with drug, patient and physician factors. This suggests that physicians tend to place more consideration on known risks and benefits such as adverse effects and efficacy of opioids, patient aberrant drug behaviours and knowledge of prescribing opioids when making prescribing decisions. These findings are consistent with other studies investigating physicians' perspectives on prescribing opioids for chronic pain (e.g. Blake et al., 2015; Spitz et al., 2011). Given that psychological variables constituted a very small part of a larger body of survey questions, i.e. one to eight survey items, it is difficult to conclude to what extent these variables affected decision-making, or indeed, if they do at all.

The results from Burgess et al. (2011) present interesting data for discussion. Physicians considered to be more conservative in their political ideology were more likely to prescribe strong opioids against a backdrop of unsatisfactory patient-physician encounters. These findings contrast that of other studies which report physicians' tendencies toward reluctance to prescribe, especially when confidence was low due to concerns about adverse effects, patient aberrant drug behaviours, lack of clinical experience or inadequate training (Blake et al., 2015; Johnson et al., 2013; McCracken et al., 2008).

Of the four studies that explored trust and ambivalence, two used qualitative methods (Barry et al., 2010; McCrorie et al., 2015), which may be more suited to explore these aspects of the patient-physician relationship than questionnaires; whereas semi-structured interviews and focus group discussions appear to be platforms more fitting to allow for these themes to emerge, as well as to apprehend nuances in complex clinical decision-making. For example, McCrorie et al. (2015)

cite a physician who prescribed opioids even when contraindicated because it was hoped that acceding to the patient's request would build sufficient rapport within which, in the longer-term, alternative solutions could be openly discussed. Although building rapport is in line with findings from studies suggesting that collaboration and trust in the patient-physician relationship is the primary determining factor in achieving treatment success (Norcross & Lambert, 2011; Vowles & Thompson, 2012), physicians need to be aware of the dangers of prescribing opioids under pressure and when they are not indicated.

### **Strengths**

This study applied a systematic approach to explore the variables that are explored in self-report surveys of physicians' beliefs on opioids for chronic non-cancer pain. The findings show that the respondents emphasised drug, patient and physician factors; in particular, adverse effects, patient behaviours and physicians' knowledge and expertise. Psychological variables comprised only a small part of the surveys, suggesting that researchers give less consideration to non-medical factors when conducting surveys or that physicians did not consider them important to mention on free-text questions.

The review included only studies that used medical doctors as the target population. This reduces the variance of the findings in studies that also included non-physicians such as nurse practitioners and physician assistants who receive different education/training (e.g. Jamison et al., 2016).

The quality assessment of the studies included in this review showed that the most studies were generally of good quality – aims, study design, selection of outcome variables and measures were appropriately described and used. Results were also clearly presented and limitations were discussed.

## **Limitations**

From the quality assessment, one limitation identified was the challenge of determining whether non-respondents differed from survey respondents in any way systematically, and whether respondents drawn from a particular sampling frame were representative of the target population, e.g. primary care physicians. Thus, for instance, there is the possibility that the people who participated in the studies included in this review are, as a group, more confident than non-respondents or non-members of the networks from which participants were recruited (see Duensing et al., 2010; Keller et al., 2012; Turk et al., 2014). This finding contrasts the results in Ebbert et al. (2018), which found that less than 47% of primary care practitioners (including nurse practitioners and physician assistants) were confident in caring for patients with chronic pain.

As most of the studies were cross-sectional and used correlational data, the direction of influence between the variables being studied cannot be determined. For instance, the relationship between confidence/trust variables and prescribing frequency or reluctance may be mediated by the number of patients with chronic pain seen by physicians, e.g. physicians who are more confident may take on more patients with chronic pain, or that physicians who see more patients with chronic pain gain confidence over time in making opioid-related decisions.

Another limitation of this review is that the categorisation of variables (Table 2) was conducted by a single researcher and relied heavily on subjective assessment. A different researcher might have classified the variables differently, or may have extracted other psychological variables not included in this review. To improve on this review, inter-rater assessment would have been beneficial at several stages of the

study, e.g. database search, variable extraction and quality assessment of included papers, to support the reliability of findings.

### **Clinical and Research Implications**

The implication from the findings and recommendations from several studies in this review seem to be that when physicians have increased knowledge about opioids from training programmes, their confidence increases, which in turn leads them to be more willing to prescribe opioids to patients. It is well worth bearing in mind the assumptions inherent in some research studies (e.g. Burgess et al., 2011; Duensing et al., 2010), in that surveys were conducted at a time when the dominant narrative of the medical field was in favour of prescribing opioids for chronic pain (see clinical guidelines before 2010, e.g. Chou et al., 2009). Contemporary research studies aimed to explore barriers to opioid prescription so as to mitigate the under-treatment of chronic pain. Increasing physicians' confidence by increasing their knowledge so as to provide effective pain management and treatment was consistent with prevalent views at the time.

However, this paper contends that associating confidence with prescribing patterns says little about the reliability of physicians' prescribing decisions. It is debatable whether the reports by physicians (in the reviewed studies) of the influence of psychological variables on their prescribing decisions actually makes a difference to the treatment or to the direction of the effects found. For instance, confidence in prescribing may bear little association with clinical competence or the assurance that physicians are safely prescribing opioids to patients. Thus, confidence may be a poor indicator of clinical decision-making and treatment outcomes.

Hence, one implication is for future research to study psychological variables influencing decision-making and prescribing consultations using methods that rely



less on physicians' self-report. The study by Matthias and colleagues (2014) used video-recordings of clinical consultations and interviewed patients after the consultation to gain insight into aspects of the patient-provider relationship affecting treatment outcomes. The findings concluded that the way conversations about opioids are approached by physicians and patients' attributions have an impact on effective pain management, patient satisfaction and therapeutic alliance.

Given that it is not uncommon for physicians to report feeling frustrated, pressured and dissatisfied following clinical consultations with patients with chronic pain (e.g. Barry et al., 2010; McCrorie et al., 2015), another avenue to explore might be to investigate the emotions that are experienced and expressed during clinical consultations and the role they might play in influencing physicians' decision-making on opioids.

A suggestion for future research includes further study on the role of ambivalence in decisions about opioid prescribing. Ambivalence occurs when physicians hold both positive and negative attitudes toward an object/event, whether that be a patient or opioids. More specifically, ambivalence as defined by Baek (2010) is a "psychological state caused by contrasting evaluative orientations toward an object, which influences an individual's decision-makings or behaviours" (p. 611), and is distinctly different to being unsure of how to proceed; 'uncertainty' being defined by Downs (1957) as a "psychological state indicating a lack of knowledge" (p. 77). In reference to the threshold model of decision-making, ambivalence may potentially contribute to practice variance among physicians. For instance, McCrorie et al. (2015) observed that continued prescribing occurred in the context of a relationship in which the physician experienced dissatisfaction but alleviated the patient's distress, even if only provisionally. Another physician in a

similar situation might choose to withhold prescribing in favour of the belief that opioids would do more harm than good to the patient. Recent findings from a qualitative synthesis exploring healthcare professionals' experiences of prescribing opioids suggest that ambivalent feelings are common because of the complexities of making a decision to prescribe opioids (Toye, Seers, Tierney, & Barker, 2017). Further research is required to understand the physician factors contributing to practice variance, particularly when physicians deviate from practice guidelines, e.g. prescribing over the recommended maximum dose.

Few studies have examined the role of trust and trustworthiness in the patient-physician relationship, despite it being acknowledged as a central component to the clinical relationship in chronic pain management (e.g. Matthias et al., 2010, Upshur, Bacigalupe, & Luckmann, 2010). The research by Buchman and colleagues (2016) sought to address the gap in the chronic pain literature by interviewing patients and physicians for their views on trust within the clinical consultation. The findings suggest that perceived mutual trust is fundamental to negotiating discussions on opioid use, subjective pain symptoms and addiction. Further research on physicians' perspectives in relation to the therapeutic relationship would contribute to understanding how physicians perceive and navigate consultations in which making decisions about opioids are often complex and frustrating.

This review was primarily interested in the psychological variables found in survey questionnaires on physicians' beliefs toward opioids, and thus, did not include 'clinical decision-making' as part of the database search terms. Future reviews could build on current findings by including search terms encompassing both decision-making and specific psychological variables in the search strategy. Qualitative

studies may also be included in the search terms as they have been found to provide richer and nuanced information (e.g. Seamark et al., 2013).

## **Conclusion**

In conclusion, the role of psychological variables in physicians or within the patient-physician relationship has not been extensively studied in the chronic pain literature (Matthias et al., 2010). This review identified two psychological variables found in the questionnaires used to survey physicians' beliefs towards opioids for treating chronic pain. Confidence and trust were associated with willingness/reluctance and frequency of prescribing opioids. However, measuring physicians' confidence in clinical knowledge and skill has little bearing on clinical decision-making. There is sparse evidence discussing the relationship between psychological variables and clinical decision-making. The influence of specific psychological factors such as trust and ambivalence in the context of the patient-physician relationship on physicians' prescribing decisions are areas for future research in efforts to provide quality healthcare in chronic pain management.

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**Part 2: Empirical Paper**

**Understanding Pain Specialists' Decision-Making on Prescription of Opioids for  
Chronic Non-Cancer Pain**

## Abstract

**Aims:** This study investigated the decision-making processes of pain specialists treating patients with chronic non-cancer pain using opioids. It sought to understand the factors which influence physicians' decisions in relation to opioid prescription for chronic pain. It also explored the role of emotions, both patients' and physicians', in influencing decision-making processes.

**Method:** Consultants in pain medicine with experience of treating patients with chronic pain were recruited using purposive sampling. Fourteen participants took part in a semi-structured telephone or face-to-face interview. Qualitative data was analysed using thematic analysis (Braun & Clarke, 2006).

**Results:** Interviews yielded six themes representing the factors influencing pain consultants' decision-making on prescribing opioids for chronic non-cancer pain: 1. Adhering to best practice; 2. Thorough understanding and application of expertise on opioids; 3. Paying attention to patient factors; 4. Maintaining doctor-patient relationship; 5. Clinicians' emotions have little bearing on decisions; and 6. Recognising limitations of current prescribing climate.

**Conclusions:** Pain consultants rarely initiated or increased opioids for patients with chronic non-cancer pain; they tended to recommend tapering or stopping them instead. The study's findings also identified both patients' (as appraised by clinicians) and clinicians' emotions with influence on clinicians' decisions in the management of chronic pain. These results have implications for how clinicians approach consultations and reflect on their decision-making, recognising that emotions, both the patient's and their own, affect clinical decisions.



## **Introduction**

### **Chronic Pain**

Chronic non-cancer pain is a common cause of disability worldwide (Vos et al., 2013). The International Association for the Study of Pain (IASP, 1986) defines chronic pain as prolonged and persistent pain experienced for at least three months. A systematic review and meta-analysis of population studies in the UK estimated a prevalence of 10.4% to 14.3% of the population (an estimated median of 7.9 million people) reporting chronic pain that is either moderately or severely limiting (Fayaz, Croft, Langford, Donaldson, & Jones, 2016). Similarly, a European prevalence study found that more than 1 in 10 adults in the UK suffer from chronic pain, which, in the study, was defined as experiencing pain for at least 6 months (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006). An average of 40% of adults in the study sample reported inadequate pain control from pain prescription medication, which included non-steroidal anti-inflammatory drugs (NSAIDs), weak and strong opioid analgesics, and paracetamol. 12% of UK respondents were taking strong opioids; the European average was 5%. The two most common causes of pain were osteoarthritis/arthritis (40%) and traumatic injury (18%), with 3 in 10 adults reporting severe pain, i.e. indicating a pain intensity rating of 8, 9 or 10 on a 0-10 numerical rating scale (Breivik, 2000).

The impact of chronic pain on quality of life is well documented (Breivik, Eisenberg, & O'Brien, 2013). Pain affects physical functioning (Breivik et al., 2006), the ability to work (Patel et al., 2012), mortality (Smith et al., 2014), and increases the risk of mental health problems (Breivik et al., 2006). For instance, 24% of people with chronic pain in the UK self-reported having been diagnosed with depression by a medical doctor as a result of their pain (Breivik et al., 2006). Chronic pain is also

associated with productivity losses, early retirement and disability pensions (Nielsen, 2013). In the United States (US), the economic cost of functional disability due to pain was estimated to range from \$560 to \$635 billion in 2010 (Gaskin & Richard, 2012). Recent figures for the UK are not available; however, a European study reported the healthcare and socioeconomic costs of chronic pain in 3 countries (Ireland, Sweden and Denmark) as running in the billions annually and representing 3-10% of gross domestic product (Breivik et al., 2013).

### **Opioid Treatment for Chronic Pain**

Opioids are the most potent analgesics available for treating acute, post-surgical and cancer pain. For cancer and other advanced and progressive illnesses (e.g. kidney disease) and palliative conditions, opioids are the first-line recommendation for analgesia (National Institute for Health and Care Excellence [NICE], 2012). Increasingly, opioids are being used to treat chronic non-cancer pain (Fishman, 2014; Ruscitto, Smith, & Guthrie, 2014).

However, there is a lack of strong evidence that opioids provide effective analgesia in the long-term (defined as longer than two months). A recent overview of Cochrane reviews found limited evidence in support of the efficacy of long-term use of opioids in chronic pain and robust evidence of harm, i.e. adverse effects, associated with chronic opioid use (Els et al., 2017). The widespread use of opioids for chronic pain raises concerns about common short-term side effects such as constipation, nausea and somnolence – a systematic review of 1145 patients from 11 studies found 80% of patients had experienced at least one adverse event (Kalso, Edwards, Moore, & McQuay, 2004). Severe adverse effects of long-term opioid use include hyperalgesia (Angst & Clark, 2006; Lee, Silverman, Hansen, & Patel, 2011),

endocrine dysfunction (Brennan, 2013) and opioid addiction (Juurlink & Dhalla, 2012).

Data from the US report increasing numbers of accidental deaths related to opioid overdose, and the problems of tolerance development and long-term adverse effects, such as cognitive impairment, addiction and neuroendocrine changes (Ballantyne, 2014; Ballantyne & Mao, 2003). In the US, the prescription of opioid analgesics for chronic pain increased fourfold from 1999 to 2010 (Centers for Disease Control and Prevention, 2011), and correspondingly, there has been a threefold increase in the death rate from opioid overdose since 1990 (National Centre for Injury Prevention and Control, 2011). In the UK, opioid prescription has also increased, albeit at lower rates and absolute figures than the US (Mordecai, Reynolds, Donaldson, & Williams, 2018; Giraudon, Lowitz, Dargan, Wood, & Dart, 2013). Zin and colleagues (2014) observed a trend of escalating strong opioid prescribing for chronic non-cancer pain in the UK primary care setting between 2000 and 2010. A study which extracted annual data on opioid prescribing in England between 1998 and 2016 showed a 34% increase in opioid items prescribed (from 568 per 1000 to 761 per 1000 population); an increase of 127% in total volume prescribed when oral morphine equivalency (OME) was accounted for (from 190 000mg to 431 000mg OME per 1000 population) (Curtis et al., 2019). There was, however, a levelling off of national prescribing trends from 2014 onwards. Figures provided by the British Medical Association (2017) report nearly 2000 opioid-related deaths (including misuse of non-prescription opioids) in England and Wales in 2015, an increase from 1500 from 2011. Higher prescribing rates were found in the north of England and in areas of greater social deprivation (Mordecai et al., 2018). This suggests that people with chronic pain from lower socioeconomic backgrounds are

being prescribed opioids long-term and achieve poorer outcomes in pain management, exacerbated by the lack of access to specialist pain resources in northern regions of the country.

In efforts to manage the risks associated with prolonged, high-dose opioid therapy, professional and government health bodies have published recommendations for the prescription of opioids for chronic non-cancer pain. For instance, the Royal College of Anaesthetists (2017) published an online resource, *Opioids Aware*, that provides guidelines to healthcare professionals on prescribing opioids in the long term for chronic pain, including stopping and switching opioids. Some key recommendations include a reduction in pain of at least 30% to justify long term prescribing, and stopping or switching opioids when a patient develops intolerable side effects.

The extant literature on pain management uses randomised controlled trials (RCTs) as the gold standard for evaluating the effectiveness of interventions. Moore (2013) questions the usefulness of clinical trials in studying analgesic effects of pain management, as the tendency of such trials is to report mean figures on pain measures, failing to capture individual differences or bimodal distributions of pain responses observed in some pain treatments. There is a danger that basing guidelines on average values distorts the summary of what works, and for whom. The use of group averages, comprising both responders and non-responders, may also underestimate the benefits to responders (Katz, 2009), potentially leading to the erroneous conclusion that an analgesic is ineffective. Clinically, this means that physicians need to be vigilant to individual patients' responses to treatments, and to exercise the flexibility to change or stop opioid therapy when adequate analgesia is not achieved (Moore, 2013; Stannard, 2013). Nevertheless, primary care practitioners

still find it difficult to know what constitute good stopping and switching rules, and question the evidence from clinical trials and practice guidelines (Lincoln, Pellico, Kerns, & Anderson, 2013). Ballantyne (2014) cautions against physicians' failure to recognise when opioid treatments harm more than benefit the patient, and the need to be aware of the danger of escalating doses without observing improved analgesia and taking into account long-term adverse effects. This failure may be more predominant in physicians who are conceptually guided strongly by the therapeutic aim of alleviating pain, despite awareness of the limited efficacy of long-term opioid use (Toye, Seers, Tierney, & Barker, 2017). Furthermore, possessing an understanding of the necessity to discontinue use when opioids no longer work may not necessarily translate into action, especially if physicians feel that there are no alternative pain management approaches to offer to patients in pain (Tournebize, Gibaja, Muszczak, & Kahn, 2016).

It is also critical to understand the context and history of opioid prescribing for chronic non-malignant pain. Following the implementation of the World Health Organisation (WHO) pain ladder in 1986 for the management of cancer pain, opioid analgesics were similarly applied to the treatment of chronic non-cancer pain on the premises of providing humane medical care and enabling function in patients. This led to liberal prescribing in the 1990s and the first decade of the millennium, and a concurrent increase in opioid-related side effects and death, outcomes which in hindsight have caused more harm than benefit to chronic pain patients (Ballantyne, Kalso, & Stannard, 2016). In recent years, there has been greater awareness of the harms of long-term prescribing and an urgent move to de-prescribe or limit doses and to promote alternative treatments (Owen et al., 2018). By extension, it is likely that updated consultant training has produced younger physicians who are less liberal in

their opioid-prescribing practices, whereas older consultants may have practiced at a time when opioid therapies were mainstream for chronic pain management.

### **Decision-making for Prescribing Opioids**

Theories of decision-making fall broadly into two categories (see Djulbegovic & Elqayam, 2017 for a review). Firstly, there are the normative theories, which address the question of how people ‘should’ make their decisions. These include evidence-based medicine and expected utility theory (EUT) (Pauker & Kassirer, 1975). An evidence-based medicine approach to rationality would entail a belief in what is true based on the trustworthiness of the evidence, having been deemed credible through the application of rigorous processes (Djulbegovic, Guyatt, & Ashcroft, 2009), e.g. clinical practice guidelines which draw on the evidence of randomised-control trials (RCTs) are likely to command more authority than guidelines that do not. The assumptions of EUT are that good decision-making involves rationally considering the probabilities of net benefit, administering treatment in the instance where perceived benefits (e.g. pain relief) outweigh perceived harm (e.g. adverse effects), and withholding or stopping treatment when the reverse is anticipated. Yet, EUT has been found to be a poor predictor of the actual decisions made by physicians because it neglects important consideration of aspects such as context, individual differences, and intuition (Tsalatsanis, Hozo, Kumar, & Djulbegovic, 2015). EUT also accounts little for the role of emotional processing in both physician and patient in biasing treatment decision-making, perhaps even when the benefits do not outweigh harm or when detrimental effects are obvious.

The second category consists of descriptive theories of rational decision-making, which represent how people actually make their decisions. There are several

key ones; however, for the sake of brevity, the dual processing theories (DPT) of rational thought (Stanovich, 2010) will be discussed. The theory postulates that human cognition is governed by two sets of processes. Type 1 processes are fast, automatic, affect-based and rely on intuition, while type 2 processes are slow, analytical and logical (Kahneman, 2003, 2011). Several dual processing theories explain how the two sets of processes work and interact. They can be classified into two main categories: parallel competitive theories and default-interventionalist theories. The former posits that type 1 and 2 processes operate in parallel and compete for control of decisions and actions (Evans, 2011). The latter proposes that type 1 generates a rapid response, which may or may not subsequently activate a type 2 response, depending on the availability of information or resources (Kahneman, 2011).

Crucially, DPTs allow us to account for the role of emotions, and in particular, regret, when weighing the benefits and risks of decisions (Slovic, Finucane, Peters, & MacGregor, 2004). Regret is a cognitive emotion because it uses counterfactual reasoning processes to justify our actions; it is an aversive emotion, as it causes us to behave in ways intended to avoid a future experience of regret (Zeelenberg, 2015).

Physicians are expected to use guideline recommendations (Dowell, Haegerich, & Chou, 2016; NICE, 2013) to ensure safe prescribing of chronic opioid therapy. However, patients with similar presentations are recommended different treatment by different physicians (e.g. Wennberg, 2011) and one reason for this may be that physicians have different thresholds of risk in decision-making for prescribing medication.

Djulbegovic and colleagues (2015a) proposed a model for medical decision-making which integrates the dual processing theory with the threshold model. It combines the categorical function, i.e. to prescribe or not to prescribe a certain treatment, with a 'toggle' function, i.e. to do so at either processing system's threshold level, which is dependent on the control exerted by each system at the point of making the decision. The variance seen in clinical practice may be explained by the treatment threshold (Djulbegovic et al., 2015a), whereby the task of weighing the benefits and harm (of treatment options) and integrating these with available diagnostic information is construed and acted upon differently by different physicians. For instance, the reluctance of primary care physicians to prescribe opioids, e.g. having fears of patients becoming addicted, triggers the rapid, automatic and experiential processes of type 1. Analogously, physicians who over-prescribe may also be accessing type 1 processes when placed in an affect-rich situation; for instance, feeling pressured to prescribe higher dosages when confronted with a patient's distress (Sullivan, 2010).

### **Emotion in Decision-making**

A recent systematic review synthesised the empirical evidence for the role of emotion and emotional intelligence in clinical decision-making by healthcare professionals (Kozlowski, Hutchinson, Hurley, Rowley, & Sutherland, 2017). Physician samples were used in 10 out of 23 studies, but only three addressed the influence of emotions on decision-making as an explicit aim. The findings suggest that a majority of physicians were confident that emotion did not play a factor in their clinical decision-making, but the data showed that their decisions had been influenced by emotions and gut feelings (e.g. Harun, Finlay, Salek, & Piguet, 2015; Tentler, Silberman, Paterniti, Kravitz, & Epstein, 2008). Croskerry and colleagues



(2010) suggest that developing clinicians' emotional competence, i.e. emotional self-awareness, recognition of own affect biases, and acknowledging the influence of emotions on decision-making improves patient safety. This view is echoed by Heyhoe et al. (2016) who assert that emotion is "central to patient safety throughout the course of care" (p. 56) and recommend that researchers and clinicians recognise the influence of emotion on patient safety and decision-making.

Given the variance in opioid prescribing practices in chronic pain (Torrance et al., 2018) and common reports of feelings of uncertainty, frustration and mistrust experienced by both physicians and chronic pain patients (Buchman, Ho, & Illes, 2016; Toye et al., 2017b), it is timely to take a closer examination of the role of emotion on clinical decision-making, particularly in relation to the prescribing of opioids for chronic pain. Furthermore, opioid prescribing and usage has associations with ethical and moral implications; physicians are often confronted with complex prescribing decisions while bearing in mind the needs to protect patient and community health, engage with their own beliefs as well as with patients' beliefs about opioids, and to consider stigma and moral issues (Knight et al., 2017).

### **Rationale and Aims of this Study**

Clinical research has focused mainly on medical decision-making in diagnosis and initial treatment. However, ongoing treatments form the bulk of opioid prescriptions and yet do not have similar representation in the research literature (Becker, Fraenkel, Kerns, & Fiellin, 2013). This study investigates the decision-making processes of pain consultants who treat patients with chronic non-cancer pain with opioids and specifically, concerning decisions made following initial or ongoing treatment consultations. Much of the literature has focused on the decision-making and attitudes of primary care physicians, including general practitioners,

specialist nurse practitioners and physician assistants (Jamison, Sheehan, Scanlan, Matthews, & Ross, 2014). The current study endeavours to survey doctors specialising in pain medicine and to explore their decision-making processes in recommending opioid treatment options for patients with chronic pain. It also seeks to examine the role of emotion in clinical decision-making in reference to the dual-system processing framework as proposed by Tsalatsanis and colleagues (2015) and to build on the current literature relating to emotions and decision-making (see review by Kozlowski et al., 2017).

The study will employ qualitative self-reports via telephone or face-to-face interviews to gather physicians' responses in order to enhance understanding of the cognitive and emotional rationales regarding their decision-making on opioid prescription for chronic pain. The first research question is specific in asking about the various prescribing possibilities so as to better draw out the factors at play. The second and third research questions seek to explore how patients' emotions as perceived by physicians, and physicians' own emotions, potentially influence the clinical consultation and prescribing decisions.

The following research questions will be addressed:

1. What factors are considered by pain specialists in deciding to increase, decrease, switch, or stop opioids?
2. Does the physician's appraisal of the patient's emotions affect decisions about prescribing opioids?
3. Do the physician's emotions affect decisions about prescribing opioids?

## **Method**

### **Participants**

Consultants specialising in pain medicine were recruited for this study. The inclusion criteria for this study were medical consultants currently working in a pain clinic who have obtained the Fellowship of the Faculty of Pain Medicine of the Royal College of Anaesthetists (FFPMRCA). A purposive sampling strategy of recruitment was used, and five pain clinics located in London and Oxford were shortlisted. Formal consent to recruit participants was gained from each pain clinic and their respective Trust Research and Development departments. The study received approval from the UCL Research Ethics Committee (REC) (11139/001; Appendix C) and the NHS Health Research Authority (HRA) REC (228662; Appendix D).

### **Procedure**

Participants were recruited through invitation emails addressed directly to pain consultants working in pain clinics. Where individual email addresses were not available, a generic recruitment email (Appendix E) was sent to the pain clinic administrator with a request to forward the email to pain consultants. The email contained information about the study and an invitation to contact the researcher should they be interested in participating. The email was resent a fortnight later. Two months after recruitment had started, the email was sent a third time to the administrator or individuals who had not yet participated in the study. The number of consultants in each of the pain clinics ranged from three to 10. While exact figures are not available, it is estimated that there were approximately 32 consultants eligible to participate in the study.

All participants were provided with an information sheet (Appendix F) about the study in the invitation email. Respondents provided demographic details on ethnicity, age, number of years of medical practice and number of years of pain medicine practice (Appendix G). They also completed a form indicating informed consent for participation (Appendix H). The researcher then contacted interested participants to confirm a mutual time for the telephone or face-to-face interview. Participants were informed at the start of the interview that the conversation would be audio-recorded and transcribed. This information was also relayed in the participation information sheet and consent form.

Respondents received no direct compensation for their participation. A small monetary donation of £5 was made to a pain charity for every completed interview.

### **Data Collection**

Semi-structured interviews were used to collect data from the participants. The interview consisted of a series of questions designed to explore factors considered by clinicians when making a prescribing decision involving opioids for treating chronic pain, and the influence of the emotional presentation or state of clinicians and patients on the clinician's decision-making. Interviews were estimated to last for thirty to forty-five minutes, considering that clinicians often have busy schedules and may be less willing to commit to speaking on the phone for a longer stretch of time. This detail was communicated to clinicians in the participation information sheet and again at the start of the interview.

Interviews were conducted over two time periods: October 2017 to March 2018, and February 2019 to March 2019. All interviews were recorded on an audio device and transcribed verbatim by the researcher. Personally identifiable information was removed during the transcription stage so as to ensure participants'

anonymity. All data provided and gathered during the study were treated in accordance with the General Data Protection Regulation (2018).

### **Interview Protocol**

The interview schedule consisted of 13 questions, of which seven asked about factors influencing opioid-related decisions, with the remaining questions focused on the effect of physicians' and patients' emotions on decisions. The questions on factors asked participants to describe what they considered when making specific opioid-related decisions, i.e. to increase, decrease, switch or stop opioids. The questions on emotions invited participants to first describe the emotions patients presented with during consultations and to reflect on how that might influence their decisions. Finally, participants were asked to reflect on their own emotions during consultations and whether this had any impact on their decisions. Prompts were used to facilitate participants in elaborating their answers. The interview schedule was reviewed and discussed with a pain consultant and the researcher's supervisor, a consultant clinical psychologist working in a pain clinic. Following discussion, amendments were made to some questions to ensure face validity and clarity of the interview questions. A final draft of the interview schedule (Appendix I) was approved by the UCL and HRA RECs.

### **Data Saturation**

Determining the number of participants required in a qualitative study depends on several factors, including the scope of study, nature of topic, quality of data, number of interviews per participant and study design (Morse, 2000). Various authors have suggested recruiting between 10 and 20 participants when conducting semi-structured interviews in a relatively homogeneous group (Braun & Clarke, 2013; Guest, Bunce, & Johnson, 2006). Sampling stops once data saturation has been

achieved, i.e. the point at which no new information is forthcoming. This would be indicated by answers given by ensuing participants yielding familiar codes and themes during the data collection and analysis phases.

### **Data Analysis**

The interview data were analysed using a thematic analysis method (Braun & Clarke, 2006) which was chosen for its flexibility in its potential applications across a range of epistemological positions and its independence of pre-existing theoretical frameworks. Thematic analysis allows for the identification and analysis of meaning across the data set, as well as focus on a particular aspect of a phenomenon in depth (Braun & Clarke, 2012). Thematic analysis was used to examine themes in relation to decision-making processes in opioid prescription, and more particularly, to narrow in on the influence of emotion of physician and patient on physicians' decision-making processes. This particular approach was data-driven, i.e. data analysis was inductive, with themes closely related to the data themselves and not bound to a particular theoretical framework.

The six phases of thematic analysis, as set out by Braun and Clarke (2006) were followed: 1. familiarisation of the data set; 2. coding by systematically identifying and labelling relevant features of the data; 3. generating themes; 4. reviewing themes; 5. defining and naming themes; and 6. developing a coherent analytic narrative.

**1. Familiarisation with the data.** The first phase of thematic analysis involved listening to the audio recordings and reading through the anonymised transcripts several times. This enabled the minimisation of errors made during the transcribing process, and to hear and notice verbal and non-verbal nuances in the data.

## **2. Systematically identifying and labelling relevant features of the data.**

Initial notations were documented by hand and NVivo 11 for Windows Software (2015) during the readings of the transcripts, resulting in initial codes being developed. Ideas were identified and labelled in a line-by-line analysis of the smallest units of meaning. Each data item was coded equally, while bearing relevance to the research questions. An inductive approach was taken, such that codes were generated directly from the data, rather than from any pre-existing theory or personal assumption. Annotations were made for unusual features in the data, for example, when a participant paused for a significant length of time. Appendix J demonstrates an example of how initial codes (see right-hand margin) were recorded in the preliminary analysis of a transcript excerpt.

**3. Generating themes.** Codes were then grouped into categories or themes through a method of ‘constant comparison’ by noting similarities and differences, and were discarded when they were deemed not to fit, or combined when categories presented as similar. Thematic maps were used to capture initial links or relationships between potential themes. Appendix K shows an example of a preliminary thematic map.

**4. Reviewing themes.** Themes were reviewed again and checked against the coded extracts and the entire dataset. Figure 1 shows the organisation of themes and subthemes.

**5. Defining and naming themes.** Ongoing analysis of the data was incorporated during the writing process of the Results section. Themes and definitions were further refined so as to present a coherent narrative. This stage included incorporating the feedback from the first batch of participants (October

2017 to March 2018) who reviewed the summary of themes extracted from the interviews.

**6. Developing a coherent analytic narrative.** The final part of analysis was the selection of relevant quotes to illustrate themes generated from the dataset and relating these back to the research questions and literature.

### **Credibility Checks**

To increase transparency and credibility of the qualitative research, two techniques were applied at the data collection and data analysis stages (Guest, MacQueen, & Namey, 2012).

The first check involved having a peer reviewer independently look over a random selection of coded text to see if connections between raw text and code definitions were intuitive. There was a high level of agreement of the codes identified by the researcher and the peer reviewer. Any differences were discussed and resolved.

The second check was testimonial validity, also known as ‘member checking’ (Seale, 1999). This involved inviting participants to review and provide feedback on the summarised data of the interviews to see if the data accurately reflected their intents and meanings. Participants were emailed the summary a few months after participating in the study with a request for feedback; however, this was optional. Two out of eight participants replied with comments on the summary. An example is shown in Appendix L. This check was not replicated following the second data collection.

### **Reflexive Statement**

A reflexive position is stated to allow the reader to consider the context and potential biases of the researcher. I am a female Singaporean Chinese trainee clinical



psychologist training at University College London. My preference for using qualitative research methods stems from an interest in hearing people's personal stories, which contributes a richness and depth not afforded in quantitative research. Coming from a society and family that places a high value on pragmatism, I adopt an epistemological stance somewhere midpoint on the positivist-phenomenology spectrum, preferring to go with 'what works' in a given context and time. In my clinical practice, I am inclined to using psychological models of cognitive-behavioural therapy and integrative and systemic approaches. Ideas of taking a non-expert position and curiosity have been influences in the way I think about professionals in traditional expert roles; while I highly respect their expertise, sometimes I also think it permissible for them to not have to know it all. I have endeavoured to adopt this position when conducting participant interviews and in navigating both medical and psychological knowledge domains relating to the subject of chronic pain in the course of my research. In accordance with the application of thematic analysis (Braun & Clarke, 2006), I attended to the similarities and differences in participants' accounts during the data collection, analysis and interpretation. When I commenced this research study, I did not hold strong opinions for or against opioids for treating chronic pain.

## **Results**

### **Participant Characteristics**

Fourteen pain consultants from three hospital sites participated. Three women and eleven men took part, with a mean age of 46 (range = 38 – 58). The number of years of medical practice ranged from 12 to 33 years, while the number of years spent in specialist pain practice ranged from three to 26 years. Nine participants were White British/Other; the remaining participants were of Middle Eastern, South Asian

and East Asian ethnicities. Participant characteristics are intentionally not displayed in a table format to protect confidentiality. Thirteen telephone interviews and one face-to-face interview were conducted.

### **Data Saturation**

Interviews should stop once data saturation is achieved, and when no new information is forthcoming (Morse, 1995). An empirical study investigating the number of interviews required to reach data saturation asserted that saturation occurred within 12 interviews, with overarching themes evident after six interviews (Guest et al., 2006). Fourteen participants were interviewed for the current study; little new information was gained in the latter interviews, indicative of a reasonable confidence in approximating data saturation as representative of the sample population.

### **Overview of Themes**

The factors influencing pain specialists in their clinical decision-making regarding prescribing opioids for chronic non-cancer pain are classified into six themes comprising 18 subthemes. The first theme ‘Adhering to best practice’ comprises factors related to a reliance on the evidence base, clinical guidelines and clinical experience to inform decision-making. Notably, the bulk of clinicians’ practice involved decreasing opioids for patients.

The second theme ‘Thorough understanding and application of expertise on opioids’ refers to clinicians’ vast knowledge with regards to opioids and the careful application of their knowledge to a patient’s specific presentation and in conjunction with his or her expressed goals so as to provide bespoke treatment. This theme also includes a section describing the exceptions made by clinicians to prescribing opioids.

The third theme ‘Paying attention to patient factors’ refers to clinicians’ consideration of the psychology – emotions, attitudes and behaviours – of patients as well as their social circumstances during the course of opioid-related decision-making.

The fourth theme ‘Maintaining doctor-patient relationship’ describes the fundamental aspects of clinician-patient relationships that determine the success (however this may be defined) of consultations and the receptivity of patients to treatment recommendations. While these factors are not unique to any clinician-patient relationship, they are particularly heightened in the context of a chronic pain setting, in which the relationship possibly plays an even crucial role in promoting patients’ well-being and quality of life (Toye, Seers, & Barker, 2017).

The fifth theme ‘Clinicians’ emotions have little bearing on decisions’ explores the role of clinicians’ emotions and how they are perceived by clinicians themselves in clinical decision-making and within the broader work context.

The sixth theme ‘Recognising limitations of current prescribing climate’ comprises factors which, while not directly bearing on decisions made in the consulting room, nevertheless situate day-to-day decisions in a wider context posing both limitations and safeguards that clinicians are aware of and which inform adjustments to their practices.

Figure 1 shows these themes and their constituent subthemes.

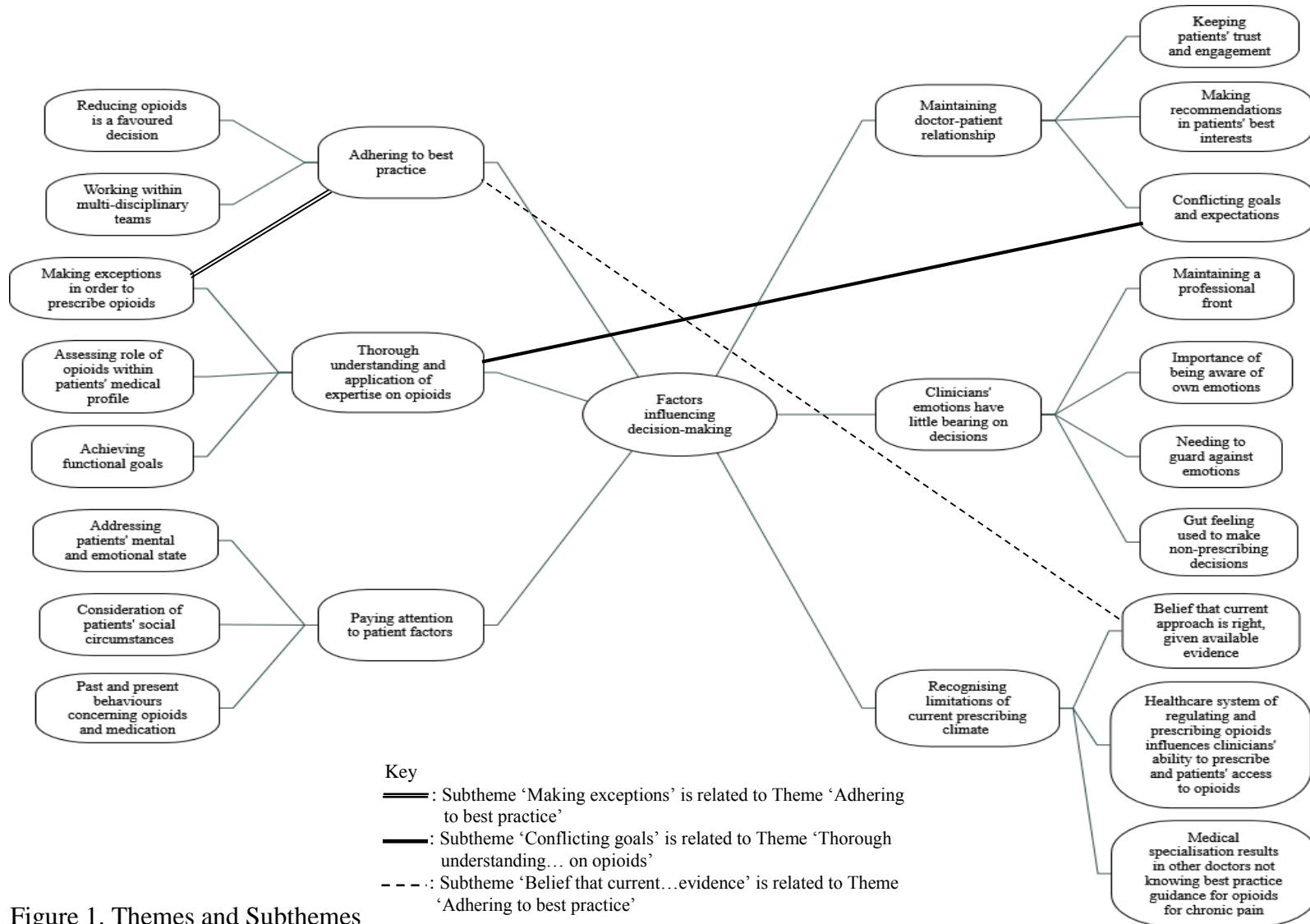


Figure 1. Themes and Subthemes

## Theme 1: Adhering to Best Practice

This theme relates to good clinical practice followed by clinicians, all of whom made reference to the evidence base on opioids for treating chronic non-cancer pain. Many also cited current guidelines, e.g. British Pain Society (BPS), on prescribing opioids as a key factor in making their decisions. In addition, pain consultants found it highly useful to be working within hospital-based multi-disciplinary teams, another best practice standard for the care and treatment of patients with chronic pain.

**1.1. Reducing opioids is a favoured decision.** All clinicians agreed that reducing opioids, especially if patients were already taking high doses, was a recommendation they often made. They cited the evidence base to justify the decision to reduce or stop opioids that are not providing analgesic benefit or that make patients feel worse.

*P2: The word is reduction. Majority is evidence-based, and yes, and I suppose, you educate the patient as to what the literature tells us and what the guidelines indicate.*

*P8: I've just seen someone today who's on 200mg of morphine a day, and the pain is not under control and is actually, um, you know, er, causing side effects. Because quite often they have problems, er, with the hormonal status. It affects their ability, you know, the immune system. So, er, you know most of them are on huge doses, and I try very hard to take them off the medication.*

Most clinicians were quick to reference the BPS guideline of prescribing no more than 120mg morphine equivalent a day as the recommended upper dose. Thus,

if patients were currently taking above that, clinicians would definitely recommend reducing the dose to 120mg. If patients were started on a trial of low-dose opioids, clinicians might consider prescribing a slow increase to a maximum of 120mg morphine equivalent.

*P12: I say well you're on 150 twice a day of morphine MST, um, you know, and then I'll be thinking that's gonna have to come down because clearly that's not safe, you know, it's well above the, um, British Pain Society's maximum recommended daily dose for opioid that's effective. And then I'll be looking to come down from that.*

*P10: The dose might be very small, but there's clearly been a difference since starting them, so then there'd be a role for just edging them up a little bit more, bearing in mind that there are, you know, guidelines and limits that we would never go beyond, so I generally follow the British Pain Society guidelines – 120mg morphine dose equivalent per day.*

However, such a guideline also attracts controversy. One clinician noted that the recommended upper limit dose of 120mg is arbitrarily set, particularly if applied out of context without consideration of other factors.

*P1: It's a process, I suppose, and it's not...and it's a very individual matter. I mean, you can't just say "you're on 150mg of morphine equivalent, you must come down to 120mg"... They're all like grey numbers.*

Clinicians agreed that the literature provided little or no evidence for switching opioids, and were inclined toward making decisions that involved reducing or stopping opioids, rather than switching.

*P10: I haven't seen that there's good evidence that when one has been ineffective and tolerated up to a big dose, that switching to another is, is beneficial.*

*P13: I don't feel that that works. I would only consider doing that if they have a genuine reduction in their pain on their opioids, but for the vast majority, it really does not work. Um, we have lots of evidence...*

Clinicians expressed concerns about the known long-term harmful consequences of opioids, a major influence on the decision to reduce or stop patients' opioids.

*P4: The side effects that they'll be experiencing because of that and the benefits they'll have from reducing opioids. Harmful side effects like constipation and opioid hyperalgesia, nausea and immune function and those things.*

*P7: If they're on high doses and er well I suppose the pain is still present, or if I think that actually the higher doses [are] causing in fact more pain, opioid-induced hyperalgesia, then I would have even more reason to encourage them to reduce.*

Some clinicians spoke of assessing and managing pain within a biopsychosocial model – another guideline-recommended approach to pain

management – taking care to assess the benefits, side effects and evidence of pain reduction in patients taking opioids.

*P11: The pain assessment is fairly extensive, that we do in clinic, so I'm sure there are other, there'd be co-existing medical conditions, so you know, renal failure, liver impairment, all that type of thing... There's social circumstances, there's the educational level, there's employment, there's psychological aspects, you know, so it's all part of the biopsychosocial, um, mix or make-up of each individual patient.*

**1.2. Working within multi-disciplinary teams (MDTs).** All participants were based in MDT Pain departments of NHS hospitals. Clinicians could refer patients to the opioid reduction service located within the clinic, particularly those patients who did not have strong social support networks. Multi-professional teamwork was cited as a key aspect in helping patients reduce, switch or stop opioids.

*P6: I think if somebody who had a very limited support network, and I felt they were fragile and I felt they were highly dependent on their opioid medication, I might be even more inclined to get them involved in a multi-disciplinary programme to reduce their opioids as opposed to just asking their GP to work on it.*

Clinicians appreciated the value of working with various colleagues providing different expertise. Medical colleagues, e.g. nurse specialists, helped with



decisions to initiate opioids, while non-medical colleagues, such as clinical psychologists and physiotherapists, were able to provide interventions from their respective expertise.

*P3: In my clinic, I would have a nurse with me most of the time, and well, I've worked with some of these nurses for 20 odd years, so we're in a position to actually evaluate the situation, to discuss it and bounce the ideas off each other. In the consultation, we will often ask each other in front of the patient questions so there's transparency as to what's going on, and erm, make joint decisions... In the complicated patients, the psychologists will potentially be in the room with me as well, so the patients with the most distress, the most complicated issues; it's not unusual for me to have a psychologist in the room helping [inaudible] or supporting any decisions that we make outside the guidelines.*

*P13: Whereas in our multi-disciplinary pain set-up, you've got targeted pain physiotherapists who have a great deal of familiarity with these conditions. They're often working combined with psychologists and the pain management programme so again, they are very cognisant of the issues here that might not be there in a general sort of musculoskeletal problem. Um, so they would tackle the pain slightly differently.*

Three clinicians further noted that they were prompted to access MDT support when patients presented with extreme distress.

*P6: So if a patient's very very distressed, it doesn't necessarily change my goal but it might change how we deliver it or [how] much support I offer them... If a patient's distressed, I might be more inclined to give them an MDT support to get them off their opioids, rather than just ask the GP to do it.*

Colleagues in the MDT also functioned as a source of emotional support, especially useful when clinicians see patients with complex medical and psychological profiles and need to make difficult decisions.

*P10: We've got a psychologist, so that you always feel in a more, in a better position when there's two of you, it kind of shares, the dynamics are improved. Used to be one of the senior nurses but I prefer it when it's a psychologist really 'cos they can, you know, look at things from different angles, and that's very supportive actually.*

*P9: We've got a really good team here and the support. We discuss these patients so you don't feel alone in making those decisions.*

However, clinicians acknowledged that there were still service gaps in holistic pain management. Pressure on the Pain service meant long waiting lists to see a pain clinician or a psychologist. One clinician also pointed out the lack of psychiatric services specialising in treating addictions to pain medication, and that general psychiatric services did not have the available resources to treat pain patients addicted to prescription opioids.

*P3: Big problem with the psychologists is the waiting list.*

*P5: Psychological services are quite hard to access in our area, with a lot of community services being pulled back.*

*P9: If there were more services with psychiatry and addiction services surrounding prescription opioid medication, I think, might find that really useful.*

## **Theme 2: Thorough Understanding and Application of Expertise on Opioids**

This theme expounds on the expertise that pain consultants bring to their practice and how expertise relates to both the adherence to best practice and the understanding of the role of opioids in each patient's unique presentation and goals. The subtheme 'Making exceptions in order to prescribe opioids' is represented by a double line connecting to the theme 'Adherence to best practice' (see Figure 1) because while clinicians are generally conscientious in following clinical guidelines, they also make decisions contrary to the norm.

**2.1. Making exceptions in order to prescribe opioids.** Clinicians usually made a decision to prescribe or increase opioids when patients experienced acute exacerbation of pain. This might be in the context of a patient's need for short-term pain relief post-surgery, notwithstanding the pain from an existing chronic condition, or to provide brief respite while changing a wound dressing that might be exceptionally painful.

*P6: If they were coming in for an operation in the context of acute-on-chronic pain, I would increase the opioids, because I would assume they have a baseline requirement for opioids and actually I'm really balancing acute pain.*

*P4: Or if there was a particular incident which was causing pain, for example, a patient that needs a dressing changed, which is particularly painful but doesn't require a lot of extra opioid apart from when they're having the dressing changed.*

Clinicians also considered trialling a dose of opioids following the failure of other non-opioid analgesic drugs to provide pain relief. Interestingly, five clinicians were more tolerant of prescribing opioids to patients who were elderly and allowing them to remain on opioids longer-term, a decision in stark contrast to patients in the younger age brackets.

*P7: I would be more relaxed about it if they're old, just 'cos they are older, and maybe just a low dose will carry them through.*

*P11: Anyone under the age of 60 I would try and steer away from opioids, I think... I think um, I'm more, um, I'm more relaxed, is that the right word, not quite sure what the right word is. I'm more tolerant of opioids in elderly patients because I kind of think the long-term concerns maybe are not there, and if they're helping then I would, I would rather they have an improved quality of life albeit a shorter period of life for their remaining life.*

*P11: You certainly wouldn't want to be having a 20-year-old taking morphine for the rest of their lives. i.e. that concern about a 90-year-old taking a little bit of morphine in the last 4 or 5 years of their life, um I think if I'm honest, I think I'm less concerned.*

A small number of clinicians spoke of the time when they prescribed opioids when it was not actually indicated. One clinician prescribed opioids to appease a patient, while others did so in order to aid the patient to tide over a short period of time, for example, to enjoy a holiday or to attend to a family bereavement.

*P5: I guess rarely, if I'm really backed into a corner and someone's demanding something, I might prescribe opioids to someone I normally wouldn't prescribe but I make sure that it's a very small dose just at the time; find a middle way of doing what they want, but not in a way that's going to maybe compromise their safety.*

*P2: [On] that occasion, I go against the evidence because I want to accommodate the lady's request to have a nice wedding with her daughter, or cruise or whatever else is important in their lives. And you provide that short-term pain relief knowing for a fact that the patient will be grateful and it's going to mean a lot to her do that extra bit of activity.*

*P9: Did actually see a patient with a serious congenital condition called osteogenesis imperfecta who had a recent bereavement and had to travel distance to clear out her father's house and she needed pain relief to be able to do that.*

## **2.2. Assessing the role of opioids within patients' medical profile.**

Clinicians considered the profile and risks of the different types of opioids when making decisions. A minority of clinicians preferred prescribing short-acting opioids over long-acting ones to give patients more control over their pain.

*P11: I would prefer to have someone taking PRN short-acting opioids than regular long-acting opioids. And I think that goes against what the taught, the teaching was 5 or 10 years ago. That's because, and I, in clinic, I draw out a diagram of the wobbly line and I say, look your pain isn't static, your pain doesn't go along on one line, so there's no point having this myth of this constant drug in your system that deals with all your pain. 'Cos when you look at the wobbly line, you say look over here it's overdosing you, and here it's under-dosing you, so I'd rather you took some immediate relief stuff when your pain is particularly severe and then gradually get rid of the background stuff.*

Simultaneously, most clinicians perceived short-acting opioids as highly problematic – patients were more likely to develop dependence and addiction, increased risk of diversion and inappropriate use, i.e. for euphoric effects, and are more difficult to wean.

*P6: Ones that are rapid-acting have benefits or desirable qualities that are not necessarily analgesic, so I think they get euphoric and I think people can feel better because of the euphoric element without actually achieving much analgesia.*

*P3: They feel psychologically better and then of course they lose that; so you're potentially developing an addiction problem because they're only acute-release.*

Clinicians were also partial to recommending weak opioids over strong ones, and avoiding prescribing opioids that are associated with psychological effects.

*P8: The important thing is to bear in mind that whatever you use has got to be very short-term and only for finite period, and try not to use erm, very strong opioids to start off with.*

Adverse effects were prominent in clinicians' minds; all of them spoke about the side effects of long-term opioid therapy which included nausea, constipation, drowsiness and, on rare occasions, hallucinations. Even more concerning were the long-term consequences such as endocrine dysfunction, opioid-induced hyperalgesia, risk of overdosing and physical and mental dependence. Adverse effects and long-term harm were the most frequently cited factors for any prescribing decision and the main reasons to recommend reducing, switching or stopping opioids if patients experienced significant adverse effects.

*P1: Some generic side effects of constipation, nausea, dizziness...*

*P12: ...falling asleep, monoclonic jerks, constipation, um. I think the big factor would be drowsiness through the day.*

*P14: They use opioids inappropriately, so just to achieve cognitive side effects from opioids and think less about pain, but there is no genuine pain relief effect, so that's a third fact. And the fourth is that they have, once they go above certain level, they will have more pain and will have opioid-induced hyperalgesia... once they learn that it's very harmful, so the pain is increased by the usage of these drugs. That's like an eye-opening statement information*

*to them. Then you list all the other problems, low immunity infection rate, um, endocrine dysfunction...*

Given that opioids are highly controlled drugs where overdose is a serious risk, clinicians emphasised several safety measures to be put in place when prescribing opioids. These included documenting a formal opioid contract with the patient, prescribing on a trial basis, ensuring regular reviews and building in an exit strategy, i.e. inserting a clause for withdrawing opioids if necessary.

*P1: A restricted dose based on opioid contract or hopefully a limited period of time.*

*P5: Have an exit strategy, so make it really clear to the patient at the beginning that we will be taking away the opioids if we don't find them to be helpful.*

In addition to the specificities of opioids, clinicians also assessed the patients' medical profile, accounting for risk factors such as diabetes, infections, obesity or sleep problems, and other medications patients were taking.

*P5: Patients who are overweight with sleep apnoea, or even overweight without sleep apnoea, then I'd be much less likely to prescribe them opioids because the risks are so high. And also, patients who are also taking diazepam or sleeping tablets as well, I'd be a bit more cautious about giving them opioids, and again, I suppose it's the short-term risks that I'd be worried about respiratory depression.*



*P13: You might choose different versions of drugs, for example if they happen to be on a neuropathic drug and they happen to have some organ dysfunction like kidney failure, then there are drugs which are first-line like gabapentin and um, for reasons of cost, there are second-line drugs like pregabalin. In that context, I would explain to the GP why I'm recommending the more expensive drug to be used in the first instance, because medically it would be better to protect their kidneys.*

Clinicians further assessed the history of opioid intake by querying patients' responses to opioid type, dose and effectiveness in order to inform their decisions.

*P14: I would like to find out whether...well, the history how opioids were increased in the past up to the level which patient presented. And whether this is a, what is the result of it, what the outcome and whether the patient improved function, does it give them pain relief or a situation with side effects.*

**2.3. Achieving functional goals.** Functional goals were key considerations for justifying opioid-related decisions, whether that was to initiate, increase, maintain, reduce or stop opioids. For clinicians who reported taking a reticent stance in initiating or prescribing opioids, they were willing to consider initiation if the opioids proved to improve functioning and reduce disability.

*P10: It's if people are really stuck in a rut and you're doing it to aid, you know, mobilisation, to aid getting back in community, to give them a bit of a break, to sleep, the whole package.*

More commonly, clinicians spoke of reducing opioids if no functional benefits were observed in patients after being on doses expected to have worked. Side effects were also a concern as an impediment to a quality of life that could be enjoyed, even though this meant that the pain might not be necessarily reduced.

*P11: So I stress that it's not to make them pain-free, it's to allow them to have a functional improvement. They are given a trial of a dose of opioids, if they improve, fantastic, if it doesn't make any difference to their functioning ability, to their pain, the answer is not to increase it, the answer is to stop it, wean it.*

### **Theme 3: Paying Attention to Patient Factors**

This theme examines the patient factors that clinicians take into consideration when assessing patients and making recommendations while practicing within the biopsychosocial model of care.

**3.1. Addressing patients' mental and emotional state.** As part of the comprehensive assessment of pain, clinicians assessed patients' psychological issues, taking care to note any signs of depression, suicidal risk, anxiety and distress, and addressing these accordingly.

*P4: So suicidal ideation [is], sort of, we standardly ask for the pain assessment. It's not something that's, you know, particularly around opioid prescription. And as I said, it's very rare for us to see someone who's acutely suicidal and I wouldn't be giving that person a whole lot of tablets no matter what.*

If patients presented as very distressed, clinicians would not prescribe or increase opioids, or they might consider postponing the commencement of opioid reduction. They attended to patients' distress prior to discussing opioids. Clinicians might also prescribe anti-depressant medication themselves or refer very depressed patients to a psychiatrist.

*P7: With the distress, I wouldn't start opioids on them because they are distressed. No.*

*P3: If someone was severely depressed with suicidal ideation, I would liaise with the GP, and then there would have to be a decision made as to whether or not the psychiatrist is involved, so which stray more from a reaction of depression into adult mental health side of things, I probably wouldn't prescribe.*

Clinicians expressed their concern that patients' emotional difficulties were potential barriers to clinical outcomes or compliance. Patients with depression, anxiety and personality disorders were perceived by clinicians as more likely to struggle with pain. Depression also affects patients' cognitive functioning and may inhibit rehabilitation. Clinicians were less likely to prescribe opioids if patients presented as angry and hostile.

*P9: We find that they're very anxious, angry, their mood seems sometimes, um irrationally, they don't seem to listen as much, or seem, um, to have to, they seem to be some of the most difficult patients to shift their thinking, to get through to.*

*P8: They're anxious about me trying to stop their opioids. They become very defensive, erm, you know. Quite a few of them are depressed, er, and it affects their cognitive function.*

*P10: If they're really distressed and irrational, then it's probably that I'm less likely to go down the therapeutic drug route, you know, maybe, so that's the only thing really. Or if they're angry or hostile, then I'm less likely to.*

Clinicians often reported that patients' distress influenced the way they would approach the clinical consultation, and did not necessarily mean that their opioid-related decisions would be influenced.

*P2: It changes the way I approach the subject, but it doesn't change my decision... It's a joint conversation and a joint decision that I'm trying to reach.*

*P13: And look at what their fears and concerns are, and you know, try and sort of get a better understanding of what they would like. That doesn't change my decision process but it does mean that I spend a bit more time to try and work on their understanding and have a shared sort of manageable plan that they would feel a bit more comfortable with.*

**3.2. Consideration of patients' social circumstances.** Clinicians were thoughtful about patients' social networks and level of support. There was a perception that patients who were well-supported by their family and social networks would have better access to help with monitoring opioid use and be less at-risk of opioid abuse.

*P6: It's important for the patient to have a support. You know, coming off opioids is a really challenging and difficult time for people on them, on high dose of opioids. You have to have an idea of what their support system and support network [is].*

*P11: I think if somebody's from a stable, well-supported, um, environment, then there's less likely to be potential abuse. Um, I get very nervous about drugs like these being in a house of young families, I get very, I get nervous about people who have got former history of personality-types that mean they're more likely to abuse it, so you know, drugs and alcohol and smoking and that type of thing.*

Clinicians expressed worry if patients' lives seemed 'chaotic' and were more likely to recommend them to come off opioids. Additionally, if patients had little social support, clinicians were more likely to consider and make a referral to the multi-disciplinary programme to support with opioid reduction, as opposed to simply referring the patient back to their GP to manage the reduction.

*P12: It probably involves a lot of um, maybe not stereotyping, which is a bad term to use, but you know, you've seen lots of people in similar situations and you know, the whole situation they tell you, um, what they're doing at work, how their relationships are gives you a flavour of how their life is. Um, it might make you more worried if it's a chaotic life, that there are lots of people coming in and out, that they also seem to be, you know, smelling of alcohol and you know, that kind of thing would be your gut instinct to say, this person*

*definitely needs to come off the opioids... Versus somebody else who comes in, um, and everything seems to be ordered in a very organised...*

Clinicians also considered whether patients drove or had children, and were careful to convey to patients the message to use and store opioids safely. These considerations were not specific to opioids; these concerns could be generalised to most prescriptions involving sedating drugs.

*P4: Things like driving, profession, children in the house, safety, suicidal risk ideation.*

*P5: I would make sure that parents of children would have a locked cabinet at home or some means of storing the opioids away from any children.*

### **3.3. Past and present behaviours concerning opioids and medication.**

Clinicians reported that patients were known or found to be using opioids inappropriately, e.g. for cognitive numbing or to prevent withdrawal effects, rather than what they were intended for, i.e. analgesic benefit and/or improved functioning. Clinicians considered the patients' risk of opioid addiction, diversion and dose escalation and other risk markers such as a history of mental ill health, drug and/or alcohol abuse and forensic activity.

*P5: I think the patients with a lot of distress can use opioids very much as a crutch, both for their pain but also for their psychological upsets.*

*P11: I get nervous about people who have got former history of personality-types that mean they're more likely to abuse it, so you know, drugs and alcohol and*

*smoking and that type of thing. Um, if they're, if there's any criminality, if there's any risk of diversion.*

Clinicians' suspicions were aroused when patients reportedly visit different practices, demand higher doses despite being given a rationale for reducing, and indicate a preference for particular opioid types. These behaviours were suggestive of an intention to obtain opioids for inappropriate consumption or distribution. In turn, clinicians were more likely to proceed with greater caution when making prescribing decisions.

*P14: They come because they went to many clinics in the past, they've been under multiple specialities, so the level of their knowledge how to achieve the result they want is high and they are more manipulative.*

#### **Theme 4: Maintaining Doctor-Patient Relationship**

This theme refers to the clinicians' task of engaging patients through establishing trust, building rapport, engaging in collaborative decision-making and providing education so as to have a helpful consultation which would enable patients to manage their pain better. The patients' best interests were central in every difficult conversation or decision clinicians had to have or make, even if this meant a conflict with the goals and expectations of the patients.

**4.1. Keeping patients' trust and engagement.** Clinicians reflected that the benefits of a relationship in which trust and engagement are present include patients feeling listened to, experiencing less heightened or unpleasant emotions and being better able to accept clinicians' recommendations.

*P3: That's about building trust with the patient and beginning to show them, well actually this helped, this didn't help, it's a long-term commitment, so there will be a degree of responding to the patient. Because you have to have them working with you.*

*P9: Even when a patient can be quite difficult, you try and maintain the relationship because you're never going to get them to reduce or use their opioids properly if you've not got a good, trusting relationship with them.*

Perhaps more importantly, the role of a good and trusting relationship enabled patients to better engage in opioid reduction with a greater degree of motivation and confidence. In comparison, patients whom clinicians struggled to make a connection with tended to fare worse, e.g. poor adherence to medication or recommendations.

*P11: You don't want all hope to die. You want to try and empower these people to try and um, you know, you want them to come away with some positive messages as well and positive thoughts.*

*P9: Often they have a lack of trust with the medical profession because they've never, they've been diagnosed late, or you know, they've had lots of procedures that haven't really helped them.*

A patient-centred approach involves understanding patients' priorities and encouraging joint decision-making. One clinician spoke of using motivational interviewing skills to help patients understand the effectiveness of opioids and the rationale for weaning them.



*P13: You've got to have a long, frank and meaningful conversation with the patient to try and understand what is the source of their pain, where are they on their pain journey to get a better understanding of what it is that they need. And what, it's got to be in conjunction with the patient, so there are lots of things that I might feel are beneficial, like clinical psychology, and I feel very strongly about it and I have very good experience with, but if the patient doesn't feel that that's right for them, again, they're not going to be ready to accept that, so again, it's about recognising the patient's priorities and syncing in your offered treatments in line with that.*

*P11: I try and use sort of things like motivational interviewing techniques and reflective listening to sort of try and get them to say whether or not they think the opioids have a role.*

#### **4.2. Making recommendations in patients' best interests.** Clinicians

conveyed a strong sense of obligation to do their best for patients, whether this meant making firm decisions despite upsetting them or veering toward slightly unethical practice, i.e. concealing information from a patient on dose level during opioid switching.

*P14: I'm trying to explain patients honestly about their future, that's what makes the difference. I tell them that, how limited I am in this situation of chronic pain and give them an idea of options, obviously try not to be paternalistic, but of course, we are, quite often.*

*P7: Sometimes I actually have done as well where we've, [for] the patient's sake, we've told them to rotate, and sold it to them as it's to get best pain control,*

*but actually we've, the equivalent dose, is that we've under-dosed it, but just use that as placebo, or whatever you want to call it, just to, just so that we can reduce the actual opioid dose that they're getting by changing it to another opioid. I've told the patient this is the equal when actually it's being less than the equal.*

Some clinicians acknowledged the importance of understanding their own and professional limitations and needing to be aware of one's biases getting in the way of providing optimal care. They also recognised the reality of not being able to make some patients better; chronic pain, by its very definition, is frequently not possible to cure completely.

*P2: Neutral being very very, correct, just trying to remain unbiased to my own biases, to the patient's biases and to other doctors' opinions. My task is to accommodate patients to the best of my abilities within the evidence provided and my experience and my comfort zone.*

*P8: I don't, you know, profess to be able to treat everybody. And, there'll be some patients who, you know, I won't be able to treat, I won't be able to get them better.*

During the course of making recommendations that clinicians determined to be in the best interests of the patient, clinicians may wrestle with ambivalence and conflicting emotions. They described worrying about having made the decision to not prescribe opioids believing that that was the right call, but simultaneously

wondered if it might have been a missed opportunity for the patient to have derived some benefit.

*P12: I worry that I might be missing that, you know, patient that might go on to opioids, get on to a set dose, be on it and have good analgesia, but I don't really see them very much in my experiences being that I'm, it's very rare to find them. Um, so sometimes, I often think, you know, I regret not having put them on in the first place, if I can say it that way. That maybe I should be putting more patients on to them, and trialling them and then saying actually this is getting out-of-hand and then come off.*

**4.3. Conflicting goals and expectations.** This subtheme closely relates to the theme 'Thorough understanding and application of expertise on opioids' (represented by the bold line in Figure 1). Given clinicians' knowledge of the risks and long-term consequences of opioids and evidence for reducing, stopping or not prescribing opioids for chronic pain, the above factors can be a stark contrast to patients' expectations of pain-free solutions in the form of being prescribed opioids or increasing the dose. Thus, conversations are often difficult and emotion-laden when they are about reducing, stopping or not prescribing opioids and patients disagree with the clinician's professional opinion.

*P7: Their emotions, they get emotional if I, if I'm talking around reducing morphine, then they, that's when they, you know, they become really defensive about it, more often than not.*

*P1: Anything from anger, frustration, disappointment with them and/or yourself. Or kind of 'I don't care, whatever' ... You're disappointed with the whole system and how, sort of, how this person's journey ended up.*

Clinicians reflected that it was often difficult to engage patients and 'get them on board', feeling under immense pressure in dealing with patients' expectations and sometimes exasperation at patients' non-adherence. These challenges stem from a mismatch between expectations and reality. For instance, patients received conflicting messages from their GP and the pain clinician regarding opioid prescription, leading them to feel let down, not properly advised or looked after. Patients often did not want opioids taken away even if there was no evidence of opioids working for their pain; clinicians reported considerable challenge trying to persuade patients otherwise.

*P8: It's exasperation, because we've gone through the whole thing time and time and time again, and they still don't want to. So basically, you see, their argument will be to try to find a way of trying to counter whatever I say. So, you know, it's often exasperation, thinking 'oh you didn't listen, you didn't think whatever I was saying to you the first time', I have to explain it two or three times.*

*P1: You probably could do some tests [inaudible] there isn't actually any evidence of harm. And if not, and they really want to continue, and they feel it's benefiting them and so forth, it's going to be difficult, it's a hard-sell to convince them to reduce. Oh, we certainly try.*

The above issues emphasise the importance of clinicians needing to possess good engagement skills in making the consultation worthwhile for both parties. Clinicians were careful to ensure clear communication and documentation of the recommendation to patients and their primary care doctors. For some, focusing on engaging the patients took precedence over implementing the recommendation because the chief concern was to maintain the doctor-patient relationship through trust and a desire to help.

*P13: ...making sure that my concerns about the patient are both communicated in an honest way to the patient, but also in a clear fashion to the GP.*

*P5: I want to keep the patient on board and I want the patient to kind of trust me and listen to what I'm trying to tell them. There's no point losing a patient relationship completely because then you've got a chance to educate or support that patient.*

### **Theme 5: Clinicians' Emotions have Little Bearing on Decisions**

This theme explores the question of whether clinicians' emotions were an influencing factor on decision-making. Participants' responses in the discussion on emotions varied; most acknowledged that it was important to be aware of one's own emotions but that this did not necessarily exert an influence on decisions made; some perceived emotions as implying illogical or irrational thinking; and a minority postulated that their emotions ought to play no role in decision-making or in the consultation process.

**5.1. Maintaining a professional front.** Clinicians were keen to portray a professional manner when interacting with patients. There was a prevalent perception

among participants that decision-making should be logical and rational, and not driven or influenced by their emotions. They emphasised the importance of maintaining a neutral emotional stance, especially when needing to contain patients' emotional distress.

*P5: I have to bring objectivity and knowing about long-term side effects and things. Of course that doesn't mean that I'm affected by emotions, however, I'm used to feeling, you know, being in an uncomfortable situation with patients and therefore, kind of hold boundaries and lines.*

*P13: The emotions can range in terms of how I am feeling, but I like to try and sort of get it back to what I use as, if you like, as my sort of professional, um, manner, really to try and disengage on anything that I'm feeling where somebody's feeling angry and aggressive or frustrated or tearful, to try and sort of get me and the patient back to whatever point it is we're discussing.*

**5.2. Importance of being aware of own emotions.** Some clinicians reflected that their own emotions could potentially influence decisions unconsciously, though they hoped they did not accede to these influences.

*P11: Obviously I'd like to say that they [emotions] don't influence them [decisions] in any way, shape or form, but I think that would be naive. I am probably being influenced in ways that I'm not necessarily aware.*

*P1: I would like to say no but probably does.*

Several clinicians were mindful that work pressures and personal life stressors had the potential to influence their decisions or interactions with patients. One clinician also noted the potential downside of positive emotions such as empathy, i.e. feelings of empathy toward patients' distress and pain should not influence making a prescribing decision that may inflict harm on a patient.

*P12: If I'm tired, or if I've got other things going on in my life, or I'm feeling particularly stressed, you know, you do not want to have this conversation now.*

*P3: You need to be careful that you're empathetic and understanding, that you have to try and avoid what you'd expect to be normal reaction and frustration potentially going into anger because then obviously, you know, you have to obviously be aware yes you might have empathy and become sympathetic but that actually should not change your practice.*

**5.3. Needing to guard against emotions.** Among some clinicians, there was a perception of treating one's own emotions as something to 'fight' against or disengage during the consultation. One clinician spoke of striving to exclude emotion during consultations, preferring instead to focus on the message that he was keen to convey to patients.

*P14: I'm trying to be professional. If I'm in a good mood in terms of that, I mean, so I have energy to interact. So I don't want to be any, well, surprise myself from the situation and not, um, don't allow negative emotions to come into the play.*

P8: *I try very hard not to be emotional about what I do, because it should be exactly the same, you know, every single time.*

**5.4. Gut feeling used to make non-prescribing decisions.** A question in the interview schedule asked clinicians if they ever used gut feelings in making decisions. Most clinicians said they did not use gut feelings; they relied on the evidence base and their clinical judgment to inform their decisions.

P2: *My gut feeling is about not doing a dangerous thing, rather than doing the right or wrong thing... Er, so I don't rely on my gut feeling when I prescribe or initiate something, if you know what I mean. It's a joint consultation. No, gut feeling doesn't play a major component of my work.*

Three clinicians reflected that if they ever used gut instincts, it was more likely to involve a non-prescribing decision, i.e. having a felt sense that opioids would not work for the patient's pain, despite there being insufficient indication to withhold opioids.

P6: *My gut feeling is that actually their pain is not responsive to opioids, even if it had been responsive in the first place. But when people are on a very very high dose of morphine-based treatment, I think actually my gut feeling is that this shows you are not responsive to opioids. So my gut feeling is if you reduce the opioids, you will feel better.*



## **Theme 6: Recognising Limitations of Current Prescribing Climate**

This theme explores the role of systemic factors and beliefs that bear on prescribing decisions on a meta-level, that require a nuanced understanding of the specific contexts in which clinicians work and make decisions. Many clinicians shared insights that were thoughtful and profound; they spoke of their worries, regrets and appreciation as pain specialists practicing in the UK NHS healthcare system.

**6.1. Belief that current approach is right, given available evidence.** This factor relates closely with the discourse in Theme 1 ‘Adhering to best practice’ (represented by the dotted line in Figure 1). Clinicians practiced in accordance with the extant evidence base and best practice guidelines, which they believed to be right. As expected, most clinicians expressed no regrets for their prescribing and non-prescribing decisions, trusting that their clinical judgment was proper and sound.

*P12: In the last 5 years, no. God I'm great, aren't I, no (laughs). I'm sure if I think about it long enough, I'd like to say yes I have. There's a lot of things you do in medicine you regret, um, but it's usually not around opioids anymore.*

*P3: I can't think of any time specifically, and that's probably because I work within guidelines.*

There were exceptions. Three clinicians reported past instances in which they had regretted prescribing opioids to patients and in which events had taken a turn for the worse because of inadequate boundaries and poor monitoring of the patient's prescriptions.

*P5: We ended up increasing her opioids just to manage her on the ward, and then the opioids were never decreased again when she went into the community. So this was a lady who was quite vulnerable ending up on very high doses of opioids, and she really hasn't done very well at all, and I think, now she's been on opioids for years, it's very difficult to get her to understand that we need to get her dose down. She doesn't feel able to do that, and I just think we've not done her any favours actually, which is a pity.*

*P7: But I had very much in mind, I'm going to start off them, and then I'm gonna review him and then stop it if it hasn't helped. Then we lost him totally to follow-up, and the next thing I know, he's back in clinic and the doctors elsewhere had increased it and he was on like 200mg... so that's regretful and I, er, because my intention was not to go that high. It was to introduce, to see the pain response, keep it at that level and maybe, if anything, just a touch higher, and not go from 10 (laughs) to 200mg.*

Three clinicians reflected on the impact of the medical community's certainty of 'what's right' then and now in prescribing opioids to patients with chronic pain in desperate need for pain relief. There was an element of anticipatory regret, present alongside feelings of doubt and guilt, at potentially withholding opioids from patients who might have needed or benefitted from them.

*P6: Sometimes [I] feel guilty for perhaps I'm not doing the best thing for the patient. The doubt, actually, doubt about what the best thing is for the patient... Sometimes, I feel anxious about being so vehement about not prescribing opioids for non-cancer pain. You know, on the basis of current*

*best practice.*

*P11: If the pendulum swings the other way, if there's a certain cohort or groups that really benefit from opioids, and I'm currently saying you can't have them, then I might regret that down the line.*

**6.2. Healthcare system of regulating and prescribing opioids influences clinicians' ability to prescribe and patients' access to opioids.** A few clinicians articulated a reluctance to prescribe opioids in part because of the healthcare system within which they operated. Some regret was expressed by clinicians who recognised that the current set-up of care provision did not promote a safe space to trial selected patients on prescriptions – heavy caseloads and the ease with which patients are discharged following non-attendance for appointments makes it difficult to monitor patients' progress safely. Thus, clinicians become more risk-averse and are less likely to recommend opioid trials for patients whom they think might have stood a chance at benefitting from opioids.

*P10: But primary care doesn't really work like it used to in the old days. They are trying to get back 'named GPs', but when I first started, the GP had their 2000 patients. They generally, that was 500 families or 600 families. They knew the families.*

*P12: If you've got these high-risk patients who don't want to see you, then it makes you very, you know, uneasy about starting. And I agree, it's the nature of the system, makes you prescribe differently.*

A few clinicians highlighted one benefit of not being direct prescribers of opioids; it was the GPs, not pain clinicians, who issued prescriptions based on the latter's recommendations for the patients referred to the Pain service. This arrangement puts some distance between the pain clinician and the patient, acting as a safety net against unsafe prescriptions. Clinicians also observed that the mistakes committed in the US serve as a cautionary tale; more restrictive regulations in the UK protect patients and clinicians alike from the risks of over-prescribing, opioid abuse, diversion and death.

*P14: I don't prescribe myself, I ask GP to consider as an option. I don't do prescription in the clinic for opioids.*

*P12: I think we're very much informed by where opioid prescribing has gone very wrong in the US where you have very much more of a, a buyers' market, you know, people go away as consumers and they would pick the doctor that they want, and the doctor that prescribes opioids very easily is more likely, whether consciously or subconsciously, to be the one getting the business.*

**6.3. Medical specialisation results in other doctors not knowing best practice guidance for opioids for chronic pain.** A few clinicians reflected that they were in a better position to advise on opioids by virtue of their specialisation. Conversely, they noted a lack of education on opioids among primary care doctors (through no fault of their own) contribute to the opioid problem, and were keen to educate prescribers to prevent further harm to patients.

*P4: I don't think that most practitioners apart from pain doctors know what a recommended safe level is. In terms of, for example, British Pain Society guidance, is that we shouldn't really be prescribing more than 120mg morphine a day. So I don't think anyone, other than pain professionals, knows that, and I don't think that's their fault, I think that's the multi-factorial, that's the kind of failure of medical education... That's a failure of the fact that we just have increasing doses of opioids available, which you hear about from history, from palliative care, but it's now, it's sort of then people translate that palliative care prescribing of patients with non-cancer pain and of which is usually unhelpful.*

*P9: We're at the moment trying to go out and talk to GPs about opioid prescribing, educate them; that's part of our programme within our department.*

Clinicians also observed that medical school teaching had changed in the last decade or so. Younger clinicians are schooled in the dangers of opioids during consultant training, and this is reflected in the way they spoke about the decisions, usually non-prescribing ones, they made. One clinician spoke of having to revise his previously-held belief that opioids were useful and humane for chronic non-cancer pain.

*P11: I started as a consultant, I started in 2014, and fortunately, awareness about the dangers of opioids were starting to surface then.*

*P6: Historically, maybe 5, 10 years ago we felt very strongly as a medical community that we were under-treating people who had chronic non-cancer*

*pain. That we were actually depriving people of opioid medications, and I really bought into that argument. And I liked that argument, because I thought that it was being humane. And now I think we've swung completely the opposite way, and we're sort of contradicting [the] messages that we gave before.*

Clinicians shared that there seemed to be a prevalent public perception that pain consultants often initiate or increase opioids for patients referred to the Pain service, a view that is at odds with what clinicians actually do, given that they reported spending most of their consultations attempting to persuade patients to come off opioids. This perception is perpetuated by the widespread belief held by patients, doctors and the general public that 'nobody should be in pain'.

*P9: Which is strange, because a lot of people would think, well you would be starting them on it, um, but no, we spend our lives reducing.*

*P1: So a lot of it I think is about healthcare, other healthcare professionals, GPs and so forth who have this mentality that nobody should be in pain, which is true, but that's not about chronic pain. You know, it's like saying nobody should be diabetic. Well the reality of it is that a lot of people are going to be in pain, in chronic pain, and erm, the reason that they are in this very multi-factorial...the treatment options are actually very poor because if these medications were that good, nobody would have been in chronic pain.*

In summary, pain specialists considered a range of factors in their clinical decision-making. The factors outlined in Themes 1 and 2 were the most predominant

considerations influencing decision-making. Clinicians mainly worked toward getting patients to decrease to acceptable levels (as recommended in clinical guidelines) or to stop opioids. It was rare for them to be initiating or increasing opioid prescriptions.

In addition, clinicians also considered patient-specific characteristics (Theme 3) in informing their decisions. Where patients presented with higher risk in the form of complex medical and psychiatric histories, and psychological or emotional distress, clinicians tended to apply further caution in decision-making.

Theme 4 described the interpersonal aspects of the clinical consultation and decision-making processes. A good doctor-patient relationship is a valuable foundation that enables clinicians to deliver difficult decisions in ways that patients feel better able to receive and accept, though not always.

In terms of the influence of clinicians' emotions on their decision-making (Theme 5), clinicians were divided in their opinions. Some clinicians perceived that emotions are not helpful, and it should be logic and rationale taking precedence during the consultation and decision-making. Others reflected that emotions, specifically unpleasant ones, may be present and need to be acknowledged (to oneself) so as to not make a wrong decision. Three clinicians recounted instances of feeling regret over past decisions to prescribe opioids. While they did not connect previous regretful events to their current prescribing practices, it may be possible that such incidents serve to inform, consciously or unconsciously, clinicians to practice henceforth with more caution.

Finally, meta-level factors were at play in decision-making (Theme 6) – healthcare regulatory systems and updated consultant training indicate that pain clinicians today are less likely to prescribe opioids; they are more likely to suggest

reducing or stopping them in patients with chronic pain. Furthermore, patient referral systems may act as a barrier to safe trialling and monitoring opioid use in patients who may derive some benefit from them.

### **Discussion**

This study set out to examine the factors influencing pain specialists' decision-making for prescribing opioids for treating chronic non-cancer pain, with a particular interest in the influence of patients' and clinicians' emotions on decisions to increase, decrease, switch or stop opioids.

The findings show that clinicians' foremost reasons for stopping or reducing opioids, which were the most common recommendations they tended to make, were adherence to best practice guidelines (Theme 1) and a thorough understanding and application of their expertise on opioids (Theme 2), e.g. considerations of long-term adverse effects, risk-benefit analysis of opioids, goal-setting and careful monitoring. These findings are consistent with other studies (Owen et al., 2018; Seamark, Seamark, Greaves, & Blake, 2013) and in accordance with best practice guidelines (Royal College of Anaesthetists [RCA], 2017).

Consistent with findings from Hollingshead and colleagues (2015), clinicians in this sample used information about patients' pain severity or type of condition, paying close attention to patient-specific characteristics (Theme 3) to better inform their decisions. Clinicians reported attending more closely to patients presenting with psychological or emotional distress by exploring the distress, taking care not to prescribe opioids (which some patients had been using inappropriately to relieve psychological, rather than pain, symptoms) and were more likely to consider a referral to colleagues in the MDT. The latter is in line with using best practice models of a team-based approach to pain care and management (Reuben et al.,



2015). This multi-disciplinary approach may augment patients' wellbeing more than relying solely on opioid prescriptions for pain management (Frank et al., 2017).

Other factors cited by various clinicians that influenced decisions were the interpersonal aspects of the doctor-patient relationship (Theme 4), the possibility of clinicians' emotions and stress levels (Theme 5) bringing to bear on the consultation process and recommendations, and the influence of healthcare structure systems (Theme 6), e.g. patient referrals and procuring of medication acting as facilitators or barriers to safe prescribing. The above highlights the subjectivity in prescribing, wherein clinicians sometimes felt the need to make concessions to maintain therapeutic relationships, similar to findings by Toye et al. (2017a), and demonstrated variability in weighting patient factors. For instance, age was a factor cited by five clinicians in this study as a concession they would make by prioritising quality of life via short-term opioid analgesia over the long-term risks they carry. Other reasons for making exceptions to prescribe opioids were to keep the patient engaged and open to accepting difficult recommendations in the longer term, or to allow patients to tide over a brief time-limited period. The clinician's empathy for the patient's plight is potentially another influential factor in recommending a prescription; in this study, two clinicians highlighted the need to be self-aware so as to ensure that their feeling empathic towards patients does not result in making what was considered a bad decision, e.g. prescribing when contraindicated. Tentler and colleagues (2008) similarly found that a third of physicians in their study acknowledged that their clinical judgement had been skewed by their emotional reactions of annoyance or empathy to the patients' situation and requests.

It is also pertinent to point out that clinicians have the very difficult task of balancing patients' goals and expectations with clinicians' understanding of the long-

term risks of opioid therapy and their attendant decisions. As noted by Reach (2014), patients with chronic conditions are more present-oriented, i.e. desiring to be pain-free, whereas doctors focus more on the long-term adverse effects – predictably, this presents a situation in which a mismatch in patients’ expectations and the reality that clinicians hope to convey occurs. It would follow on that difficult emotions on the part of both clinician and patient inevitably arise, with clinicians’ expressing frustration for patients not taking on board recommendations made in view of the patients’ best interests, and patients feeling disappointed at clinicians’ ‘failure’ to provide viable solutions.

Clinicians reported being aware of experiencing emotions during consultations, with the majority reporting being conscious not to allow subjective feelings to influence the decision-making process in the belief that it would be unhelpful to patients. Harun and colleagues (2015) found that clinicians in their study were likewise confident that their emotions played no part in clinical decision-making, yet were unaware that emotions inadvertently played a role in biasing their decisions, e.g. authorising a hospital discharge was less likely if the clinician liked the patient. It may be that clinicians are trained to be detached, balanced and objective in their clinical practice, for which subjectivity and emotions have little role (Good, 1994), although there is increasing evidence to suggest that emotional intelligence in clinical practice is an influencing factor in clinical decision-making and has implications for patient safety (Heyhoe et al., 2016). Similar to Brown (2005), some clinicians in the current study emphasised their keenness to remain objective, which they referred to as a desire to remaining ‘unemotional’. However, the evidence that clinicians were able to entirely exclude their emotions from decisions is debatable; given the ease of recall and incidence of difficult emotions

such as frustration or exasperation experienced by clinicians during consultations, it is possible that their emotions could influence decisions, as some did acknowledge. For instance, feelings of unease or ambivalence in complex situations may cause clinicians to act in various ways, e.g. apply more caution, seek inter-professional support or reappraise an initial decision.

In reference to the dual-system processing framework (Tsalatsanis et al., 2015), the influence of emotions on decision-making resides in the domain of type 1 processes, i.e. those which are fast, automatic, affect-based and intuitive. Clinicians who assert their use of logical thinking and reliance on the evidence base and clinical guidelines to make clinical recommendations would be applying type 2 processes, those which depend on rationality, reflective ability and critical thinking (Evans, 2011). Furthermore, specialised training and experience over time enables pain clinicians to use type 1 thinking more than the novice or general practitioner (GP), and with much better results (Cooper & Frain, 2017). Where clinicians report exerting more caution when presented with a patient's distress in the consultation room, being aware of the potential influence of patients' emotions demonstrates a utilisation of type 2 processes in attempts to be more critical of the decision at hand.

Additionally, it is equally, if not more, important for clinicians to be aware of their own biases and use of heuristics, i.e. mental short-cuts (Croskerry, 2014). For instance, one clinician candidly related his frustration when seeing patients whose first language is not English, thus requiring an interpreter, because of the difficulties in communicating the characteristics and expression of pain, especially where there may have been cultural nuances he was unaware of. A self-awareness of his prejudices having the power to influence emotions negatively and resulting in undesirable effects on the therapeutic relationship meant that the clinician needed to

remind himself to be mindful of his own emotions potentially affecting the quality of such consultations and the resultant decisions. Again, this would be an example of overriding type 1 thinking with type 2 processes with the aims of maintaining a good enough clinician-patient relationship and making sound clinical decisions.

Clinicians' accounts of feelings of regret and ambivalence were nuanced. Three clinicians, all of whom had many years (range = 10 – 19) of specialist pain clinical experience, shared their experiences of regret of commission, i.e. prescribing opioids; in hindsight, having witnessed the undesirable outcomes of patients who end up on too-high doses and continue to struggle with pain leading to a sense of regret for having prescribed them in the first place. Three clinicians, who had 10 years and under of specialist pain practice, expressed anticipatory regret of omission and spoke of their concerns about not prescribing opioids to patients for whom opioids seemed to be the only helpful option. The latter was borne out of reflections on the drastic changes in the guidance for prescribing opioids from a decade ago – a time when clinicians were encouraged to prescribe opioids for chronic non-cancer pain – to the present day, when prescribing opioids is now strongly discouraged, and whether the changes have truly benefited patients living with chronic pain. Regret is a powerful emotion that comprises cognitive and affective constituents; it allows simultaneous recall of previous episodes of regret and planning ahead to avoid situations that would trigger the emotion (Zeelenberg, 2015). A study by Djulbegovic and colleagues (2015b) showed that lower regret is associated with physicians' tendency toward satisficing, i.e. 'good enough' solutions. More than half of the clinicians (n = 8) in the current study reported no decision regret over prescribing opioids, suggesting that clinicians were largely confident that their decisions were 'good

enough' on the basis of adherence to clinical practice guidelines and exercising good clinical judgment in light of patient-specific characteristics.

Despite a seemingly predominant importance on the preference for type 2 processes in making good decisions, as borne out by the emphasis on rationality, knowledge and reflective thinking on clinicians' biases and emotions, that is not to say that type 2 processes are superior to type 1 processes. Where three clinicians spoke of using gut feelings to make a non-prescribing decision, even in the face of a lack of clear indication to withhold opioids, this suggests that intuition and experience (the domain of type 1 processes) are at the forefront of this particular decision. Research has stated that clinicians' use of type 1 thinking, facilitated by specialised training and years of experience, is able to produce efficient and effective results (Cooper & Frain, 2017). What this means is that neither type is necessarily better than the other in the decision-making process; it is about discerning when to use which mode in the specific context one is presented with – in Croskerry's (2014) words: 'it is a dynamic process' (p. 25).

### **Strengths**

This study's main strength lies in the recruitment and study of the decision-making processes of pain specialists. Previous studies on this topic have sampled GPs and healthcare professionals including clinical nurse specialists. Where studies have involved pain specialists, e.g. anaesthetists or palliative care physicians (e.g. Turk, Dansie, Wilson, Moskovitz, & Kim, 2014), they have usually been part of a larger sample of practitioners. This study has focused solely on the perspectives of doctors specialising in the treatment of chronic non-cancer pain and working in very specific settings, i.e. hospital-based pain clinics, that are better-resourced than general practices. All clinicians in this sample cited the availability and accessibility

of support and non-pharmacological options for pain management as factors that facilitated the tapering of opioids. This is in contrast to the results from a study of GPs and patients in the UK that reported long-term opioid prescribing often continued because of a perceived lack of alternative options (McCrorie et al., 2015).

This study also focused on the role of emotion on clinical decision-making in prescribing opioids for chronic pain, a subject that is beginning to garner interest (Kozlowski et al., 2017), thereby contributing to the literature on emotions in clinical decision-making. In particular, it is useful to understand if and how the perspectives of clinicians who have received specialist training in pain management differ from GPs prescribing opioids who likely have less access to specialised training and feel less confident about prescribing. Clinicians in this study conveyed their confidence – a confidence that is likely rooted in their specialist training and experience – in making non-prescribing decisions when it was not indicated. This finding contrasts with previous studies which found that clinicians' uncertainty about when to prescribe opioids was associated with inadequate training in relation to pain management (Hutchinson, Moreland, Williams, Weinman, & Horne, 2007; Toye et al., 2017b).

### **Limitations**

The participants whose views are represented in this study were from three sites in London and Oxford, thus the findings cannot be generalised to the target population (clinicians specialising in pain medicine) – of course, generalisation should not be the aim of qualitative research. The findings should be interpreted in this particular context, bearing in mind that not all pain clinics in the country may have equal access to resources or that the factors considered by pain clinicians during the clinical reasoning process will be similar. Additionally, clinicians from general

practices over the country may have variable access to pain clinics to which they may refer patients for a specialist's opinion and differing extent of collaboration or communication with pain clinics – these will invariably affect the factors considered in decision-making at a primary healthcare level (Mordecai et al., 2018).

Time pressure was a consideration in this study as participants opted for interview slots that were either during the lunch break or toward the end of the work day; this may have led to answers that were cursory or less thought through. In one interview, the conversation was interrupted twice; once, for the clinician to attend briefly to a patient, the second time, to speak to a colleague. In addition, the extent to which any clinician will necessarily be able to identify their emotions during their interactions with patients, or subsequently in the process of reflecting on them as part of an interview, is questionable.

Testimonial validity is a credibility check that involves inviting participants to review and provide feedback on a summary of the themes at the data analysis stage. This check was carried out once with the first batch of eight participants, but not following the second round after a further six participants were recruited and interviewed. Judging from the poor response in the first round, it was not deemed crucial to administer this check again following the second data collection; hence the omission.

While every effort was made to ensure confidentiality, clinicians were likely to be aware that the study's results would be seen by the interviewer's research supervisor who works in the same clinic as the majority of the participants. The knowledge that the supervisor's access to interview data and who could potentially identify them may have resulted in participants being reticent about the information they provided and could also have given socially desirable responses (Groves, 1990).

## **Clinical Implications**

The findings of this study suggest that both patients' and clinicians' emotions have some influence on clinicians' decisions in the management of chronic pain. When patients express distress or present with depression or anxiety, clinicians are primed to consider more conscientiously various factors within a biopsychosocial model, with a greater emphasis on assessing the psychosocial components and targeting treatment along those lines by recommending psychological or physical therapies. Patient engagement through validating patients' emotions, besides providing education on opioids, is important for developing mutual trust and promoting better pain care (Buchman et al., 2016). This study echoes the view that paying attention to and acknowledging patients' psychological and emotional distress, engaging in joint decision-making and developing mutual trust are essential to the clinician-patient relationship, especially when those decisions are hard to deliver and receive, as is common in consultations about chronic pain.

This study discusses the finding of medical specialisation resulting in knowledge discrepancy between pain specialists and GPs; the acknowledgement that GPs may not always be well-acquainted with current best practice guidelines for chronic pain (RCA, 2018) or display a similar degree of confidence in making opioid-prescribing recommendations as do pain clinicians. This may result in a culture of blame and arising of tensions between specialists and generalists (Abel & Thompson, 2011); for instance, GPs blame hospital specialists for starting patients on opioids (e.g. for post-surgery analgesic relief) and failing to advise a cogent plan following discharge, while hospital clinicians blame GPs for indiscriminately continuing prescriptions and failing to monitor properly once patients are back in the community. While this study was useful in understanding the perspectives and self-



reported practices of pain clinicians, the question remains as to the ease with which primary care physicians can consider multi-faceted care and access resources for their patients, and simultaneously exercise care to avoid engaging in a dualistic biopsychosocial model that runs the risk of, once biomedical causes have been ruled out, patients feeling stigmatised when provided with psychosocial explanations for their pain (Toye et al., 2017a). McCrorie et al. (2015) further noted that the absence of a shared management plan due to time constraints limits GPs' ability to assess the patient's need for opioids thoroughly, educate them of the risks and set appropriate boundaries and monitoring for opioid use. Clinicians in this study felt professionally and emotionally supported by their teams; do doctors in primary care have similar support systems?

Kozlowski and colleagues (2017) recommend building emotional capabilities in clinicians as a critical step toward increasing patient safety and clinicians' feelings of self-efficacy. It is important for clinicians to acknowledge how they feel in themselves, to recognise the potential influence of work and personal stressors on work performance, and to attend to how their emotions potentially influence the thought processes involved in decision-making. Having said that, for clinicians to recognise, name and acknowledge how their emotions may affect clinical practice is hard, given a culture of medicine/medical training that demands of clinicians to adopt an attitude of objectivity and invulnerability while performing very difficult, emotionally-demanding tasks (Elton, 2018). Toye and colleagues (2018) highlight the need to consider the emotional costs to healthcare professionals treating patients with chronic pain. There is an urgent need for more openness (and safeness) for conversations about physicians' emotions and emotional wellbeing to occur.

## **Research Implications**

A number of clinicians in this study spoke of the value and need to educate primary care physicians on appropriate opioid prescribing for chronic pain. While this move is commendable and encouraged, it would be interesting to study the effects of education on actual prescribing patterns and not just in response to hypothetical scenarios, and if found to be not effective, what other endeavours need attempting. A recent study on whether chronic pain management education changed opioid prescribing rates concluded that there was some evidence of a reduction in initial opioid prescriptions in the training group, but not in overall opioid cessation (Holliday et al., 2017).

It would be useful to understand the factors influencing the decision by primary care practitioners to refer patients to tertiary pain services. One pain clinician, citing ineffective pathway protocols devised by Clinical Commissioning GP groups, reflected that patients are often seen late in their pain journey by a specialist; had patients been referred earlier, there would have been more available options to trial. Given the known benefits of collaboration among healthcare professionals and the breaking down of professional hierarchies (Toye et al., 2018), it would be judicious to explore the problems inherent in patient referral systems and to identify solutions that would enable prompt and better patient care and minimise the frustration experienced by all parties involved.

Future research on this topic might want to ask about emotions in less direct ways because the de-emphasising of emotions in the culture of medicine makes the endeavour to talk about emotions challenging. Given that this study was exploratory and relied on clinicians' self-report, thus it was not possible to measure the mechanisms of the impact of emotions on actual decisions. As studies have shown

that emotions inadvertently played a role in biasing clinicians' decisions (e.g. Harun et al., 2015), future studies could study emotions in patient-clinician interaction using other methods, such as video-recording a consultation session and having independent observers rate patients' and physicians' emotions in the exchange.

### **Conclusion**

In conclusion, the factors considered by clinicians specialising in pain medicine when making opioid-related decisions for treating patients with chronic pain include adhering to best practice, applying knowledge and expertise on opioids, paying attention to patient factors and striving to maintain good relationships with patients. Observations on the current prescribing climate influencing decisions were also described by participants. Clinicians rarely prescribed or increased opioids; reducing or stopping opioids were standard recommendations as part of routine clinical practice. The results show that clinicians were conscious of patients' emotions and that they placed fairly high importance on maintaining objective clinical judgment. Both patients' and clinicians' emotions had the potential to influence clinicians to modify their approach during the consulting process, and although some clinicians acknowledged the prospect of their own emotions influencing decisions, they struggled to articulate specific examples. These results have implications for how clinicians approach consultations and reflect on their decision-making in the recognition that emotions, both the patient's and their own, affect clinical decisions.

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### **Part 3: Critical Appraisal**



## **Introduction**

In this critical appraisal, I will discuss and reflect on the process of undertaking this research project. I consider the practical challenges of conducting the research and the assumptions I bring to the research as a trainee clinical psychologist and researcher. I conclude with reflections on meaning-making through the use and interpretation of language and thoughts on conducting research within doctoral training. The section ‘Addendum’ was written a year after this critical appraisal was first written; it represents further reflections on my research journey.

## **Research Rationale**

Prior to embarking on clinical training, my research interests in health-related quality of life of paediatric patients with cancer and my clinical work with young people with physical and intellectual disabilities fuelled my interest to pursue a research project that would allow me to investigate some element of physical and psychological health in patients. My first research proposal aimed to use mixed methods to explore the experiences of pain management and quality of life in patients in advanced stages of cancer using state-of-the-art intrathecal drug delivery devices. Of particular interest was patients’ experiences of using the devices and how that had changed their lives.

## **Challenges**

### ***Project Feasibility***

The first challenge I encountered was in regard to project feasibility. Although the proposal was considered by reviewers to be a useful and interesting project it had to be abandoned because of the potential difficulties of recruiting participants from a highly vulnerable and extremely small population.

Following discussions with my research supervisor and considering together the practicalities of ethics applications, conducting research with vulnerable populations and the project timescale, we decided to switch the focus to undertaking research with clinicians on the subject of prescribing opioids for chronic pain. Specifically, I was interested to know if and how emotions impacted physicians' decision-making for chronic pain treatments.

### ***Ethical Approval***

The second challenge related to the process of applying for ethical approval. For a project that seemed relatively straightforward and low-risk, I did not anticipate spending seven months on form-filling and correspondence with numerous staff from university and Trust research departments and pain clinics before receiving approval to start recruiting participants. Because the nature of the project was deemed low-risk, the project did not require a full or partial National Health Service (NHS) Research Ethics Committee (REC) approval and was instead assessed by the Health Research Authority (HRA). Projects that go through the HRA usually take shorter times to be processed and approved. Nonetheless, the paperwork required for a HRA assessment is similar to a full REC assessment. The administrative burden and efforts of applying for both UCL and HRA ethical approvals was immense and, in hindsight, not commensurate with the outcomes hoped for. As a result of the length of time spent on ethics applications, the projected start date for recruitment was delayed by several months.

### ***Recruitment***

Most of the contact information of potential participants was obtained through my research supervisor's links with colleagues. It helped that the pain healthcare community is relatively small and making initial contact to request for

permission to conduct research was not hard. However, once ethical approval was granted for the project to commence, very few people responded to the invitation email that was sent three times over two months. Despite having made every effort to reduce the (anticipated) inconvenience to consultants for taking part in a research study, e.g. letting them select a preferred timeslot and keeping the length of the interview short, the uptake remained low. As is common in many research studies, it is difficult to obtain the reasons for why non-responders choose not to participate, e.g. no interest, lack of time, etc., or to know whether there are any systematic differences between responders and non-responders that may result in non-response bias (Couper & De Leeuw, 2003).

### ***Arranging and Conducting Interviews***

Interested participants were free to indicate a timeslot that was convenient for them. Although I had clinical placement commitments several days a week, I endeavoured to accommodate participants' schedules. A consultant who had expressed interest in participating eventually did not take part following multiple failed attempts to find a mutual time. Conversely, I was pleasantly surprised to find that other participants invited me to meet them at their workplaces for the interview; however, in adhering to the protocol as set out in the ethics application form, I could not accede to the request as all interviews were to be conducted over the phone.

Being more accustomed to conducting clinical interviews with patients, conducting research interviews with consultants was an entirely different experience for me. Consultants came across as very confident in the way they described their clinical work and decisions and many of them were concise with their words. Whereas patients generally have a lot to say, it was sometimes hard to elicit further elaboration from clinicians. This could have been either because they were sure that

that was all there was to say in answer to the question(s) or that they were unwilling to disclose sensitive information in regard to emotional content and decision-making. De Leeuw and Hox (2015) noted that self-administered surveys are more likely than interviewer-administered surveys to perform better in answering questions of a sensitive nature, i.e. there was more openness in reporting sensitive or unwanted behaviour using the former method. Still, in the short length of time that the interview permitted, clinicians conveyed their emotions, e.g. exasperation or frustration with patients when talking about patients' non-adherence or disagreement with clinicians' opinions, through verbal cues such as speed and tone of voice. This provided valuable insight into how clinicians might be feeling when they meet with their patients.

### ***Data Analysis***

Thematic analysis is a recursive process which requires the researcher to be immersed in the raw data, label codes and review themes by going back and forth between the data and the developing analysis so as to produce an account that demonstrates an integrity to the voices of the participants (Braun & Clarke, 2013). All this often takes place 'behind-the-scenes', which the reader usually does not see in the impressive-looking Results sections of published manuscripts. At one stage of the analysis, I was feeling stuck as the themes did not seem to 'fit together'. Following suggestions for improvement from my supervisor, I was reminded of the sound advice by Braun and Clarke (2013) to 'be prepared to let things go' (p. 234) by not becoming too attached to emerging themes, which can often be a challenge for researchers new to thematic analysis.

## **Lessons Learnt**

Having had no experience with the NHS – as a researcher, employee or patient – prior to clinical training, being required to engage with the NHS on multiple fronts, i.e. research department staff, administrative clinic staff, heads of departments and individual consultants, as well as navigating complicated systems to apply for ethical approval was at times an overwhelming and emotive experience. This latter experience is echoed by other trainee clinical psychologists who reported similar experiences with the ethics application process, highlighting a sense of powerlessness and a ‘them and us’ dynamic with RECs in the course of conducting doctoral research (Brindley, 2012). Anecdotally, it is unsurprising that many trainees prefer to avoid embarking on projects requiring HRA/NHS REC approvals. Despite being given advanced notice that the process would be challenging and taking steps to start the process early, it is not always easy to avoid the emotional and mental pitfalls. It is essential to be conscientious in following the required steps in order to advance the project, and equally important to harness support and information from peers and supervisors.

In my role as a researcher on doctoral training, there was always an acute awareness of how tight timescales were, particularly when research proposals and ethics application forms required several revisions. While I would advise someone considering an NHS research project to be clear on what s/he is taking on in terms of the ethics approval process, I would also add that the process necessarily builds one’s capacity for stress tolerance, effective time management, endurance of uncertainty, and resilience.

In hindsight, in regard to recruitment matters, I might have increased the chances of recruiting had I widened options for advertising the study. For example, I

could have offered to do a brief presentation during staff meetings to explain the purpose of the study and answer questions. This would have given me the opportunity to increase the visibility of the study and to build initial rapport with people who expressed interest. Additionally, another option might have been to request for permission to put up recruitment posters in pain clinic offices since emails can be easily overlooked or land in spam folders. These ideas would have had to be set out in detail on ethics application forms before they can be tried. In retrospect, these means might potentially have led to an increase in recruitment and hence, a larger sample size.

### **Examining My Own Assumptions**

Over the summer in 2017 while processing documents for ethical approval, I was also undertaking a clinical health psychology placement in a community setting. My work involved providing psychological therapy to patients with chronic physical health conditions. All of them were either house or bed-bound and the majority of them experienced chronic pain. I witnessed how debilitating pain can be on normal everyday functioning and psychological wellbeing (Cimpean & Drake, 2011) and the ways in which pain elicited care-giving from those around the patient, including myself.

One of my assumptions when embarking on this research project was that seeing someone in distress activates empathic feelings and a desire to help. This thought led me to hypothesise that doctors may prescribe opioids or increase doses, perhaps unwittingly at times, in their desire to be helpful to patients complaining of unrelieved pain. Simultaneously, while undertaking clinical work, some of my clients mistook me for a medical doctor, and I had to explain that my role was to work with their psychological and emotional health but that if they had any physical health

queries, they would need to consult their GP. I observed that it can be difficult for any healthcare professional to tease apart the elements of the interplay between physical and psychological pain, and equally hard to know when to advise patients to approach their pain with acceptance (Vowles, McCracken, & O'Brien, 2011) or to obtain further medical advice. Patients often relied on the GP to prescribe pain-relieving medication, and were upset and frustrated when the medication did not seem to be working. GPs are considered 'gatekeepers' as they have to make decisions whether to change a prescription that does not seem to be working, or to refer to a specialist for diagnosis and further treatment (Anderson, Foster, Freeman, Luetsch, & Scott, 2017). When consultants in this study were asked whether patients' distress impacted them and whether they felt their own emotions had any impact on decision-making, their answers showed that a desire to help stemmed from holding firm beliefs about the negative effects of opioids and that not prescribing them (particularly if patients were already on high doses) was the better way forward for physical wellbeing even if clinicians felt deep empathy for their patients. Roche and Harmon (2017) observed that medical expertise appeared to cause clinicians to down-regulate their empathic responses to the pain of others so as to defend themselves from feelings of inadequacy when they cannot relieve patients' pain. Clinicians' down-regulation can ultimately impact on the ways they interact with patients and how patients perceive the help they receive.

Prior to starting interviews, my readings on qualitative research led me to consider how my position as a researcher combined with my own assumptions or beliefs could influence the research. Starks and Trinidad (2007) wrote about the concept of 'bracketing' which is defined as the setting aside of a priori knowledge and assumptions. I realised that 'bracketing' is an ideal that is quite difficult to

achieve. The practice of bracketing may be extended to clinical practice in healthcare when professionals attempt to keep pre-existing beliefs and biases separate from what they perceive should be a helpful consultation that also strengthens the therapeutic alliance (Lapping-Carr & Heavey, 2017). Upon reflection, a comment by one participant comes to mind: 'My task is to treat the patients that I like and patients that I don't like in the same way'. Although I attempted to conduct interviews the same way each time and tried to keep the tenor of the conversations relatively similar, it was difficult not to have variations in the engagement with participants depending on the material they brought and the verbal cues they used. I realised that my responses and the interaction between us was sometimes contingent on whether participants made me feel anxious, interested or amused. This led me to wonder to what extent healthcare professionals, including myself, are unaware of their own reactions arising from the emotional presentation of patients, their own emotions, and the emotional exchange in what Quintner and colleagues (2008) termed the 'third space', where the 'experiences of both patient and physician are shared and negotiated...thereby resisting socially or culturally determined stereotypes' (Cohen, Quintner, Buchanan, Nielsen, & Guy, 2011, p. 1640).

### **Conducting Qualitative Research**

One of the things I enjoyed about conducting qualitative research was the ability to receive direct feedback from the participants and to use the feedback to make minor improvements to the study. Various participants gave their opinions of the interview questions which prompted me to consider making minor changes to the wording used and the order of the questions asked (see Appendix M for amended interview protocol). After I had done this, subsequent interviews appeared to proceed less clumsily; although this could also be attributed to my gaining confidence after



having conducted the first few interviews. Other feedback was provided in the form of testimonial validity (see Appendix L) and even a comment about the layout of the consent form. While the latter had no bearing on the results of the study, the fact that a participant had deemed this detail important to mention was duly appreciated.

While this study did not use a language-based approach (e.g. discourse analysis), I wondered about the power and meanings in language that might have influenced how people perceived the study and motivations of the researcher. In using the word ‘prescribing’ to denote the activity of dispensing opioids, which to me carried a neutral connotation, I thought about how an administrator had given me forewarning about participation interest (or lack of) during our email correspondence – ‘As a department, we are very much against the prescription of opioids for non-cancer chronic pain’ – might just the way the wording of the title of the invitation email (see Appendix E) have put people off from considering participation? Unsurprisingly, not a single consultant from that particular department responded. Additionally, when I started interviews with participants and asked the first question about the factors they thought about when prescribing opioids, many of them immediately informed me that it was rare for them to prescribe opioids; it was more common for them not to do so. From the two examples above, there was a sense that the word ‘prescribe’ in the context of opioid use was taboo, one that the medical community are keen to be dissociated with, given that the prevailing standpoint is to discourage the practice of prescribing opioids long-term for chronic pain (Juurlink, 2017).

### **Addendum**

I completed writing Part 2: Empirical Paper in July 2018; however, subsequently embarked on a second round of ethics applications, participant

recruitment, data collection and analysis, and re-writing of the Results and Discussion sections in the several months that followed. This was because the first recruitment of eight participants was considered to not have achieved data saturation and was deemed insufficient for a rigorous thematic analysis. The second round of recruitment yielded a further six participants, and a re-analysis of the new data with the old was done from scratch.

I endeavoured to do things a little differently the second time by trying out some of the ideas mentioned above. For instance, I re-worded the invitation email to potential participants in an effort to reduce the stigma attached to the word 'prescribe', i.e. 'invitation to participate in a study on opioid-related decision-making for treating chronic pain' replaced the email title 'invitation to participate in a study on prescription of opioids for chronic pain'. Although most of the pain departments that I approached were generally open to hearing about the study, it is difficult to measure the impact this minor change in wording had on the consultants who received the invitation.

Another amendment to the study was the inclusion of face-to-face, in addition to telephone, interviews. Of the six participants recruited in the second round, only one chose the former option. Although it was just one instance, I found it relatively easier to build rapport and gain traction when asking and probing questions that were more sensitive compared to over the phone, when many non-verbal cues are decidedly absent.

In the second iteration of thematic analysis, I understood what it meant to 'let things go' as advised by Braun and Clarke (2013) by starting the analysis from scratch and attempting a fresh perspective at the collective data. The work was often tedious, sometimes painful, and mostly lonely when grappling with the data by going

over it multiple times in the reading of transcripts, labelling and clustering of codes and refining of themes, but highly satisfying when a coherent narrative started to take form.

### **Conclusion**

This critical appraisal aimed to highlight the negotiation of challenges faced during the course of conducting qualitative research while undertaking doctoral training. Notwithstanding those challenges, this endeavour has afforded me many opportunities for reflection on the complexities of healthcare provision from both a researcher's and clinician's viewpoint. From the conceptualisation of the project to the writing up of the paper, I have gained valuable research skills as well as a better appreciation of assuming the role of scientist-practitioner in a very demanding environment that is the NHS.

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## **Appendices**

## Appendix A: AXIS Tool

	Allen et al. (2013)	Burgess et al. (2011)	Duensing et al. (2010)	Hutchinson et al. (2007)	Keller et al. (2012)	Lin et al. (2007)	Macerollo et al. (2014)	McCracken et al. (2008)	Morley-Forster et al. (2003)	Regunath et al. (2016)	Turk et al. (2014)	Wolfert et al. (2010)
<b>Introduction</b>												
1. Aims/objectives of the study clear?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
<b>Methods</b>												
2. Study design appropriate for the stated aim(s)?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3. Sample size justified?	DK <sup>1a</sup>	Y	N <sup>3a</sup>	DK <sup>4a</sup>	DK <sup>5a</sup>	Y	Y	Y	N <sup>8a</sup>	Y	N <sup>10a</sup>	DK <sup>11a</sup>
4. Target population clearly defined?	Y	N <sup>2a</sup>	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
5. Sample frame taken from an appropriate population base?	DK <sup>1b</sup>	Y	DK <sup>3b</sup>	Y	DK <sup>5b</sup>	Y	Y	Y	Y	Y	DK <sup>10b</sup>	Y
6. Selection process likely to select participants representative of the target population?	DK <sup>1c</sup>	DK <sup>2b</sup>	Y	DK <sup>4b</sup>	Y	Y	Y	Y	N <sup>8b</sup>	Y	Y	Y
7. Measures undertaken to address and categorise non-responders?	N	N	N	N	N	Y <sup>6a</sup>	N	N	N	N	N	N
8. Risk factor and outcome variables measured appropriate to study aims?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

	Allen et al. (2013)	Burgess et al. (2011)	Duensing et al. (2010)	Hutchinson et al. (2007)	Keller et al. (2012)	Lin et al. (2007)	Macerollo et al. (2014)	McCracken et al. (2008)	Morley-Forster et al. (2003)	Regunath et al. (2016)	Turk et al. (2014)	Wolfert et al. (2010)
9. Risk factor and outcome variables measured using instruments trialled, piloted or published previously?	Y	DK <sup>2c</sup>	Y <sup>3c</sup>	Y	N <sup>5c</sup>	Y	Y	Y	Y	N <sup>9a</sup>	Y	N <sup>11b</sup>
10. Is it clear what was used to determine statistical significance?	Y	Y	Y	Y	Y	Y	Y	Y	N <sup>8c</sup>	Y	Y	Y
11. Methods sufficiently described to enable them to be repeated?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
<b>Results</b>												
12. Basic data adequately described?	Y	Y	DK <sup>3d</sup>	Y	Y	Y	Y	Y	Y	Y	Y	Y
13. Does response rate raise concerns about non-response bias?*	Y	Y	Y	Y	Y	N <sup>6b</sup>	Y	DK <sup>7a</sup>	N	N	Y	Y
14. If appropriate, was information about non-responders described?	N	N	N	N	N	Y <sup>6b</sup>	N	N	N	N	N	N
15. Results internally consistent?	Y	Y	N <sup>3e</sup>	Y	Y	Y	Y	Y	Y	Y	Y	Y
16. Results for the analyses described in the methods presented?	Y	Y	N <sup>3d</sup>	Y	Y	Y	Y	Y	N <sup>8d</sup>	Y	Y	Y



	Allen et al. (2013)	Burgess et al. (2011)	Duensing et al. (2010)	Hutchinson et al. (2007)	Keller et al. (2012)	Lin et al. (2007)	Macerollo et al. (2014)	McCracken et al. (2008)	Morley-Forster et al. (2003)	Regunath et al. (2016)	Turk et al. (2014)	Wolfert et al. (2010)
<b>Discussion</b>												
17. Authors' discussions and conclusions justified by the results?	Y	N <sup>2d</sup>	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
18. Limitations of the study discussed?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
<b>Other</b>												
19. Any funding sources/conflicts of interest that may affect the authors' interpretation of the results?	N	DK <sup>2e</sup>	Y	DK <sup>4c</sup>	DK <sup>5d</sup>	DK <sup>6c</sup>	N	N	Y <sup>8e</sup>	N	DK <sup>10c</sup>	DK <sup>11c</sup>
20. Ethical approval/participant consent obtained?	Y	Y	Y	Y <sup>4d</sup>	Y	Y	Y	Y	Y	Y	Y	Y

Y = Yes; N = No, DK = Don't know.

<sup>1a</sup>No projected target sample size. <sup>1b</sup>Lack of discrete sampling frame. <sup>1c</sup>Low response rate.

<sup>2a</sup>General internal medicine physicians were randomly sampled from all physicians in the US. Unclear as to why general internal medicine physicians were selected for sampling, and results later generalised to physicians. <sup>2b</sup>Randomly sampled from database containing data on all US physicians; unclear if selection process likely to select participants representative of the target population. <sup>2c</sup>MA scale has been trialled before (Merrill et al., 1995). For other dependent measures, it was not stated how the questions and measurements were derived. <sup>2d</sup>Results from analyses of secondary hypotheses not discussed. <sup>2e</sup>Funding sources declared, unclear whether interpretation of results was affected.

<sup>3a</sup>No explanation as to how the number of participants to be recruited were determined. <sup>3b</sup>Recruitment was from existing pool of individuals who had agreed to participate in market research. <sup>3c</sup>Piloted with small group of respondents; however, not stated who these respondents are. <sup>3d</sup>Some figures mentioned in text not described in tables; not all results were presented. <sup>3e</sup>Information in table on physician demographics is not consistently presented.

<sup>4a</sup>No explanation as to how the number of participants to be recruited were determined. <sup>4b</sup>Sample included GPs who attended postgraduate training events on pain and other subjects. Unclear whether there might be selection bias. <sup>4c</sup>No declaration section. <sup>4d</sup>No mention of approval from ethics committee. Informed consent implied.

<sup>5a</sup>No explanation as to how the subset number of 81 participants was determined. <sup>5b</sup>Participants were recruited from a Practice-Based Research Network which comprise 125 physicians; unclear whether physicians in this network differ from primary care physicians who are not part of the network. Potential sampling bias not discussed. <sup>5c</sup>Survey was unstandardised and psychometric properties are unknown. <sup>5d</sup>Funding sources declared; unclear whether interpretation of results was affected.

<sup>6a</sup>Demographic information of non-respondents was available as the target population was made up of all the staff physicians from that particular hospital.

<sup>6b</sup>No significant differences found in the characteristics of respondents and non-respondents. <sup>6c</sup>No declaration section. First author is from the same department as the sample population; unclear whether there might be potential conflict of interest.

<sup>7a</sup>Low response rate of 35%; however, the absolute figure of 414 participants surpasses the sample sizes of several studies included in this review.

<sup>8a</sup>No explanation as to how the number of participants, i.e. 100, to be recruited were determined. <sup>8b</sup>Participants were included if they reported writing 20 or more prescriptions (for GP group), and more than 40 prescriptions for palliative care (PC group) in the preceding four weeks. <sup>8c</sup>In Methods section, researchers stated means and 95% CIs were calculated to allow for sample weighting; these were not reported in the Results section. <sup>8d</sup>For items measured on 7-point scale, only the percentages of participants who indicated agree (i.e. 6 and 7) were included. Data between GPs and PCs were not compared/weighted (e.g. using chi-square analyses), apart from reporting percentages. Means and CIs not reported. <sup>8e</sup>Funding received from pharmaceutical company. Study referenced a study which reported prevalence of untreated chronic pain, thus concluding that opioids are underutilised in Canada. The study was conducted by the same authors of current study.

<sup>9a</sup>Questionnaires were developed by study authors and approved by Internal Medicine faculty but were not trialled, piloted or published previously.

<sup>10a</sup>No explanation as to how the number of participants to be recruited were determined. <sup>10b</sup>Participants were recruited from a Web-enabled panel, of which they were members, maintained by a private company. Unclear whether participants differ from physicians who are not members of the panel. <sup>10c</sup>Funding sources declared; unclear whether interpretation of results was affected.

<sup>11a</sup>No explanation as to how the number of participants to be recruited were determined. <sup>11b</sup>Survey was unstandardised and psychometric properties are unknown. <sup>11c</sup>Funding sources declared, unclear whether interpretation of results was affected.

\* Response rate raises concerns about non-response bias, however, the researcher discusses this point, i.e. invites reader to interpret if the response rate is likely to lead to non-response bias or limitation of non-response

## Appendix B: CASP Qualitative Checklist

	Barry et al. (2010)	McCrorie et al. (2015)	Seamark et al. (2013)
<b>Section A: Are the results of the study valid?</b>			
1. Was there a clear statement of the aims of the research?	Y	Y	Y
2. Is a qualitative methodology appropriate?	Y	Y	Y
3. Was the research design appropriate to address the aims of the research?	Y	Y	Y
4. Was the recruitment strategy appropriate to the aims of the research?	Y	Y	N <sup>3a</sup>
5. Was the data collected in a way that addressed the research issue?	Y	Y	Y <sup>3b</sup>
6. Has the relationship between researcher and participants been adequately considered?	N	N	Can't tell <sup>3c</sup>
<b>Section B: What are the results?</b>			
7. Have ethical issues been taken into consideration?	Y	Y	Y
8. Was the data analysis sufficiently rigorous?	Can't tell <sup>1a</sup>	Y <sup>2a</sup>	Y
9. Is there a clear statement of findings?	Y	Y	Y
<b>Section C: Will the results help locally?</b>			
10. How valuable is the research?	Y <sup>1b</sup>	Y <sup>2b</sup>	Y <sup>3d</sup>

Y = Yes; N = No

<sup>1a</sup>In-depth description of analysis process and how themes were derived was provided. Quotes are appropriately used, however, not properly referenced (i.e. unable to tell who the quotes are ascribed to). Contradictory data, if any, not included. Researcher did not critically examine own role, potential bias and influence during analysis and selection of data for presentation. <sup>1b</sup>Study's contributions and limitations are adequately discussed.

<sup>2a</sup>Derivation of categories/themes from the data not discussed. Role of researcher, potential bias and influence during analysis and selection of data for presentation not discussed. <sup>2b</sup>Study's contributions and limitations are adequately discussed.

<sup>3a</sup>No explanation provided for how participants were selected for both focus group and individual interviews. No discussion around recruitment, i.e. reasons for non-response. <sup>3b</sup>Mostly yes. Data saturation not discussed. <sup>3c</sup>Lead researcher conducted reflexive analysis, but few details are provided. <sup>3d</sup>Study's contributions and limitations are adequately discussed.

## Appendix C: UCL REC Approval Letter

UCL RESEARCH ETHICS COMMITTEE  
ACADEMIC SERVICES



12<sup>th</sup> June 2017

Dr Amanda C de C Williams  
Research Department of Clinical, Educational and Health Psychology  
UCL

Dear Dr Williams

### **Notification of Ethical Approval**

**Re: Ethics Application 11139/001: Understanding clinicians' decision-making on prescription of opioids for chronic pain**

Further to your satisfactory responses to my comments, I am pleased to confirm in my capacity as Chair of the UCL Research Ethics Committee that I have ethically approved your study until **30th September 2018**.

Approval is subject to the following conditions:

### **Notification of Amendments to the Research**

You must seek Chair's approval for proposed amendments (to include extensions to the duration of the project) to the research for which this approval has been given. Ethical approval is specific to this project and must not be treated as applicable to research of a similar nature. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing the 'Amendment Approval Request Form':

<http://ethics.grad.ucl.ac.uk/responsibilities.php>

### **Adverse Event Reporting – Serious and Non-Serious**

It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator ([ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk)) immediately the incident occurs. Where the adverse incident is unexpected and serious, the Chair or Vice-Chair will decide whether the study should be terminated pending the opinion of an independent expert. For non-serious adverse events the Chair or Vice-Chair of the Ethics Committee should again be notified via the Ethics Committee Administrator within ten days of the incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Chair or Vice-Chair will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

Final Report

At the end of the data collection element of your research we ask that you submit a very brief report (1-2 paragraphs will suffice) which includes in particular issues relating to the ethical implications of the research i.e. issues obtaining consent, participants withdrawing from the research, confidentiality, protection of participants from physical and mental harm etc.

With best wishes for the research.

Yours sincerely

**Dr Lynn Ang**  
**Interim Chair, UCL Research Ethics Committee**

Cc: Bernice Lee

Academic Services, 1-19 Torrington Place (9th Floor),  
University College London  
Tel: +44 (0)20 3108 8216  
Email: [ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk)  
<http://ethics.grad.ucl.ac.uk>

APPROVED Amendment Request 11139/001

VPRO.Ethics

Thu 15/11/2018 12:30PM

To:Lee, Bernice <email REDACTED>

2 attachments (122 KB)

11139001\_UCL Amendment approval request form\_Bernice Lee.docx; Appendix Ib GDPR Compliant Template Participant Information Sheet May 20....docx;

Bernice, Thanks for the confirmation. I am pleased to confirm that your amendment request has now been approved by the UCL REC Chair. Please take this email as confirmation of that approval.

**IMPORTANT: For projects collecting personal data only**

Change to legal basis for the processing of data: If you are processing (i.e. collecting, storing, using, disclosing or destroying) identifiable personal information about living individuals as part of your research then you should ensure that you comply with the requirements of the GDPR and the Common Law Duty of Confidentiality. An appropriate legal basis for the processing of your data must be identified, and you must be explicit about this and document it as part of your ethics application, and in the information you provide to your research participants. UCL's view is that, for the vast majority of research undertaken at UCL, the appropriate legal basis will be 'a task in the Public interest': the processing is necessary for UCL to perform a task in the public interest - rather than 'consent'.

However, even though the legal basis for the processing of a person's data is most likely to be 'a task in the public interest' rather than 'consent', from an ethical perspective, obtaining a person's informed consent for their involvement in the research is still likely to be required in order to abide by the fairness and transparency elements of principle GDPR Article 5(1)(a) or to meet confidentiality obligations.

We have recently changed the data privacy section of our template participant information sheet (PIS) to reflect this change to the legal basis for data processing – see attached. You will need to update your PIS accordingly.

With best wishes, Helen

Helen Dougal  
UCL Research Ethics Administrator  
Office of the Vice-Provost (Research)  
University College London  
2 Taviton Street, London, WC1H 0BT  
Email: ethics@ucl.ac.uk

## Appendix D: HRA Approval Letter

Dr Amanda Williams  
Research Department of Clinical, Educational &  
Health Psychology, UCL  
Gower Street  
London  
WC1E 6BT

Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)

02 October 2017

Dear Dr Williams

### Letter of HRA Approval

**Study title:** Student Study: Understanding clinicians' decision-making on prescription of opioids for chronic pain  
**IRAS project ID:** 228662  
**Sponsor** University College London

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

### Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

*Appendix B* provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.



Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from [www.hra.nhs.uk/hra-approval](http://www.hra.nhs.uk/hra-approval).

## Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

## After HRA Approval

The attached document “*After HRA Approval – guidance for sponsors and investigators*” gives detailed guidance on reporting expectations for studies with HRA Approval, including:

- Working with organisations hosting the research
- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

## Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at <http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/>.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

### **User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

### **HRA Training**

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

Your IRAS project ID is **228662**. Please quote this on all correspondence.

Yours sincerely

Kevin Ahmed

Assessor

Telephone: [REDACTED]

Email: [REDACTED]

*Copy to: Ms Jessica Broni-Tabi, Sponsor Contact, Joint Research Office University College London*

**From:** hra.amendments@nhs.net [mailto:noreply@harp.org.uk]  
**Sent:** 20 December 2018 09:56  
**To:** Williams, Amanda <email REDACTED>; randd@uclh.nhs.uk  
**Cc:** hra.amendments@nhs.net  
**Subject:** IRAS Project ID 228662. HRA Approval for the Amendment

Dear Dr Williams,

<b>IRAS Project ID:</b>	228662
<b>Short Study Title:</b>	Clinicians' decision-making on opioid prescription for chronic pain
<b>Amendment No./Sponsor Ref:</b>	Number: 1 Date: 28 November 2018
<b>Amendment Date:</b>	28 November 2018
<b>Amendment Type:</b>	Non Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the conditions outlined in your categorisation email.

### **User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known, please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

**Mr Michael Higgs**

**Assessor**

**Health Research Authority**

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

**E.** [hra.amendments@nhs.net](mailto:hra.amendments@nhs.net)

**W.** [www.hra.nhs.uk](http://www.hra.nhs.uk)

## **Appendix E: Recruitment Email**

Subject title: Invitation to participate in a study on prescription of opioids for chronic pain

Dear [Administrator],

I would be grateful if you could kindly forward this e-mail to medical consultants working in the [name of hospital] pain management service team.

I am a trainee clinical psychologist recruiting for a study on understanding clinicians' decision-making on prescription of opioids for chronic pain. The project is supervised by Dr Amanda Williams, Reader in Clinical Health Psychology, UCL. The project has received UCL REC Ethics approval (11139/001) and HRA approval (228662).

Thank you,  
Bernice Lee  
Third year clinical psychology trainee, UCL

Dear consultant,

You are invited to participate in a research study to investigate the decision-making processes of pain specialists for patients with chronic non-cancer pain who are using opioids or for whom they consider prescribing opioids. It is a qualitative study, involving a single telephone interview, estimated to last 30 minutes.

The inclusion criteria for participation are that you are currently working in a pain management service in an NHS Trust and have obtained the FFPMRCA.

Please read the enclosed Participant Information Sheet for full details of the study's content and purpose.

If you are willing to take part in this study after reading through the Participant Information Sheet, please sign and return via e-mail the enclosed Consent form and the Participant Details form.

Thank you for taking the time to consider participating in this research study. If there is anything that is not clear, or if you would like more information, you can contact me or my supervisor Dr Amanda Williams by e-mail (below).

Yours sincerely,  
Bernice Lee  
Trainee Clinical Psychologist  
University College London  
[email REDACTED]

Dr Amanda Williams  
Reader in Clinical Health Psychology / Principal Investigator  
University College London  
[email REDACTED]

## Appendix F: Participant Information Sheet



### RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL AND HEALTH PSYCHOLOGY

#### PARTICIPANT INFORMATION SHEET

**Study Title: Student study - Understanding clinicians' decision-making on prescription of opioids for chronic pain**

**This study has been approved by the UCL Research Ethics Committee (11139/001):**

You are being invited to take part in a research study. Before you decide whether you would like to take part, it is important for you to know what the research is about and what it will involve. Please read this information sheet carefully and discuss with others if you wish. If there is anything that is not clear, or if you would like more information, you can contact us. Your participation in this study is completely voluntary and you may choose to withdraw at any time.

#### **What is this study about?**

This study forms part of University College London Doctorate of Clinical Psychology research thesis by Bernice Lee, Trainee Clinical Psychologist, and is supervised by Dr Amanda Williams, Reader in Clinical Health Psychology at UCL.

The study aims to investigate the decision-making processes of pain specialists for patients with chronic non-cancer pain who are using opioids or for whom they consider prescribing opioids. Telephone interviews will be carried out.

#### **Why have I been invited to take part?**

This study is an invitation to consultants in pain medicine who have obtained the FFPMRCA and are currently working in pain management centres or pain clinics in NHS Trusts.

#### **What will happen if I take part?**

Your participation involves you having a telephone interview with the researcher, Bernice Lee. If you are happy to take part in this study after reading through this information sheet, you will be asked to give consent by signing the consent form. Please indicate your preferred contact number, days and times outside working hours to be contacted in the participant details form. You will be contacted via email for confirmation of your participation and telephone interview time.

#### **What will I be asked to do?**

The telephone interview will be conducted outside working hours at a time of your choosing, and will be arranged with you following receipt of your signed consent form and participant details form. Interviews will be held between October 2017 and March 2018. The interview will be audio recorded and transcribed. The audio files will be stored on a UCL secure remote connection, and deleted from the recording device. Electronic transcript notes will be analysed using NVIVO software on the UCL secure remote connection. No identifiable information will be included in the transcript. These measures ensure that data is not stored on portable devices and that your anonymity is maintained.

During the interview, you will be asked some questions about clinical decisions about opioid prescribing, patients' presentation and your own experience of consultations. The interview will last approximately half an hour.

A summary of the themes in your interview will be shared with you via email. In the same email, you will be invited to provide feedback on the interview themes. This process is designed to increase the validity of the study's conclusions. This step is optional.

**Are there any risks in taking part?**

Overall the risks of taking part in this study are minimal. If, after you have given consent to participate, you decide that being involved in this research does not suit you, you are free to withdraw at any point. Any of your data that has been collected will be destroyed. We will also signpost you to other services if you need further support.

**What are the potential benefits?**

If you decide to participate in the study, a donation of £5 will be made to Pain Concern, a charity working to support and inform people with pain and those who care for them. Participants will not be paid for taking part in this study.

The information gathered during this study is important in informing our understanding of how clinicians make decisions regarding opioid prescriptions for chronic pain. We anticipate that this will be a step towards contributing to the knowledge base of medical decision-making in opioid prescriptions for chronic pain.

After the study has been completed, we can send you a copy of the final study report, if you request it.

**Will my taking part in the study be kept confidential?**

All information collected about you over the course of the study will be kept confidential unless we become aware of something which makes us worry about you or someone around you, in which case we will discuss the issue with you. Once the study has finished, University College London (UCL) will keep the study data in a secure location. The data used for the study will be anonymised and it will not be possible to trace the results back to individual participants.

**What happens when the research study stops?**

The results of the research study will be written up as part of Bernice Lee's research thesis for the Clinical Psychology Doctorate at UCL. The report of the study could also be published in relevant journals outside UCL. You will not be identifiable from these results.

**What if something goes wrong?**

Every care will be taken in the course of this study to protect you. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. You should contact Dr Amanda Williams, who is the Principal Investigator for the research, and based at UCL.

**Who is organising and funding the research?**

The research has been organised by Bernice Lee, Trainee Clinical Psychologist. She is conducting this study as part of her Clinical Psychology Doctorate. The research will be funded by UCL.

**Who can I contact for further information?**

**For more information about this research, please contact:**

Bernice Lee

Email: [REDACTED]

Phone: [REDACTED]

**Or if you have any concerns or complaints about this study please contact:**

Dr Amanda Williams

Email: [REDACTED]

Phone: [REDACTED]

## Appendix G: Participant Details Form



### RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL AND HEALTH PSYCHOLOGY

#### PARTICIPANT DETAILS FORM

Please provide the following information:

Name:	
Gender:	
Age:	
Ethnicity:	
Profession/qualifications:	
Number of years in medical practice:	
Number of years in specialist pain practice:	
<b>Preferred contact number:</b>	
<b>Preferred days/times for researcher to call:</b>	
<b>e-mail if you would prefer to arrange time and date of interview by email</b>	

Please complete and return this form via email to [email: REDACTED]



## Appendix H: Consent Form

**THANK YOU FOR READING THIS INFORMATION SHEET AND FOR  
CONSIDERING TAKING PART IN THIS RESEARCH.**



### **RESEARCH DEPARTMENT OF CLINICAL, EDUCATIONAL AND HEALTH PSYCHOLOGY**

Centre Number:

Study Number:

Participant Identification Number:

### **CONSENT FORM**

Title of Project: Student Study - Understanding clinicians' decision-making on prescription of opioids for chronic pain

Name of Researcher: Bernice Lee

Please initial

1. I confirm that I have read the information sheet dated 30/10/2018 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
  
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.
  
3. I understand that I will not receive any monetary incentive for participation.
  
4. I consent to the processing of my personal information for the purposes of this research study.
  
5. I understand that the interview will be audio recorded for the sole purpose of data analysis, and the audio file deleted from the recording device once it has been transferred and stored in a secure location.

6. I understand that the information that I provide will be included in the researcher's doctorate thesis, may be published in a scientific journal, and may be presented at a national or international conference. I understand that all information included will be anonymised to protect my identity.
7. I agree for research data collected in this study to be given to researchers to be used in future ethically approved research studies. I understand that any data that leave the research group will be fully anonymised so that I cannot be identified.
8. I understand that the information collected about me may be used to support other research in the future, and may be shared anonymously with other researchers.
9. I understand that all information given by me or about me will be treated as confidential by the research team. Such information will be treated as strictly confidential and handled in accordance with the provisions of the General Data Protection Regulation (2018).
10. I agree that the research project named above has been explained to me to my satisfaction and I agree to take part in this study.

Please sign below and email a copy of the signed form to [email: REDACTED]

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

## **Appendix I: Interview Protocol**

Questions for research question 1: What factors are considered by pain specialists in deciding to increase, decrease, switch, or stop opioids?

Think of a few recent patients you've had who were taking opioids.

1. What factors do you consider when prescribing opioids to a patient with chronic non-cancer pain?
2. Describe what you considered when you eventually decided to increase opioids for a patient.
3. Describe what you considered when you eventually decided to decrease opioids for a patient.
4. Describe what you considered when you eventually decided to switch opioids for a patient.
5. Describe what you considered when you eventually decided to stop opioids for a patient.
6. How did the adverse effects of opioids you considered affect your decision?
  - a. Were the risks considered short term or long term ones?
  - b. How do you weigh up the benefits and harm of opioids?
7. Is there anything else you would like to add?

Questions for research question 2: Does the physician's appraisal of the patient's emotions affect decisions about prescribing opioids?

1. What emotions do patients present with or express during your consultations in which you prescribe opioids?
2. Does the patient's distress affect your decision about prescribing opioids? Tell me how/elaborate. What about a patient who is really distressed?

Questions for research question 3: Do the physician's emotions affect decisions about prescribing opioids?

1. What emotions do you experience when you encounter a difficult situation regarding prescribing opioids, for example, when a patient requests for more opioids than is recommended?
2. Have you ever made a prescribing decision based on gut feeling? How certain did you feel about that decision?
3. Do you think your own emotions influence your decisions? Please elaborate.
4. Was there ever an occasion where you regretted prescribing opioids to a particular patient?

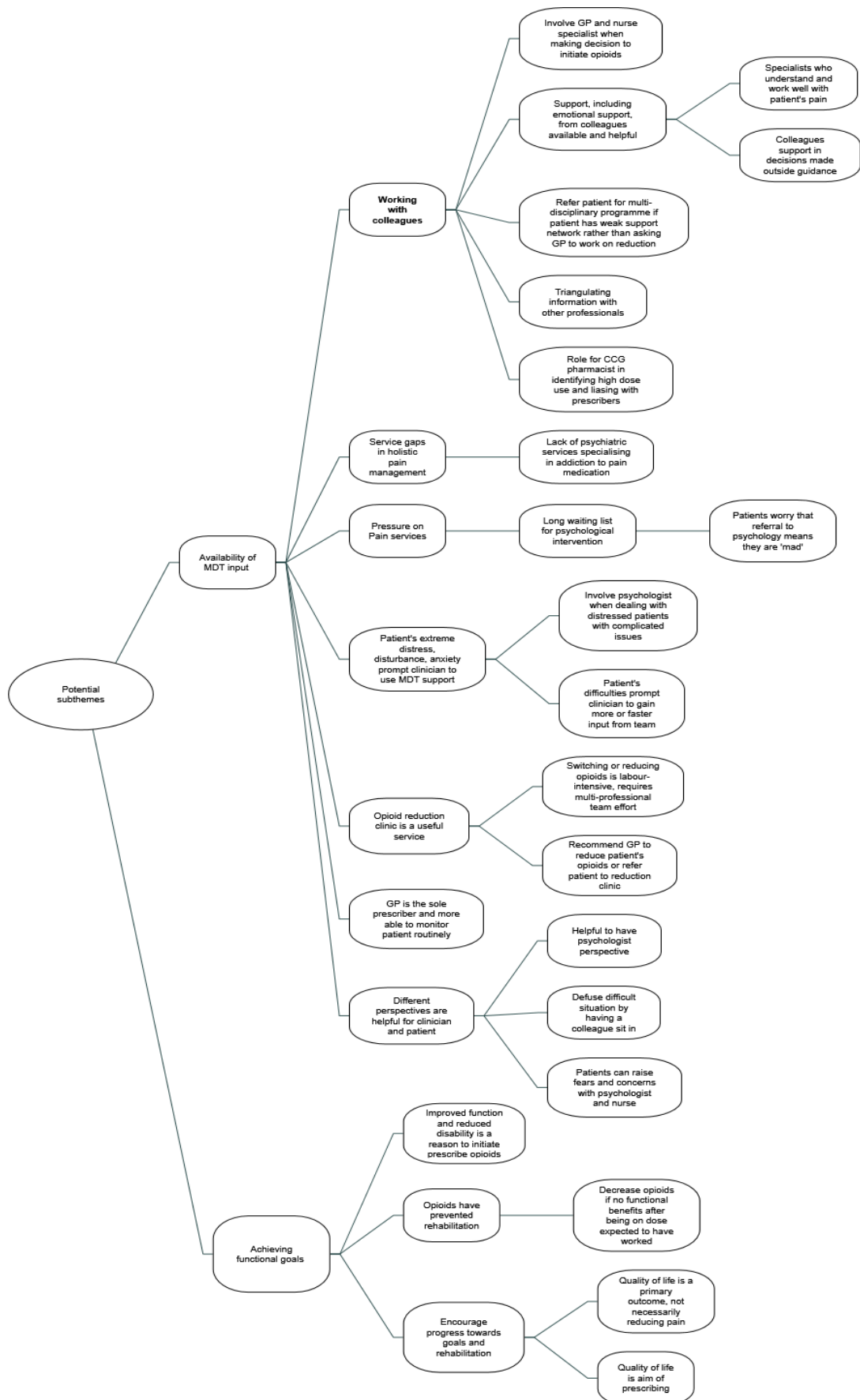
## Appendix J: Transcript Excerpt

*I = Interviewer; P = Participant*

	Text	Initial Codes
53	P: Yes, it very rarely happens (laughs). I spend my life trying to wean people off opioids, it seems, at the moment.	Starting/increasing opioids is uncommon Reducing opioids a common or favoured decision
54	I: That seems to be the main job of pain consultants.	
55	P: Yea which is strange, because a lot of people would think, well you would be starting them on it, um, but no, we spend our lives reducing.	Public perception that pain consultants start/increase opioids at odds with what clinicians actually do
56	I: Yea, okay, what about yourself, like, what emotions do you experience when you encounter a difficult situation regarding prescribing opioids, or if you're in a difficult consultation?	
57	P: Yea, you do get a lot of transference from the patients cuz often they're quite desperate, um very distressed, anxious, distraught, sometimes very, very depressed and they're often very angry at you. So you can sort of, that can bring up the same feelings in yourself, um. And um, I think, um, you know just recognising that, and also we work closely in a team. So recognising those feelings in myself and where they've come from just help me manage myself, then you know, speaking to our colleagues, um, although we work closely with them, we also listen to each other and sort of back each other up. Cuz sometimes, you know, you know, there are, the patients are always questioning you, er, you know, and you feel like, you know, especially when they're like no this is the only thing that keeps me going, the opioids, but when actually you take an in-depth assessment, you can see their quality of life is shocking, they've told you that their pain is still really bad, but they're still saying I've got to have these opioids because this is the only thing. And you're trying to take them away. That's quite a difficult sort of thing because it's not a restitution storyline is it, so you go to medical school, you know, the storyline that everybody like is, the doctor goes to the patient, the patient goes to the doctor, and the doctor makes the patient better. It's not something that we do. And it's not something that, you know, maybe their quality of life is going to improve more, but really, that's like such a long-term thing. We're not really, it's not really that, we're not going to, we're not coming in to cure their pain.	Experiences transference of patient's emotions Patient's anger at clinician  Recognition of own feelings and their sources helps in self-management Emotional support from colleagues available – clinician finds helpful Pressured in having to deal with patient's expectations  Patient fears clinician taking away opioids Patient's perception that clinician's role is to make patient better or cured  Recognises cure or reduced pain not always possible Working in chronic pain is tough
58	I: So it's not going to follow a script.	
59	P: Yea, it's not a restitution storyline so, you know, you're, it's sometimes hard to reconcile that, but you know, you know, with experience, we can see that the patients over, you know, that when they've reduced down over, say, a year, that they are taking on non-pharmacological things and understanding a bit more about their pain, and I think that's really important, the education	Conflicting goals/expectations between patient and clinician  Educating the patient on opioids

	<p>about the chronic pain mechanisms, so they can have some control and can have some insight into their condition, I think it really makes a difference. So, um, that sort of gives you, the sort of motivation to sort of keep going. But yea, they can make you, you know, feel sigh, you know, bit of heartsink sometimes when you've tried and tried and tried and they're still not doing it, but occasionally they see the penny, you know, does drop with them and then they generally improve their lives quite a lot. But it's very difficult, you know, sometimes I feel cornered by these patients, and you know, you know, I had a patient recently who was, you know, sort of, threatening, well, you know, he was threatening saying that if I don't increase his benzodiazepine, he was going to get them from elsewhere, from illegal sources on the internet or whatever, you know, and um, you know, why am I not helping the pain and he was going to make a complaint against me, but still want to see me and holding a complaint process over you. So he's quite, you know, patients can be quite depressing and frustrating and it's upsetting really. Cuz you only do try and do your best (I: Right) with these patients, but um, you know, we've got a really good team here and the support. We discuss these patients so you don't feel alone in making those decisions. I think with experience as well as you become... you have more experiences with patients, that sort of, helps.</p>	<p>Giving patients control and insight makes a difference</p> <p>Feeling heartsink after having tried their best and patient doesn't follow instructions</p> <p>Patients comply with recommendation to reduce if they understand rationale</p> <p>Sense of satisfaction when making a difference in patients' lives</p> <p>Feels cornered/threatened by patients who are aggressive or makes threats</p> <p>Goal to be helpful, do their best for patient</p> <p>Emotional support from colleagues available</p> <p>Years of experience contribute to confidence making decisions</p>
60	<p>I: It sounds like, um, being aware of what's going on with the patient, where those emotions are coming from has been really helpful for you. Um, I'm just curious whether, you know, do your own emotions influence your prescribing decisions, if at all. Like when you're sat with a patient in the room, and you described earlier that you feel cornered or someone's being very threatening.</p>	
61	<p>P: Well, you do...yea so. Well, you know, I'm usually, most of my clinics are actually run with a clinical nurse, a very experienced clinical nurse specialist, so I think that's really important for these complex patients because these are, I see chronic abdominal pelvic pain in the specialist service, so over two-thirds of my clinics are those, and back pain. Those are the two most complex patients and often are on high dose. So, I um, you know, having that other person in the room is also, the patient, is really really useful. And I think, if I had those difficult patients, I would bring them back with someone else in the room, cuz you, there's help to defuse the situation. But personally, you know, I always think, must do no harm to patients. And you just, um, you just try and, you know, obviously we always stay calm. There's no point letting the patient rile you up because that's just completely counter-productive. Even when a patient can be quite difficult, you try and maintain the relationship because you're never going to get them to reduce or use their opioids properly if you've not got a good relation-, trusting relationship with them.</p>	<p>Support from colleagues available</p> <p>Patients already on high dose</p> <p>Defuse difficult situation by having a colleague sit in</p> <p>Belief of do no harm to patient</p> <p>Responsibility to stay calm</p> <p>Develop trusting relationship with patient to help them shift mindset and reduce opioids</p>

## Appendix K: Preliminary Thematic Map



## Appendix L: Testimonial Validity

### 1. Factors affecting clinicians' prescribing decisions for chronic non-cancer pain

Clinicians took into account:

- **patient factors**, such as history of opioid use and psychiatric/psychological history;
- the **risks** of opioids were also considered, e.g. adverse effects, and
- the **benefits**, e.g. improved functioning and pain relief, particularly when treating acute-on-chronic pain.
- **safeguards**, e.g. using opioid contracts, initiating/increasing opioids for a limited period of time, advising patients to keep opioids locked away from children;
- patient **engagement** as key in helping patients understand the limited efficacy of long-term opioid use for treating chronic non-cancer pain, and to manage their expectations;
- **clinical evidence base** of long-term opioid therapy when making recommendations to patients;
- the role of the patient's **support network**, i.e. collaborating with primary care healthcare professionals, and
- availability/lack of **resources**, e.g. time, routine follow-ups, as secondary factors which contribute to effective pain management.

Clinicians usually make recommendations to decrease, rotate and/or stop opioids. On rare occasions, opioids may be initiated or increased, but this is usually in the context of an exacerbation of existing chronic pain or a new acute pain, and only when an opioid contract has been agreed upon. Otherwise, long-term low-dose opioids are also permitted.

a. Does the summary above accurately reflect your experience?

Yes

b. Would you change anything?

No

c. Would you add anything?

No



## 2. Emotions observed and experienced during consultations

Clinicians observed in patients:

- negative emotions, e.g. fear, anxiety, depression, anger
- positive emotions, e.g. pride, sense of achievement, although less commonly.

Clinicians experienced:

- negative emotions, e.g. frustration, irritation, worry
- positive emotions, e.g. pride (less commonly)
- complex emotions, e.g. doubt, guilt, regret, in situations when decisions were harder to make or communicate to the patient.
- No emotions, i.e. objective

How emotions affected decisions:

- clinicians strive to maintain objectivity
- clinicians endeavour to engage patients and build trust no matter what emotions patients presented with
- in the face of patients being demanding and aggressive, some clinicians would be more reluctant to prescribe opioids
- when patients are highly distressed, some clinicians would consider referring patients for MDT support.

a. Does the summary above accurately reflect your experience?

I am rather surprised that only SOME clinicians would consider referring patients for MDT support.

b. Would you change anything?

As below

c. Would you add anything?

In the face of patients being demanding and aggressive, the decision making is more complex and some clinicians would be more reluctant to prescribe opioids

## Appendix M: Interview Protocol (Amended)

*Changes are shown in **bold** and ~~strikethrough~~*

Questions for research question 1: What factors are considered by pain specialists in deciding to increase, decrease, switch, or stop opioids?

Think of a few recent patients **with chronic non-cancer pain that** you've had who were taking opioids.

1. What factors do you consider when ~~prescribing~~ **making opioid-related decisions for** ~~to~~ a patient with chronic non-cancer pain?
2. Describe what you considered when you eventually decided to increase opioids for a patient.
3. Describe what you considered when you eventually decided to decrease opioids for a patient.
4. Describe what you considered when you eventually decided to switch opioids for a patient.
5. Describe what you considered when you eventually decided to stop opioids for a patient.
6. How did the adverse effects of opioids you considered affect your decision?
  - a. Were the risks considered short term or long term ones?
  - b. How do you weigh up the benefits and harm of opioids?
7. Is there anything else you would like to add?

Questions for research question 2: Does the physician's appraisal of the patient's emotions affect decisions about prescribing opioids?

1. What emotions do patients present with or express during your consultations in which you prescribe opioids?
2. Does the patient's distress affect your decision (**thought process**) about prescribing opioids? Tell me how/elaborate. What about a patient who is really distressed?

Questions for research question 3: Do the physician's emotions affect decisions about prescribing opioids?

1. What emotions do you experience when you encounter a difficult situation regarding prescribing opioids **or if you're in a difficult consultation**, for example, when a patient requests for more opioids than is recommended?
2. ~~Have you ever made a prescribing decision based on gut feeling? How certain did you feel about that decision?~~
2. ~~Do you think~~ **How do** your own emotions influence your **prescribing** decisions, **if at all**?  
Please elaborate.
3. Have you ever made a prescribing decision based on gut feeling? How certain did you feel about that decision?
4. Was there ever an occasion where you regretted prescribing opioids to a particular patient?