# Identifying recommendations for an opioid weaning intervention for Chronic Non-Cancer Pain patients: A mixed-method study

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# Abstract

## Background

Chronic Non-Cancer Pain (CNCP) affects almost 20% of the UK's population and has both individual and economic burdens. Opioids have been increasingly prescribed in primary care to help manage CNCP and given the inherent nature of chronic pain, are usually issued long-term. Research over the last two decades has raised concerns regarding the efficacy of opioids for managing CNCP, and potential harm particularly in doses that exceed 120mg of Morphine Equivalent Dose (MED). There is an emerging public health priority therefore to reduce the risk of harm in those patients already established on high dose opioids. Opioid weaning has been recommended, however a caveat to this is the lack of evidence on how to best manage opioid withdrawal and patients' continued experience of pain.

## Aim

This research sought to identify recommendations for an intervention designed to reduce high daily doses of opioids among CNCP patients in primary care. To achieve this the research investigated high dose opioid prescribing in primary care across Liverpool in the North West of England and explored behaviours influencing opioid treatment with Health Care Professional (HCP) and CNCP patients.

## Methodology

A mixed-methods approach was used in the three studies of this research programme. Study 1 was a quantitative analysis of N=93,236 opioid prescriptions issued to N=30,474 patients for CNCP across Liverpool Clinical Commissioning group (LCCG) during 2016-2018. Study 2 was a thematic analysis of semi-structured interviews with HCPs (n=16) and CNCP patients (n=13) to better understand the behaviours associated with treating, and being treated with, opioids for CNCP pain. Study 3 developed a set of recommendations for an opioid weaning intervention, based on the findings of studies 1 and 2, using the 3-stage framework of the Behaviour Change Wheel (BCW). This systematically and theoretically informed the intervention content to facilitate opioid weaning. Feasibility and acceptability consultations with HCPs (n=8) and CNCP participants (n=3) were subsequently conducted online to establish consensus and refinement of the proposed recommendations.

**Results**

The findings from study 1 revealed that 3.5% (n=1,060) of patients in Liverpool are prescribed opioids above 120mg MED/day. Most patients are female (66%), with an average age of 58 years, located in North Liverpool, and likely to receive n=3 opioids attributing to their total daily dose. This provides some indication of where and who an intervention of this kind might target in Liverpool. The findings of study 2 with contributions from the literature helped identify a range of behaviours (n=34) associated with opioid weaning. Guided by the BCW in study 3, these behaviours were prioritised and 3 were selected to target the change needed to reduce or discontinue opioids. These include 1) improving adherence to opioid weaning, 2) reducing patients fear and anxiety and 3) improving information and support for opioid weaning. Feedback from HCPs and CNCP participants revealed the need to also consider addressing issues of initially engaging patients and support available for HCPs delivering the intervention and carers of patients weaning. To trigger the change needed, 6 intervention functions and 24 unique BCTs delivered via a mixture of face-to-face, online, and individual and group methods are recommended.

**Conclusion**

A small but significant proportion of CNCP patients are in receipt of opioids at doses eliciting little pain relief whilst increasing risk of harm. Given the economic and social impact of CNCP, reducing this risk of harm and optimising pain management is a public health priority. This study has proposed content for a behavioural change intervention that will target opioid weaning in a primary care setting.

**Keywords**

- Opioid
- Chronic Pain
- Non-Cancer
- Weaning
- Self-management
- Intervention
- The Behaviour Change Wheel

# Presentations

Begley, E., Montgomery, C., Poole, H., Frank, B., Sumnall, H. 2018). Opioid prescribing amongst chronic non-cancer patients in Liverpool primary care. Public Health Institute, LJMU, PhD Symposium, March 2018. (Oral presentation).

Begley, E., Montgomery, C., Poole, H., Frank, B., Sumnall, H. (2018). Developing a behavioural intervention to assist weaning from high dose opioids in chronic non-cancer pain patients. Faculty of Science, research seminar and poster day, LJMU, June 2018. (Poster presentation)

Begley, E., Montgomery, C., Poole, H., Frank, B., Sumnall, H. (2019). Developing an opioid weaning intervention in primary care for chronic non-cancer pain patients. Three Minute Thesis competition, LJMU, March 2019. (Oral presentation).

Begley, E., Montgomery, C., Poole, H., Frank, B., Sumnall, H. (2019). Developing an opioid weaning intervention in primary care for chronic non-cancer pain patients. Institute for Health Research Conference, LJMU, May 2019. (Poster presentation) - *awarded poster prize*.

Begley, E., Montgomery, C., Poole, H., Frank, B., Sumnall, H. (2019). “I wish I never started them” Investigating the experiences of UK Health Care Professionals and patients of using opioids to treat Chronic Non-Cancer Pain. EFIC, September 2019, Valencia. (Poster presentation).

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# Abbreviations

| | |
|---|---|
| CNCP | Chronic Non-Cancer Pain |
| MED | Morphine Equivalent Dose |
| DDD | Defined Daily Dose |
| HCP | Health Care Professional |
| LCCG | Liverpool Clinical Commissioning Group |
| BCW | Behaviour Change Wheel |
| IASP | International Association for the Study of Pain |
| WHO | World Health Organisation |
| ICD | International Classification of Disease |
| GDP | Gross Domestic Product |
| NICE | National Institute for health Care and Excellence |
| UK | United Kingdom |
| US | United States |
| CBT | Cognitive Behavioural Therapy |
| ACT | Acceptance and Commitment Therapy |
| REC | Research Ethics Committee |
| HRA | Health Research Authority |
| COM-B | Capability, Opportunity, Motivation – Behaviour |
| BPS | British Pain Society |
| MOR | Mu Opioid Receptor |
| CNS | Central Nervous System |
| INCB | International Narcotics Control Board |
| ACMD | Advisory Council on the Misuse of Drugs |
| GP | General Practitioner |
| PHE | Public Health England |
| EMIS | Egton Medical Information System |
| BNF | British National Formulary |
| PET | Positron emission tomography |
| fMRI | Functional Magnetic Resonance Imagining |
| SPECT | A single-photon emission computerized tomography |
| EEG | Electroencephalography |

| | |
|---|---|
| RCT | Randomised Control Trial |
| CDC | Centre for Disease Control |
| SES | Socio-Economic Status |
| IMD | Index of Multiple Deprivation |
| MDT | Multi-Disciplinary Team |

# Chapter 1: Introduction

## 1.1 Background and Rationale

### Definition of pain

Since 1979, *pain* has widely been defined as *"an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"* (IASP, 2017b). However, it has been argued that this definition excludes those who are unable to describe their experience of pain; thus a new definition was introduced in 2020 redefining pain as *"an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage"* (IASP, 2020). This perhaps signifies one of the most recent progressive movements towards understanding pain and recognising the extent of its burden.

Pain is broadly categorised into acute or chronic pain, with chronic pain defined as a *"pain that persists or recurs for longer than three months"* (Treede et al., 2019). This research focuses specifically on Chronic Non-Cancer Pain (CNCP). The term CNCP is used to describe a diverse range of non-cancerous painful medical conditions with varying underlying pathophysiological mechanisms (Mouraux et al., 2021). It is believed that this persistent or reoccurring pain is due to changes to the plasticity of the nervous system and therefore may not always be amenable to routine methods of pain control, such as opioids (IASP, 2012). Under this broad categorisation, pain can be more specifically described as either: nociceptive (where pain arises due to actual or threatening damage to non-neural tissue thus activating the nociceptors), neuropathic (where pain arises due to a lesion or disease of the somatosensory nervous system) and more recently nociplastic pain (where pain arises from nociception despite no obvious tissue damage, disease or lesion of the somatosensory system) (Trouvin & Perrot, 2019). These types of pain, however, are not mutually exclusive, and can be experienced as a combination of these different types (Kosek et al., 2016). For example, a cross sectional study of 5,024 patients across 551 primary care settings in Spain found that mixed pain (nociceptive and neuropathic) is the most common complaint among patients (59%) (Ibor et al., 2017). These patients also demonstrated greater clinical complexity, more comorbidities, adverse psycho-social factors, poorer quality of life, poor

treatment engagement and increased use of health care services. The combination of such symptoms makes it increasingly difficult for clinicians to treat pain, particularly when acute pain becomes chronic. Recognising this complexity the International Association for the Study of Pain (IASP) has recently collaborated with the World Health Organisation (WHO) to develop a classification system specific to chronic pain in the upcoming 11th revision of the International Classification of Disease (ICD), ICD-11 (Treede et al., 2019). The ICD-11 will distinguish between two main groups of chronic pain: Chronic Primary Pain – referring to pain that occurs in one or more anatomical region, is persistent or recurs for longer than 3 months and is associated with significant emotional distress or functional disability; and Chronic Secondary pain – which refers to pain syndromes linked to other diseases as the underlying cause, for example, postsurgical pain, cancer-related pain, neuropathic pain (Treede et al., 2019). It is hoped that this new classification system will help Health Care Professionals (HCPs) identify different types of pain, improve treatment pathways and strengthen clinical practice and research (Treede et al., 2019).

**Prevalence and cost of chronic pain**

Chronic pain is a growing public health problem and is currently recognised by the Global Burden of Disease (GBD) as one of the most prominent causes of disability worldwide (Vos et al., 2017). Varying prevalence figures estimate that it affects between 20% of people across Europe (Breivik et al., 2006) and 20%-30% of adults in the USA (Nahin, 2015). In England, 34% of respondents in the 2017 Health Survey for England (HSE) reported chronic pain (PHE, 2017), estimated at around 8 million people (Bridges, 2012). Furthermore, epidemiological studies have consistently found that chronic pain usually increases with age, and is more likely to affect women, individuals with lower socioeconomic status (SES), higher body mass index (BMI), lower levels of daily physical activity and multiple co-morbidities (Breivik et al., 2006; Breivik et al., 2013; PHE, 2017; Todd et al., 2019). In particular, the HSE found higher levels of chronic pain in the North of England (37%) compared to the South (35%), reflecting these geographical health inequalities (Chen et al., 2019; Todd et al., 2018).

Chronic pain and its associated impact causes significant socio-economic burden, considered as great as other healthcare priorities such as heart disease and cancer (Breivik et al., 2013).

For example, 60% of individuals with chronic pain report suffering with the condition for a duration between 2 and 15 years with a further 21% suffering for more than 20 years (Breivik et al., 2006). The duration individuals suffer chronic pain has reportedly contributed to disability and poor functioning, loss of work, quality of life and general ability to lead an independent lifestyle (Breivik et al., 2013; Todd et al., 2019). The 2017 HSE found that chronic pain affected 77% of individuals permanent ability to work and 66% of individuals who intended to work were prevented from doing so due to sickness and injury (PHE, 2017). Therefore, there is a subsequent indirect economic burden of chronic pain, driven by the associated loss of productivity, absenteeism and early retirement in employment (Breivik et al., 2013). Further direct economic burden is generated due to the increased healthcare visits and treatment costs. Chronic pain was estimated to cost the UK economy £12billion per annum, with back pain alone contributing to more than £5 billion, these however are estimated costs from 1998 (Maniadakis & Gray, 2000). More recently chronic pain is estimated to cost between 3-10% of the Gross Domestic Product (GDP) for many European countries (Breivik et al., 2013). Opioids commonly used to manage the symptoms of chronic pain attribute to significant cost. For example, a UK study with 703 patients with chronic musculoskeletal pain (the most common chronic pain complaint) reported that patients are commonly prescribed a combination of weak and strong opioids costing between £24 and £174 per annum per patient, respectively. Within this study 40% were prescribed more than three strong opioids a year costing around £236 per person (Ashaye et al., 2018). The magnitude of these costs are exacerbated when they are considered alongside further evidence that between 2017-18, 5.6 million people in the UK received at least one opioid prescription (strength not specified) (Taylor et al., 2019).

**Opioid treatment and harms**

CNCP is a complex syndrome and therefore equally complex for HCPs to treat and manage. The majority of chronic pain complaints are managed in primary care (Henry et al., 2018) where the standard practice is to prescribe opioid analgesics (Rosenblum et al., 2008). Opioids are a group of drugs derived from the opium poppy and since its first extraction in 1803, have been widely used to help relieve symptoms of pain (Haddox, 1997; Portenoy, 1986). Opioids bind to μ opioid receptors in the brain leading to analgesia, in a dose dependent fashion

(Nicholson, 2003; Rosenblum et al., 2008). Section 2.4 of the literature chapter reviews this topic in further detail. Generally, opioids are considered the most effective analgesic, yet pain specialists have debated their use for CNCP since the 1990s (Taylor et al., 2019). These debates have intensified over the past two decades, largely due to the substantial increase of opioid prescribing and related adverse events (e.g. overdose and death) being reported in America (Bonnie et al., 2017). For example, a US study investigating prescription treatment for CNCP linked an increased risk of all-cause mortality in the first 180 days of opioid therapy compared to patients prescribed anticonvulsants and low dose antidepressants (Ray et al., 2016). This is reiterated in a larger scale US study which found that pharmaceutical opioids are responsible for the highest increase in overdose related deaths increasing 4-fold between 1999-2000 (Calcaterra et al., 2013).

Opioids are undoubtedly associated with a range of side effects and adverse events (section 2.4 of the literature review discusses these in more detail). The British National Formulary (BNF) is a key reference for HCPs seeking information and advice on the selection, prescribing and dispending of medicines and cautions a number of common side effects when taking opioid medication. For example, patients may experience constipation, drowsiness, nausea and vomiting; however if taken for longer than three months patients may also be at risk of dependence, addiction and withdrawal (BNF, 2020). Furthermore, opioid use for CNCP has been linked to increased risk of heart attack, fractures, overdose, and death (Chou et al., 2015). There is growing evidence that the risk of side-effects and adverse events are linked to medium and long-term opioid use (Els et al., 2017) and are dose dependent (Bedson et al., 2019; Chou et al., 2015; Dunn et al., 2010). To assess the risk of harm, opioid medication is usually converted in to a summative *Morphine Equivalent Dose (MED)* to allow for comparison across different opioid strengths and doses consumed (Furlan et al., 2006). The threshold at which harm increases varies in the research literature but generally appears to correlate with daily Morphine Equivalent Doses (MED) above 100mgs. For example, in a US study with 9,940 CNCP patients, risk of overdose was 8.9 times more likely in those taking daily doses above 100mg MED. A systematic review investigating the effectiveness and risk of long-term opioid therapy for CNCP reported that risk of abuse and dependency increases in doses above 120mg MED and found guidance implementing a 120mg MED threshold decreased this risk of harm (Chou et al., 2015). It is concerning therefore that in the UK there is clear indication that

opioids are being prescribed long-term, are likely to increase in dose and strength and coincide with CNCP complaints (Foy et al., 2016; Zin et al., 2014). Leading healthcare bodies in the UK concur that there are no likely benefits of long-term high dose opioid prescribing and that patients risk of harm increases in doses above 120mg MED (FPM, 2015b). As a result, an online resource was developed in 2015 (Opioids Aware) to provide both HCPs and CNCP patients with advice about using opioids for CNCP. The resource advises when HCPs should consider weaning or discontinuing opioids (e.g., when risks outweigh the benefits) and factors to consider when preparing to wean patients (e.g., providing an explanation, agreeing outcomes, monitoring). Although this is useful, there remains no formal guidelines on how to safely manage withdrawal or continuing symptoms of pain among this population. The National Institute for Care Excellence (NICE) in the UK are expected to publish some guidance on safe prescribing of and managing withdrawal from prescribed drugs later this year (estimated November 2021).

**Legislation and guidelines**

The potency and increased dangers of using opioids initiated various national and international legislative controls on their supply and prescribing, for example: the UK Pharmacy Act of 1868, Defence of the Realm Act 1916, The Hague Convention 1912, the Dangerous Drugs Act 1923, the Rolleston Committee 1926 and the UN Single Convention on Narcotic Drugs Act 1961 (Berridge, 1980; BMA, 2013; Mars, 2003; "THE PHARMACY ACT OF 1868," 1868). These parliamentary acts put sanctions on the supply, manufacture, and possession of opioids (and other drugs) placing stricter controls on HCPs issuing opioids for medical care. The Misuse of Drugs Act 1971 is the current piece of legislation in the UK that defines and categorises illegal drug use, including non-prescription use of opioids. The act categorises drugs (A, B or C) according to level of potential harm, Class A being most harmful. Some drugs however are recognised as having medical benefits (such as opioids) and are regulated under section 5 of the Misuse of Drugs Regulation 2001 which authorises who can handle them (NICE, 2014b). HCPs prescribing or dispensing opioid medication are legally obligated to follow the regulations set out in schedules 2-5 (schedule 1 regulates against drugs not used medicinally). This means that HCPs must ensure that controlled drugs issued for medical purposes are not misused, particularly those likely to cause dependence or misuse

(e.g., opioids). As such, HCPs must keep a record of the medication prescribed, complete accurate documentation to facilitate the provision of medication between the prescriber and dispenser, not prescribe in quantities exceeding 30 days' supply and comply with strict rules of repeat prescriptions (NICE, 2014b).

To provide some guidance on the safe prescribing of opioids the WHO developed the analgesic ladder in 1986, originally targeting treatment of cancer pain (WHO, 1986). The three-step principle went through some modifications (in 1996) due to the development of new medical techniques and its applicability to other types of pain (e.g., CNCP), and has been widely used and promoted among health professionals for years (Vargas-Schaffer, 2010). Many local, national and international professional organisations such as IASP have developed and shared their own guidelines (see Annex 3 in (Kumar, 2007) for a comprehensive list). In the UK, some of the earlier clinical practice guidelines for managing chronic pain come from the Royal College of Nursing in 2001 (RCN, 2001) and a collaboration of several professional bodies led by the Pain Society in 2004 (PainSociety, 2004). Most of these guidelines were developed to advise HCPs specifically on the appropriate use of long-term opioid treatment for CNCP. In 2020, growing concern of the increased risk of harm with using opioids to treat CNCP long-term provoked a shift in national guidance. NICE now advised against the use of opioids in the treatment and management of CNCP and instead advocate the use of non-pharmacological therapies (NICE, 2020a).

**Incorporating health psychology**

The potential health risks associated with long-term high dose opioid treatment for CNCP have driven concerns of why it may not be effective or in a patient's best interest to continue utilising it. It is necessary therefore to help patients reduce or discontinue opioids where there is no benefit and increased risk of harm (Ballantyne & Mao, 2003). Applying models of health psychology to understand behavioural aspects of pain might offer a way to effectively respond to the issues arising from high dose opioid prescribing in CNCP. This is because its niche is to identify and understand the attributes that influence individual's behaviour and so may be used to determine targets for an intervention (Glanz & Bishop, 2010). Research has recognised that health behaviours can have a significant effect on health outcomes. For

example, in a prospective study investigating lifestyle and mortality of more than 20,000 men and women in the UK found that risk of death was four times higher in individuals who smoked, were not physically active, had high alcohol intake and poor diet (Khaw et al., 2008). The study also showed that risk of death decreased as more positive health behaviours increased, as a result giving weight to interventions targeting healthy behaviour change.

Behavioural responses to chronic pain have largely been explained by a combination of biological, psychological and social processes (Gatchel et al., 2007). The movement towards this biopsychosocial approach to healthcare was first proposed by Engel (1977) who argued that disease could be explained and more effectively treated than solely focusing on the disruption of somatic process (Engel, 1977). Revolutionising this approach Engel proposed a holistic alternative comprising the biological, psychological, and social dimensions to illness and thus developing the biopsychosocial model. This approach considers that in addition to the symptoms of pain, patients' emotional, cognitive, and social well-being is also affected and that these issues are often inseparable and frequently overlap (Gjesdal et al., 2019; NICE, 2017b). These processes play a significant role in how pain is experienced and subsequently managed recognising that achieving and maintaining analgesia requires more than just an opioid prescription. Reducing or discontinuing a CNCP patient's opioid treatment leaves the need to identify ways to manage the psychological and social processes of pain. The Fear Avoidance model of pain first proposed by Lethem *et al* in the 1980's offers a way of explaining the psychological and social processes of pain (Lethem et al., 1983). According to this model the psychological experience of pain is determined by preconceived beliefs used to interpret the level of threat or harm. Later revising this, Vlaeyen *et al.* incorporates the role of catastrophising, postulating that if the cognitive appraisal of these beliefs are interpreted negatively it triggers fear responses that catastrophise the perception and subsequent behavioural response (avoidance) to the threat (Vlaeyen & Linton, 2000). Psychological therapies such as Cognitive Behavioural Therapy (CBT) or Acceptance and Commitment Therapy (ACT) attempt to target these cognitive processes and have been shown to be effective in reducing pain intensity, improving function, quality of life and wellbeing (Chao & Ford, 2019). The development and contribution of psychology in chronic pain is discussed more in section 2.3 of the literature review. If we can understand what determines the success or acceptability of a behaviour, such as weaning/dose reduction, we might be able to

identify ways to influence changing that behaviour (Michie et al., 2011). Currently however, the evidence available indicating the use of self-management and cognitive behavioural approaches to support opioid weaning is weak (Eccleston et al., 2017; Frank et al., 2017).

**Rationale**

There is substantial individual, economic and societal burden imposed by chronic pain and so it no surprise it has become a public health priority. CNCP patients who are prescribed opioids that exceed 120mg MED a day are at increased risk of harm and without any benefit of resolved symptoms of pain (Chou et al., 2015; Dunn et al., 2010). HCPs in primary care are best placed to identify and engage with these patients, drawing awareness to the potential harms and facilitate opioid reductions. There is need however to consider that patients are often reluctant to stop using opioids (whether they work or not) because they are afraid their pain will increase, are concerned about opioid withdrawal or are sceptical about the effectiveness of non-opioid options (Frank et al., 2016; Goesling et al., 2019). Managing these concerns in addition to managing patients' pain and weaning is understandably difficult for HCPs in primary care. Psychological therapies such as CBT or ACT show some promise in targeting the psychological and social factors associated with chronic pain. Such therapies might be helpful to target some of these issues, however the evidence on which approaches are best to use is less clear. It is therefore important to understand the factors that might contribute to successful opioid weaning and reduced chronic pain so we can maximise the effectiveness of a targeted behavioural intervention.

## 1.2 Aim of the research and research objectives

The aim of this thesis is to investigate high dose opioid prescribing (> 120mg MED/day) among CNCP patients in Liverpool, UK and use insights from HCPs and CNCP patient experiences to help theoretically inform recommendations for a behavioural change intervention. The intervention will target behaviours relating to the reduction or discontinuation of high dose opioid treatment among CNCP patients in primary care.

To do this a number of objectives will be met:

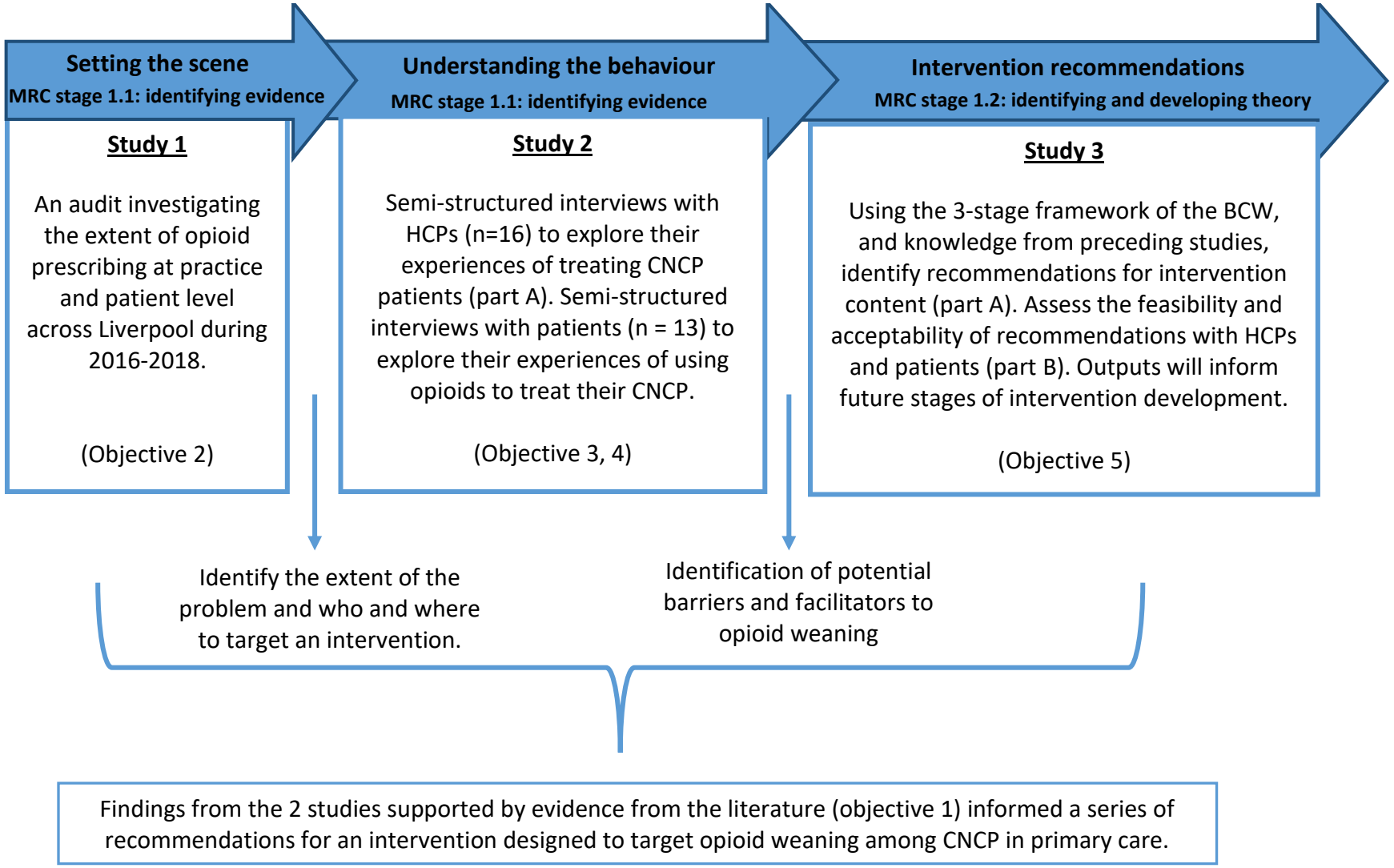
1. Establish what is currently understood in the research literature about the mechanisms and treatment of CNCP pain.
2. Investigate the nature of high dose opioid prescribing in primary care practices across LCCG.
3. Explore the behaviours of HCPs treating and managing opioid weaning with CNCP patients.
4. Explore the behaviours of CNCP patients being treated with opioids and faced with prospect of opioid weaning.
5. Use new knowledge gathered from objective 1, 3 and 4 to theoretically link components of behaviour change and identify potential content for an intervention targeting opioid weaning in patients identified from objective 2.

## 1.3 Research design

A mixed methods design involving three studies was carried out to address the objectives outlined above. Ethical approval was granted from Liverpool John Moores (LJMU) Research Ethics Committee (REC) for each of the research studies. Further ethical approval from the National Health Service (NHS) Research Ethics Committee (REC) granting Health Research Authority (HRA) for study two was obtained as it involved the recruitment of NHS patients. First a review of the literature relevant to the mechanisms and treatment of CNCP was conducted to establish the context of the field being investigated (chapter 2, objective 1). Following this, study one used quantitative analysis to investigate the prescription of opioids made in primary care practices across LCCG during 2016-2018. Findings from this study revealed the extent of opioid prescribing at practice and patient level among CNCP patients in Liverpool and provided an indication of who may benefit from alternative treatment (chapter 3, objective 2). Next, study two used semi-structured interviews with HCPs from different disciplines and CNCP patients with varying experiences of weaning to explore the barriers and facilitators commonly associated with opioid weaning (chapter 4, objectives 3 and 4). Lastly, study three used the Behaviour Change Wheel (BCW) framework to triangulate findings from objectives 1, 3 and 4 (chapters 2 and 4) to identify which behaviours need to

change and how to bring about the required change. Data from each study was analysed separately. Prescription data for study one was filtered and checks for anomalies and outliers in Microsoft Excel, imported into SPSS (version 26) for analysis. Interviews in study two were transcribed verbatim and imported to NVivo (version 12) where a combination of inductive and deductive thematic coding was performed. Feedback consultations with HCPs and CNCP participants on the recommendations proposed in study three were also transcribed verbatim and coded deductively using COM-B model framework.

**Figure 1:1: Research design**



## 1.4 Position of the researcher

There is a level of subjective interpretation inherent to researchers that may influence how they approach a topic, design a study, collect, and analyse data and understand and report their findings. Consideration of this and prior to commencing my PhD I reflected upon my own experiences and how they could impact on how I interpret the current research. For years, I have had a personal interest in public health, specifically illicit substance misuse and worked as a researcher investigating recreational drug use and young people's drinking behaviours. This experience equipped me with quantitative and qualitative research skills and knowledge of conducting research with vulnerable populations. A lot of my knowledge therefore has come from understanding substance use as a recreational behaviour and the impact of policy on controlling illicit drugs. I was also aware that I had no direct experience or knowledge of chronic pain and understood it only as a long-term condition often managed by painkillers.

To ensure that this experience did not adversely impact on my interpretation of this research, I followed a framework set out for each study and revisited study aims and objectives to maintain my focus. I also sought regular guidance from the supervisory team reviewing study progress and how my interpretation of each stage of the research was being framed to inform the next. To reflect this a pragmatic approach to the research was adopted allowing flexibility around establishing what works best to uncover knowledge about the problem in question.

## 1.5 Pragmatic paradigm

Pragmatism offers a way of perceiving knowledge as concept attained through action, consequences, and reflection (Biesta, 2010). In this sense pragmatists do not view the world in absolute terms of subjectivity or objectivity; instead, pragmatists consider that knowledge arises from transactional experiences bound by abduction, intersubjectivity and, transferability (Morgan, 2007). The adoption of this perspective offers a way to bridge the gap with other purist paradigms such as, post positivism or constructivism, that might determine use of certain methodologies (Creswell et al., 2011). The flexibility of pragmatism therefore harnesses the views of multiple realities using varied perspectives to better understand or answer a research problem (Creswell & Plano Clark, 2018). As such, the design and methods used to establish knowledge should be pragmatically selected to best address

the research problem and not determined by a philosophical standpoint (Johnson & Onwuegbuzie, 2004).

These features make pragmatism a valuable stance to adopt in health related research (Plano Clark, 2010) and are deemed particularly useful in addressing the research aims of this study. For example, the rationale set out above, identifies high dose opioid prescribing for CNCP as a real world public health problem that would benefit from drawing upon qualitative and quantitative research methodologies. Pragmatism is considered among many scholars to be the philosophical foundation for mixed method research, generating a better understanding of health problems by combing qualitative and quantitative methods (Creswell & Plano Clark, 2018; Tashakkori & Teddlie, 2003; Teddlie & Tashakkori, 2010). By combining methods from different world views, it is thought to strengthen the findings contributing to a research problem (Greene, 2006).

Following the principles of pragmatism, the study design and methods used here were selected to address the research problem, reducing high dose opioids in CNCP patients. Pragmatically, this led a need to first conduct an audit of practice level opioid prescribing for CNCP so the extent of high dose prescribing could be established (study 1). Secondly, collecting data from varying perspectives (HCPs and CNCP patients) helped to understand real world experiences (study 2). Lastly, integrating the findings from study 2 helped to structure behavioural change intervention recommendations, that could be used to support those needing to reduce their opioids identified from study 1.

# Chapter 2: Literature Review

## 2.1 Aim of the literature review

The Medical Research Council (MRC) guidance on intervention development and stage 1 of BCW framework both require an in-depth understanding of the research literature prior to intervention development. To address objective one of this thesis, the aim of this chapter therefore was to review the available literature in order to understand the phenomenon of CNCP and the behavioural responses of HCPs and patients. Section 2.3 reviews what is currently understood about pain, including the physiological and psychological pathologies explaining pain. Section 2.4 reviews the evidence for the use of opioids to treat CNCP focusing on the prevalence and effectiveness of their use. Lastly section 2.5 reviews the literature exploring patient and HCPs experiences of living with and treating CNCP and how these experiences may be improved.

## 2.2 Literature search strategy

A systematic search of the literature was initially conducted in January 2018 and subsequently repeated throughout the three-year research period using Medline, CINAHL, ScienceDirect and Google Scholar databases. Searches were limited to English language articles only with no specific publication date range. To identify relevant articles free text, abstract and title searches were performed specifically excluding cancer pain, using a combination of the following search terms: chronic non-cancer pain or chronic non-malignant pain or persistent non-cancer pain and, theory of pain; opioid therapy or prescribing; opioid analgesic; primary care; prescribing trends; self-management; pain management; pain behaviour; biopsychosocial model; psychology or psychological therapy; cognitive behavioural therapy; opioid weaning or tapering and intervention; reducing opioids; discontinue opioids and intervention; behaviour change intervention. Article titles were assessed first for relevance and then their abstracts reviewed to identify those applicable to the areas of research interest. To widen the scope of identifying other potentially relevant data, reference lists of the retrieved articles were reviewed, and grey literature was found on NICE, IASP, WHO and BPS sites also included.

The search criteria were reviewed using the medical subject heading (MeSH) on demand tool developed by the National Institute of Health (NIH), which generated the following terms: chronic pain, analgesics, opioid, pain, practice patterns, inappropriate prescribing, pain management, models, biopsychosocial, cognitive behavioural therapy. The whole literature search was re-done using the identified MeSH terms, a few new papers were found and included in the literature review.

## 2.3 Understanding pain

The most recent definition of pain defined by the International Association for the Study of Pain (IASP) is "*an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage*" (IASP, 2020). This definition considers the multidimensional aspects of pain identified through the work of Melzack and Casey (1968) comprising; sensory-discriminative cues, affective-motivation cues and cognitive-evaluative cues that interlink to influence our experience of pain (Melzack & Casey, 1968). This section of the literature review will provide an overview of the key theories that led to this understanding of pain and consider the different types of pain, specifically focusing on Chronic Non-Cancer Pain (CNCP).

Historically, pain was considered as a simple linear response to noxious stimulus (i.e. damaging or threatening events) whereby the pathology was emitted directly from injured tissue to a pain centre in the brain (Melzack, 1996). Pain was then subsequently perceived as a mechanistic behavioural response e.g. physical withdrawal from a perceived treat (Horn & Munafo, 1997). Descartes, an influential philosopher from the 17th Century, advocated this theory and postulated a stimulus response model, suggesting the magnitude of pain felt was proportionate to the stimulus exposure (Moayedi & Davis, 2013). In this sense the greater the magnitude, the greater the pain felt. Descartes believed that sensory and motor information transduced from sensory and perceptual experiences were conveyed via nerves to the brain, alluding to what is now understood as the Somatosensory Nervous System (SNS) (Moayedi & Davis, 2013). Our SNS processes bodily sensations such as pain, pressure, hot and cold stimuli, transmitting signals to the brain from peripheral afferent nerve fibres, specialised receptors subserving proprioceptive and cutaneous sensitivity (McGlone & Reilly, 2010). The crux with

theories advocating linear explanations of pain however is that they do not consider the psychological factors implicated in the experience of pain (Melzack, 1996). The implications of this meant that if pain cannot be explained by a linear model (i.e. organic pathology) then it was regarded as not real and patients were often referred to psychiatrists for treatment (Horn & Munafo, 1997). The logic therefore was to treat the tissue pathology in order to resolve the pain. Descartes' contributions allowed forthcoming physiologists to further develop and propose new philosophical and theoretical explanations, enhancing our current understanding of pain. The development of the key theories of pain are discussed below.

**Physiological theories of pain**

The past two centuries witnessed progressive scientific developments that shaped four key theoretical concepts underpinning the phenomena of pain: specificity theory, intensity theory, pattern theory and Gate Control Theory (GCT). The earlier theories of pain largely derive from stimulus response models, this section of the literature review will present a brief overview of their contributions which have been debunked for a more defined theory comprising clinical, psychological and physiological considerations of pain. Specificity theory dominated most of the 19th century with many physicians and scholars investigating the function of the spinal cord and identifying afferent pathways considered specific for processing different somatic senses (Moayedi & Davis, 2013). The sequence of scientific experiments that unfolded (by physicians such as Bell (1811) and Magendie (1822)) highlighted the significance of sensory nerves in the dorsal and ventral roots of the spinal cord for conducting information on painful stimuli (Moayedi & Davis, 2013). These developments led Muller (1840) to postulate sensory nerve specificity and establish pain as an independent sensation (Perl, 2007). These physiological and theoretical discoveries maintained the belief that there were specific fibres and pathways

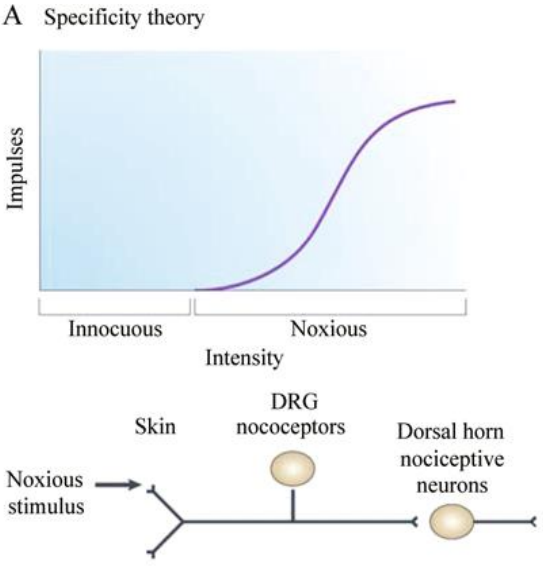



**Figure 2:1 Specificity theory**

(Source: Perl, 2007)

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for each somatosensory modality (Perl, 2007). Specific theory proposed that pain occurred due to exposure to noxious stimuli encoded by specific nociceptors (sensory neurons). The activity of these neurons is termed nociception and is believed to connect to a specific pain pathway projecting signals to a pain centre in the brain (see figure 2.1). This theory however did not account for various clinical, psychological, and physiological occurrences of pain. For example, if there were specific pain receptors projecting nerve impulses to the brain, it does not explain why pain is still reported despite surgical lesions to the peripheral and central nervous system; or why Beecher (1950) reported soldiers denying feeling pain and pain medicine despite obtaining substantial injuries (Melzack & Wall, 1965).

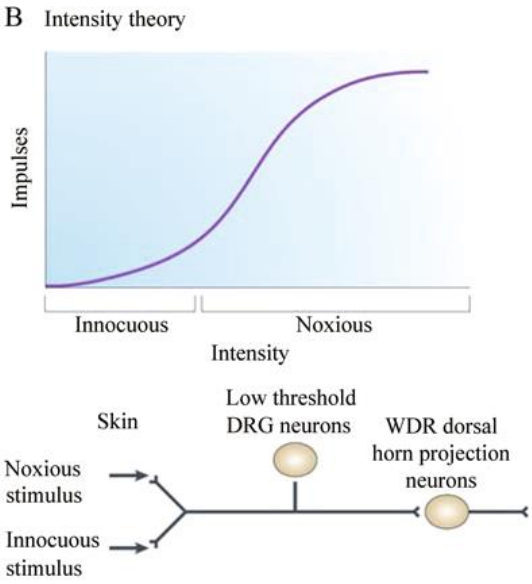


**Figure 2:2 Intensity theory**

(Source: IBID)

The discovery that the Central Nervous System (CNS) is made up of discrete cells functioning via synaptic connections that could be altered from exposure to different stimuli (e.g. mechanical, thermal, chemical), provided reason to object the notion of pain as an independent sensation produced by specific organs (Perl, 2007). Opposing specify theory, Erb (1874) also reported differences from intense stimulation and response to pain and instead argued that pain arises from intense activation of nervous pathways associated with other sensory modalities, conceptualising intensity theory (Moayedi & Davis, 2013). Intensity theory proposes that peripheral senses activate different levels and ranges of responses in afferent fibres and the intensity to which they are coded signals neurons eliciting noxious (painful) or innocuous (harmless) events (see figure 2.2) (Perl, 2007). This theory was advanced by further discoveries in physiology identifying ascending pain pathways and the function of large and small diameter fibres in eliciting painful responses.

Experiments blocking or exciting activity in afferent fibres elicited their compound action potential that established fast and slow conduction of stimulus response in the small (C-) and large (A-delta) fibres, respectively (Perl, 2007). Stimulating afferent fibres (through exposing

peripheral tissue) led to the proposal of pattern theory, postulating that intense stimulation elicits a sequence of neural patterns that evoke pain. Nafe (1929) argued that somatic senses elicit a wide range of responses, each with differing relationships to stimulus intensity; the composition pattern of activity in the afferent nerve fibres are coded by neurons that project signals to the nature and place of stimulation (see figure 2.3) (Perl, 2007).

Other versions of pattern theory emerged conceptualising proposals of central summation mechanisms evoking activity in the spinal cord and an input-controlling system modulating summation via A-delta and C- fibres considered responsible for conducting pain signals (Melzack & Wall, 1965). The concept of pattern theory contributed valuable knowledge toward understanding the mechanisms of pain. Melzack and Wall (1965) however argued it lacked unity and experimental evidence and like the other theories of pain, largely disregarded the psychological experience of pain (Melzack, 1996).

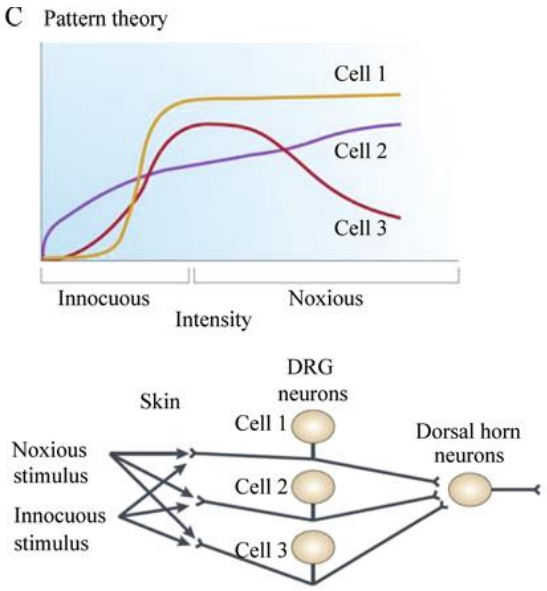


**Figure 2:3 Pattern theory**

(Source: IBID)

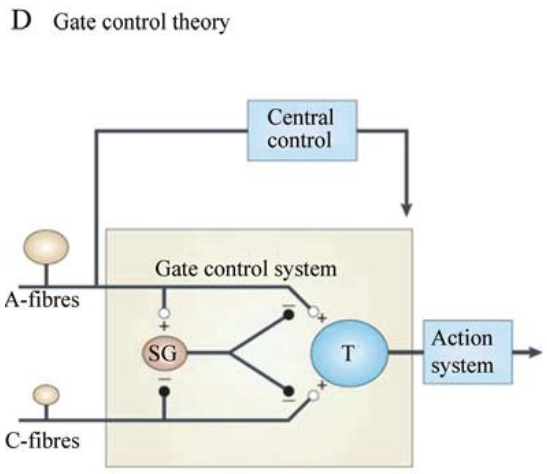


**Figure 2:4 Gate control theory**

(Source: IBID)

This led to Melzack and Wall's Gate Control Theory (GCT) which advanced previous theories by incorporating the role of the brain, thus subjective experience of pain (Melzack, 1996). Melzack and Wall recognised the significance of Goldscheider's (1894) contribution theorising a central summation in the dorsal horn in the spinal cord, Livingston's (1943) proposal of a circuit modulating summation, and Noordenbo's (1959) theory that large (A delta) fibres inhibited small (C-) fibres in the dorsal horn (Melzack,

1996). The essence of GCT postulates that pain is experienced by the conduction of nerve impulses, modulated by the interaction of three main control systems: (1) the gate control system, (2) central control trigger and (3) the action system. In their founding paper, Melzack and Wall (1965) explain how impulse patterns from the A-delta (large) and C- (small) fibres are modulated by a gate control system that facilitates or inhibits central Transmission (T) cell activity, which ultimately projects onto an action system (see figure 2.4) (Melzack & Wall, 1965). It is thought this when C-fibre activity outweighs A-delta, it opens the gate stimulating a response in the 'action system' that underpins the complex pattern and behavioural characteristics of pain (Perl, 2007). The GCT differs from other theories in that it incorporates the role of a central control trigger deciphering descending signals from the brain. Based on evidence that brain stimulation activates descending signals (Lundberg, 1964), Melzack and Wall, proposed that a mechanism (a central control trigger) activates brain processes such as attention, emotion and memory (Melzack & Wall, 1965). As a result, these processes influence sensory input that is eventually mediated by the gate control system. Such rationale may account for the absence of reported pain in soldiers despite reporting substantial injury. It is believed that the fast conducting velocity of the A-delta fibres rapidly activate cognitive processes, such as the nature and location of the stimulus, implying an interconnective combination of neural processes ascending and descending to and from the brain (Melzack & Wall, 1965). The GCT did not account for all types of reported pain. Their remained some unexplained descending somesthetic processing that warranted further theoretical consideration. For example, pain in phantom limbs of paraplegics did not fit the mechanisms of the GCT due to the inherent disconnect between the brain and the spinal gate. In an attempt to explain this experience, Melzack evolved the GCT and proposed that the brain has a genetically formed network of neurons (conceptualising the Neuromatrix theory) developed from a series of unique neurosignature patterns (Melzack, 1989). The Neuromatrix theory explains how peripheral input is not always needed i.e. "*we don't need a body to feel a body*"; to experience our body, such inputs however may trigger an output pattern which is malleable to change based on sensory experience (Melzack, 1989). Each of these theories outlined here, contain influential and sometimes conflicting aspects that drove the development of the next theory. Their inherent limitations however leave room for continued investigation as some aspects of pain still remain unclear, for example the mechanisms of

chronic pain and arguably the over simplification of the neutral architecture of the spinal cord (Moayedi & Davis, 2013).

**Psychological theories of pain**

The contribution of the GCT and Neuromatrix theory in elucidating a central neural mechanism accentuates the role of psychology as a discipline in the general experience of pain. These theories provide an explanation of how peripheral sensory input as well as genetically determined factors can be modulated by a cognitive system that determines output behaviours described and learned as pain. These cognitive processes signify that pain operates via sensory discriminative, motivational affective and evaluative dimensions (Melzack & Casey, 1968). The contribution of these theories imply that our individual response to pain is a combination of our experience and the affect and meaning we attach to sensory input. Melzack and Casey, further assumed that pain could be treated by controlling sensory inputs and influencing motivational, affective and cognitive factors. This instigated the development of psychological therapies in the management of pain that initially focused on the principles of behavioural conditioning, whereby the consequences and thus meaning of our behaviour is operant. Embracing this concept, Fordyce and colleagues, developed and delivered the first wave of psychological behavioural therapy for pain management (Fordyce et al., 1968). Their approach incorporated the principles of operant conditioning with the aim of improving function in observed pain behaviours. Operant conditioning assumes the consequences of behaviour dictates the likelihood of that behaviour being repeated, and thus is reliant on reinforcers to positively or negatively strengthen the behaviour (Fordyce et al., 1968). Through a series of investigations controlling patients' environmental events such as attention, rest and medication, Fordyce (1982) demonstrated that pain behaviours can be influenced (for example, a reduction in pain related behaviours) (Fordyce, 1982).

The evidence of psychological processes involved in the experience of pain facilitated a shift from the traditional dualistic biomedical approach, toward a multidimensional approach interlinking biological, psychological and social determinants. Contemporaneously, Engel (1977) conceptualised the biopsychosocial model of healthcare, recognising the need for a more holistic treatment approach to long-term health conditions, such as the treatment of

chronic pain (Engel, 1977). The biopsychosocial model considered the interrelationship between the objective biological disease and subjective psychosocial experience of the illness in order to better understand an individual's perception and response to pain. The reciprocal relationship between these components is supported by neurological studies investigating the role of the brain in evoking experiences of pain. The advancement of neuro-imaging techniques (such as PET, fMRI, SPECT, EEG) have provided physiological evidence of widespread brain activity in pain, and how factors such as affective, cognitive and reflexive responses influence perception, thus experience of pain (Gatchel et al., 2007). For example, pain catastrophising and anticipation has been linked to increased activity in areas of the brain associated with pain processing (Brown et al., 2014; Gracely et al., 2004). Anticipation of pain was found to increase neural activity among fibromyalgia (n=16) and osteoarthritis patients (n=16) compared to healthy controls (n=15) in an experimental study using electroencephalography (EEG) and anticipated heat stimulus (Brown et al., 2014). Specifically, increased brain activity was correlated with patient's intensity and reported pain, however, was notably higher among fibromyalgia patients. The study also found reduced activity in patients' prefrontal cortex related to poorer psychological coping. Additionally, fMRI analysis correlated pain catastrophising to increased brain activity among fibromyalgia patients (N=29) following exposure to blunt pressure (Gracely et al., 2004). The areas of brain activity identified in this study were associated with the anticipation of pain, attention and emotional aspects of pain and motor control. Brain activity was also notably higher in patients who reported higher levels of pain catastrophising thus providing neurological evidence that catastrophising influences pain perception through altering attention, anticipation and heightening emotional responses to pain (Gracely et al., 2004). An increased understanding of what brain regions are affected by pain and what factors are likely to influence neural activity gives some indication of identifying potential treatment (e.g., cognitive therapy) that may target specific responses.

Reflecting back on Fordyce's conception of the operant model of behaviour, although he offers some insight into understanding and modulating behaviour, the model was limited in its approach. For example, the operant model did not consider non-observational behaviours such as emotion and thought, instead at the time, cognitive based therapy addressed these issues separately in a second wave of psychological therapy (Penlington et al., 2019). The

approach of cognitive therapy, aimed to understand the nature and evolution of cognitive acts rather than consider the independent variables of contextual events that may alter cognitive experience (Hayes et al., 2006). Behaviour therapy and cognitive therapy cannot be solely relied upon to fully explain and understand behaviour. The interrelated connection between behavioural and cognitive components (e.g. thought, emotion and behaviour, alongside physical sensation) was recognised and both approaches were combined (Gatchel, 1999). This combination formed the basis of CBT where each component is considered to operate in a reciprocal cycle, meaning changes to one component e.g. thought or emotion, influences another e.g. behaviour or physical sensation (Penlington et al., 2019). The essence of this concept is discussed in an evidence review by Gatchel et al (2007) who draw on how the affective component of pain evokes emotional responses such as anxiety, depression and anger, subsequently influencing cognitive appraisals that may amplify the experience of pain (Gatchel et al., 2007). The cognitive appraisal of these emotions becomes part of a cycle where meaning and beliefs are attached to the experiences eliciting them, establishing a process where "*thinking affects mood and mood influences appraisal, thereby affecting the experience of pain*" (Turk & Wilson, 2010 p.2).

The cycle of cognitive appraisal can largely be explained by the Fear Avoidance model (Vlaeyen & Linton, 2000). The Fear Avoidance model depicts a three-step evaluative process whereby 1) an individual's idiosyncratic beliefs interpret threat perception, 2) negative appraisals trigger affective (e.g., catastrophising) and subsequent behavioural (e.g., fear avoidance) responses, 3) fear enhances threat perception manifesting catastrophic appraisal thus evoking avoidance of activity in order to escape re-experiencing pain (Turk & Wilson, 2010). The applicability of fear avoidance in escalating pain intensity was evidenced in a systematic and meta-analysis of N=118 studies (Kroska et al 2018). Findings from the review identified a positive reciprocal relationship between heightened fear avoidance and pain intensity and that patient's cultural beliefs may further moderate this experience (Kroska et al 2018). According to the fear avoidance model the extent to which individualised beliefs are perceived as a threat, triggers catastrophising, establishing maladaptive beliefs that are negatively exaggerated in regard to actual or potential painful experiences, evoking avoidance behaviour (Turk & Wilson, 2010).

The role of pain catastrophising in elaborating painful experiences is considered one of the key drivers in predicting pain, alongside pain related anxiety and fear, and sense of helplessness (Keefe et al, 2004). Pain catastrophising is frequently linked to increased disability and psychological dysfunction (e.g., increased depression and anxiety), pain severity, reduced quality of life, perceived injustice of the health care system, poorer treatment outcomes and lower self-efficacy among varying chronic pain conditions (Arnow et al, 2011; Craig et al, 2017; Sturgeon et al, 2017; Lami et al, 2018; Larice et al, 2020). Despite there being a large body of evidence indicating the role of catastrophising and emotional distress in chronic pain, a recent systematic review and meta-analysis of chronic musculoskeletal pain studies (N=85) argued that this association is weak (Martinez-Calderon et al, 2019). Findings from the meta-analysis indicated a high level of heterogeneity and risk of bias among the included studies, most of which were cross-sectional (92%). The consistency of pain catastrophising in predicting pain was however recognised and so the authors conclude that the existing evidence is reliable and instead call for improved study designs in order to draw more definitive conclusions (Martinez-Calderon et al, 2019).

Assessing catastrophic appraisals is important in order to address psychological dysfunction and subsequently interrupt the fear avoidance cycle. CBT therapy targets unhelpful thoughts that are linked to perpetuating psychological distress, by helping patients to identify and change thoughts and beliefs through adopting more effective ways of coping (Gatchel, 1999; Penlington et al., 2019). Many strategies employed by CBT include self-instructions (e.g. distraction, motivational, self-talk), relaxation, coping strategies (e.g. methods to increase assertiveness and reduce self-defeating thoughts), changing maladaptive beliefs, goal setting, patient education and communication (Baez et al., 2018; Gatchel et al., 2007). Systematic reviews and meta-analyses investigating the efficacy of CBT in reducing or improving a range of pain related outcomes have demonstrated its efficacy since the late 90's. For example, Morley et al., (1999) included 33 Randomised Control Trials (RCT) in their systematic and meta-analysis review, and found CBT was more effective than wait list controls or alternative treatment in improving pain experience, mood, cognitive coping, pain behaviour, activity and social interaction in chronic pain (Morley et al., 1999). Similarly, Knoerl *et al*., (2016) found that CBT reduced pain intensity in 43% of the 35 RCTs included in their review, common

strategies used included cognitive restructuring (91%), pain psycho-education (80%) and relaxation (60%) (Knoerl et al., 2016). Furthermore, compared with no treatment or care a usual, CBT produced small to moderate improvements in disability, pain intensity and quality of life in a systemic review investigating 23 RCTs with chronic lower back pain patients (Richmond et al., 2015). CBT may also be effectively delivered in primary care; an RCT delivering pain coping skills training to n=256 osteoarthritis patients demonstrated improvements in pain intensity, coping, self-efficacy, activity interference and reduction of pain medication (medication not specified) compared to care as usual (Broderick et al., 2016). Although there is a plethora of evidence indicating the positive outcomes of CBT in changing and understanding behaviour, Hayes et al., (2006) argue that CBT lacks evidence on the direct cognitive change that is needed for clinical improvement (Hayes et al., 2006). Critically reviewing behavioural and cognitive psychological theories, Hayes suggests the emergence of a third wave psychological therapy such as Acceptance and Commitment Therapy (ACT), may offer a different and promising approach. Conversely, an esteemed Cochrane review of n=75 RCTs (updating Morley *et al*., (1999)), concludes with certainty that there is sufficient evidence to indicate CBT can improve CNCP patients' pain, disability, and distress (de C Williams et al., 2020). Furthermore, the review also considers the use of ACT for CNCP management, but concludes the evidence is limited and of low quality to draw any certain conclusions.

Third wave psychological approaches use broader and more flexible therapy namely Acceptance and Commitment Therapy (ACT) and mindfulness. The goal of such therapy is to increase psychological flexibility by employing a range of psychological skills such as: the acceptance of events despite their undesirability, the diffusion of values attached to undesirable functions and thoughts and commitment to behaviour change by focusing on goal orientated values (Hayes et al., 2006). The use of ACT has proven to be effective in the treatment of chronic pain patients. McCracken, Vowles and Eccleston (2004) used methods of acceptance-based treatment in a 3-4 week inpatient setting with n=108 chronic pain patients. Their study found significant improvements in psychological (e.g. anxiety and depression) and physical functioning as well as lower health care use and lower pain intensity (McCracken et al., 2004). ACT has also been associated with significant decreases in drug use at follow up among a sample of 124 polysubstance users compared to a group who received

intensive 12-step facilitation or methadone maintenance in a random design study (Hayes, Wilson et al, 2004). As these therapeutic methods are relatively new and have not been widely tested, there is less evidence of potential predictors or moderators of treatment outcomes when treating chronic pain (systematic review of n=20 studies) (Gilpin et al, 2017). Gilpin et al., (2017) conclude that although third wave methods might be beneficial for some people it is not yet known who may benefit and to what extent. There is some evidence that those with higher psychological distress may have benefited from mindfulness-based interventions (Gilpin et al, 2017). More recently Gerdle et al. (2019) found that cognitive behavioural factors, emotional distress and pain intensity were useful to help identify subgroups that would best respond to multimodal rehabilitation programmes. Among 22,406 chronic pain patients, those reporting the lowest level of functioning demonstrated most improved outcomes, indicating that interventions may need to be tailored for patients who vary in functionality. Both CBT and ACT do not aim to reduce pain, but instead help patients to address their experience of pain enabling them to make changes within their control, thus leading to overall improved quality of life. It is possible that the fundamental components of these methods of accepting and adopting to inevitable outcomes through adaptive cognitive functioning could be used to support treatment engagement and adherence to opioid weaning programmes for CNCP patients.

## 2.4 Using opioids to treat Chronic Non-Cancer Pain

### Pharmacology of opioids

Opioids[1] refer to group of analgesic drugs commonly used to treat the symptoms of acute and chronic pain. Opiates, specifically morphine, are the naturally occurring alkaloid extracted from the poppy plant, which is why morphine's chemical structure is often considered the prototype for other opioids (INCB, 2019a). Modifications to the opiate alkaloid afforded by science categorises opioids into 3 main groups: 1) refined (i.e., from naturally occurring opiates such as morphine and codeine), 2) semi-synthetic (i.e., modifications to natural opiate structures such as dihydrocodeine or oxycodone) or 3) synthetic (i.e., chemically synthesised

[1] Opioids is the preferred term used throughout this thesis unless stated otherwise.

to mimic natural opiates such as fentanyl or methadone) (INCB, 2019a). The pharmacological potential of opioids became evident from *in vivo* experiments carried out in the 1960s and early 70's where it was found that opioids cause analgesia by acting on three opioid receptors, Mu (μ), Kappa (κ), and Delta (δ) (Corbett et al., 2006). These receptors are predominantly found in the Central Nervous System (CNS), brainstem, spinal cord and intestine (Nafziger & Barkin, 2018) and when stimulated trigger a disruption in the pain pathway by inhibiting pain signal transmission (Al-Hasani & Bruchas, 2011; Morrone et al., 2017). The analgesic effects of opioids are determined by their binding affinity to the μ opioid receptor (Corbett et al., 2006) as either agonists, partial agonists, mixed agonists, or as having antagonist effects (Morrone et al., 2017). Pure agonists don't have the ceiling effect that partial or mixed agonists do, and thus are commonly used in pain management (Nafziger & Barkin, 2018). Weak opioids such as codeine or tramadol, are indicated for mild pain symptoms as they have poorer binding potential at the μ opioid receptor compared to stronger opioids such as morphine and oxycodone which are indicated for moderate to severe pain (BNF, 2020; SIGN, 2019).

Additionally, the pharmacokinetics of opioids also determine their effect, usually measured by how they are absorbed, distributed, metabolised, and excreted from the body (Nafziger & Barkin, 2018). For example, the various preparations (e.g., tablet, liquid, patch) and formulations (e.g., oral, sublingual, skin membrane) of opioids influence their absorption rate (O'Brien et al., 2017). Additionally an individual's genetic variability of pharmacokinetics influences the metabolic rate and binding potential to opioid receptors (Morrone et al., 2017). These factors contribute to an opioids half-life, that is how long it takes for the amount of the drug to reduce by half, essentially determining their short or long acting potential. Generally, immediate release opioids have a quicker onset of action and shorter duration which allows for flexibility per required need (Nafziger & Barkin, 2018). Modified release opioids take longer to peak as the release of opioids into the body is slower lengthening the duration of effect (Nafziger & Barkin, 2018). There is no clear evidence however that any particular opioid or preparation is better than any other in terms of efficacy for managing pain relief (SIGN, 2019).

**Prevalence reports and trends of opioid prescribing**

The need to better review opioid treatment for CNCP can been seen among the widespread concern of increased figures in prescribing. Global opioid consumption has been increasing since the 1980's but prevalence reviews specifically highlight a spike in prescribing during 2000 (Bonnie et al., 2017). Globally, only a small proportion (16%) of the world's population consume the majority (86%) of the total amount morphine; mainly across North America (47%) and Europe (32.6%) (INCB, 2019a). Moreover, the USA was identified as the world's largest consumer of opioids with a 400% increase between the period 2000-2010, compared with a 65% increase in the UK during that time (Häuser et al., 2016). Currently opioid consumption in the USA is almost double of any other country, consuming on average over 40,000 tons (per million inhabitants) they continue to rank the highest across the globe (INCB, 2019a). Germany ranks second (28,862 tons) and Canada third (26,029 tons), compared to the UK who rank 15th (12,575 tons) and at the end of the spectrum Chad, Democratic Republic of Congo and Pakistan who rank 174th with estimates of 1 ton per million inhabitants. It is therefore not surprising that the USA has received a lot of attention in recent media and have declared a state of crisis regarding the prescription of opioid drugs for the treatment of CNCP. This is further reflected in other global statistics reported by the United Nations in their report of world estimates of narcotic drugs (INCB, 2019a). The UN report highlights a number of key trends highlighting that despite an overall downward trend in the global opium movement (i.e., production, stock and use) since 2005, slight increases are evident during 2011 and 2017 (although still lower than 2005). This downward trend perhaps indicates a decrease of demand being placed on opioids but equally could reflect global responses to control inappropriate prescribing and misuse of legally acquired opioids. Globally, 2017 marked the lowest level of opium importation in 20 years, however consumption of morphine has still roughly doubled since 1997 (INCB, 2019a). Additionally there is further evidence specifically across North America that there are increases in more immediate release (short-acting) opioids than extended release (long-acting) opioids (234 million versus 22.9 million respectively) (Manchikanti et al., 2012). Although there is no evidence to suggest long-acting opioids are any better or safer than short-acting, combining these formulations with higher doses for long periods of time increase risk of adverse harm (Manchikanti et al., 2012). Overall, (being the highest global opioid consumer, increasing

prevalence of long-term and high dose prescribing), has led to opioid related deaths doubling across the US since 2002 (Häuser et al., 2016).

New evidence from a recent systematic review of 42 studies in eight different counties indicates that 31% of CNCP patients are likely to be prescribed an opioid (Mathieson *et al*., 2020a). Although most of the studies were US based (n=28) and may not be generalisable to the UK (n=4), results indicated a greater likelihood of being prescribed a strong opioid (18.4%) than a weak opioid (8.5%); which increased further when a combination of strong opioids were prescribed (24.1%) compared to a combination of weak opioids (11%) (Mathieson *et al., 2020a*. There are many UK based prevalence studies that demonstrate the increase of opioid prescribing (Chen et al., 2019; Foy et al., 2016; Mordecai et al., 2018; Torrance et al., 2018; Zin et al., 2014). The UK have reported a year on year increase in opioid prescribing since 1992, rising from 228 million prescriptions to 1.6 billion in 2009 (BMA, 2017). Recently, a government commissioned report found that during 2018 there were 5.6 million adults living in England receiving at least one opioid, and despite the historical increasing trend report a decrease in prescribing compared with 2017 (Taylor et al., 2019). The most commonly prescribed weak opioid in the UK is codeine (BMA, 2017; Torrance et al., 2018), and the most commonly prescribed strong opioid is morphine (BMA, 2017; Torrance et al., 2018; Zin et al., 2014). These prevalence reports have indicated specific increases in strong opioids, for example Zin *et al*. (2014) investigated a UK national database between 2000-2010 and found that oxycodone had the greatest increase in annual number of prescriptions (Zin et al., 2014). Likewise Torrance *et al*., (2018), reported strong opioid prescriptions more than doubling in Scotland between 2003-2012 (Torrance et al., 2018); and Foy *et al*., (2016) reported weaker opioids doubled and stronger opioids increased 6-fold during 2005-2015 (Foy et al., 2016). This reaffirms recent reports that codeine is the most commonly prescribed opioid and that a small but significant minority of CNCP patients are prescribed long-term high dose opioids (Taylor et al., 2019).

**High-dose long-term prescribing**

It is difficult to assign and compare specific harms to specific doses or opioids due to differences in the pharmacokinetic profile of individuals and the inconsistent definitions of high dose or long-term prescribing in the literature (Häuser et al., 2016). This is made more difficult due to the varying strength, dose and combination of opioids that are commonly prescribed (SIGN, 2019). The equianalgesic dose of most opioids is considered to produce similar analgesia, and so provides a measurement for standardised reporting, opioid conversions and comparisons are therefore made using the Morphine Equivalent Dose (MED) (INCB, 2019b; Nafziger & Barkin, 2018). In the UK there are various conversion calculators and tables (FPM, 2015b; Quinlan, 2020; Rae et al., 2020), although the lack of comprehensive data informing these calculations render the conversions as guidance only (FPM, 2015b; SIGN, 2019). As a result, studies will commonly source opioid conversions and standardise their reporting of opioid doses in the MED to better assign where potential harm might occur. For example, Von Korff et al. (2008) and Bedson et al. (2019) converted opioid doses into MED and correlated higher opioid doses starting from 50mg MED to an increased risk of fracture, heart attack or overdose (Bedson et al., 2019; Von Korff et al., 2008). Many patients are often prescribed doses or issued multiple prescriptions that accumulate daily doses higher than 50mg MED/day, this has resulted in some studies categorising risk of harm in doses of varying amounts. For example, Dunn *et al*. (2010) published evidence that CNCP patients taking more than three prescriptions amounting to daily doses above 100mg MED are 8.9% higher risk of overdose than those consuming doses between 1-20mg MED and 50-99mg MED (Dunn et al., 2010). Manchikanti *et al*. (2012) reiterates this, discussing findings from a Centre for Disease Control and Prevention (CDC) report highlighting that the risk of overdose doubles with opioid doses over 100mg MED/day (20% of overdoses attributed to doses <100mg compared to 40% of overdoses attributing to doses >100mg) (Manchikanti et al., 2010).

Additionally, as patients often remain on opioids for long periods of time, many studies investigating the effects of long-term opioid prescribing specify the definition of long-term. For example, Von Korff and colleagues investigated opioid prescribing trends across a 10-year period (1997-2006) with the aim of characterising long-term opioid therapy (Von Korff et al., 2008). In doing this, the authors identified different cohorts of patients who received

variations of opioid treatment. They stratified patients who received opioids longer than 90 days, with 10 or more prescriptions into long-term. Other studies have applied similar approaches regarding this 90-day and multiple prescription definition (Bedson et al., 2019), however varying definitions make comparison among prevalence studies difficult. Using this ballpoint of 90-days might be indicative of what constitutes long-term; however the duration patients remain on a long-term prescription often lasts for longer. For example, a UK national report highlighted that 540,000 patients continuously received an opioid prescription between 2015-2018 (Taylor et al., 2019). Von Korff et al., (2016) also reported that patients prescribed opioid treatment often took opioids daily or near daily for an average of 1000 days (2.5 years) (Von Korff et al., 2016); similarly a longitudinal study (of 3.4 years) involving 98,140 new opioid treated patients in the UK found patients continuously received prescriptions for median length of 237 days across the study period (Bedson et al., 2019). The concern with continued opioid prescribing is that evidence indicates the longer patients receive an opioid, the likelihood of higher dose and strength increases (and the less likely they are to decrease) (Foy et al., 2016). It is also likely that patients who are established on long-term opioid treatment often continue to take their medication irrespective of effective pain relief or improvement in function (Manchikanti et al., 2012). Although there are ways to help mitigate these effects (such as, decreasing the dose, change route of administration, opioid rotation or prescribing other medication to manage the side-effect (Harris, 2008), long-term opioid prescribing remains subject to much controversial debate as it may exacerbate adverse harm.

**Adverse effects of opioids**

Opioids are widely known to coincide with many side effects and an increasing range of serious adverse events. WHO define a side effect as an "unintended effect of a pharmaceutical product occurring at doses normally used by a patient which is related to the pharmacological properties of the drug", and a serious adverse event as "any event that is fatal, life-threatening, significantly disabling, requires prolong hospitalisation, causes congenital anomaly or requires intervention to prevent impairment or damage" (WHO, 2002). Generally, all opioids have similar effects and side-effects, but as discussed in the pharmacology section above, the pharmacokinetics and the inter-individual variability may cause these to differ. Commonly, clinical trial studies have shown that 50-80% of patients will

experience at least one side-effect (FPM, 2015b). Irrelevant of dose, frequency of use, route of administration and gender, some of the most common side effects of using opioids for any CNCP may include gastrointestinal problems (e.g., constipation, nausea or vomiting), tolerance (inducing hyperalgesia), dizziness, fatigue, hot flushes or itching, (Els et al., 2017; Harris, 2008). Some of these effects are likely to improve with continued use, undesirably constipation and tolerance are unlikely to diminish (FPM, 2015b). On the other hand, the incidence of serious adverse events (e.g., dependency, overdose, fractures, heart attack or death) have been correlated to long-term, dose dependent use (Bedson et al., 2019; Chou et al., 2015; Dunn et al., 2010). Moreover, the US have linked the levels of drug related deaths and overdoses to the increase of opioid prescribing and common prescribing practices involving high-dose long-term prescriptions (Bonnie et al., 2017). These conclusions come largely from a number of studies investigating opioid prescription overdose deaths and dispensing data (Boudreau et al., 2009; Paulozzi et al., 2011; Von Korff et al., 2008). For example, Paulozzi *et al*. (2011) identified opioid prescription related overdose deaths using ICD codes and comparing national opioid sale data. The results revealed that 73.8% of overdose deaths were attributed to opioid pain prescriptions which also coincided with an increase in sale data during 1999-2008 (Paulozzi et al., 2011). Furthermore, Boudreau *et al.* (2009) and Von Korff *et al.* (2008) both used health plan data for new and continuing opioid prescriptions issued between 1997 and 2005. Defining long-term opioid episodes as those prescribed longer than 90days and more than 10 prescriptions a year they identified a steady increase in long-term opioid prescribing (Boudreau et al., 2009) and that long-term high dose opioids (>55mg MED) accounted for more than half of the opioids dispensed between 1997-2006. In comparison, although the UK has also demonstrated increasing trends of opioid prescribing (particularly of high strength opioids and long-term episodes) the number of drug related deaths does not mirror those reported from the US (BMA, 2017). However, it is difficult to accurately measure the number of deaths attributed to prescription opioids in the UK as information on death certificates only identifies the presence of drugs at time of death and not whether death was caused by a specific substance (FPM, 2016). Links may be drawn using data from the Office of National Statistics (ONS) which indicate that over half of all drug related deaths since 2006 have involved an opioid (namely heroin or morphine), specifically in 2018 there were 2,208 deaths where an opioid was mentioned in the death certificate (ONS, 2019). Despite the limited data available from death certificates, there is some

indication that the number of deaths related to codeine doubled between 2005-2009 and before tramadol was controlled in 2014, it also was linked to a significant rise in deaths (1 death in 1996 compared to 208 in 2014) (BMA, 2017). There is arguably a link between increased opioid prescribing and serious adverse events (e.g., misuse, overdose and or deaths) that is ultimately contributing to the growing concern of the continued prescription of opioids for CNCP in primary care.

**Sociodemographic factors in prescribing**

Patient characteristics associated with long-term, high dose opioid prescriptions are commonly extracted from primary care prescription databases. This is likely because most opioid prescriptions are issued from primary care (Manchikanti et al., 2012; Torrance et al., 2018; Wu et al., 2010). Recent prevalence reports depicting prescribing trends of national and international opioid prescriptions have concurrently indicated that the majority of patients receiving long-term high dose opioid treatment are more likely to be: female, aged over 60 years, and living in areas of higher social deprivation (Bedson et al., 2019; Chen et al., 2019; Foy et al., 2016; Ruscitto et al., 2015; Torrance et al., 2018; Zin et al., 2014). Prescribing rates are considered 1.5 times higher for women than men (Taylor et al., 2019) and women were also more likely to be co-prescribed benzodiazepines (Torrance et al., 2018) potentially increasing their risk of harm (Foy et al., 2016). Moreover, prescribing trends across the UK specifically indicate a substantial geographical divide between the north and south of the country (Chen et al., 2019; Mordecai et al., 2018). Cross-sectional and observational study designs using national prescription databases identified that areas in the North of England (such as, Manchester and Newcastle) prescribed more opioids compared to areas in the south (such as London) and that most prescriptions were made in areas with higher social deprivation (Mordecai et al., 2018). Similar findings were previously reported by Torrance et al., (2018), who found that strong opioid prescribing was 3.5 times more likely in areas of high deprivation than the lowest deprived areas (Torrance et al., 2018). When these findings are considered alongside other reports linking increased risk of misuse or dependency among individuals with a history of substance misuse disorder or living in deprived rural communities (Häuser et al., 2016); and individuals (male, under the age of 50) least likely to lower their

established dose (Foy et al., 2016) it calls for careful consideration when initiating and maintaining opioid treatments among this cohort of patients.

This programme of research focuses on the use of opioids to treat CNCP patients in Liverpool. Liverpool is located in the North West of England and at risk of higher prescribing rates as described in the prevalence studies mentioned above. It would be of benefit to investigate practice level prescribing in this area and establish any high prescribing areas that might benefit from a targeted intervention. Although patients receiving high dose, long-term opioids may represent a small minority of all patients prescribed opioids, it is these individuals who are at higher risk of adverse harm and pose substantial societal and personal risk to themselves. Furthermore, these individuals may not be obtaining the goals set out in their initial treatment plan, new approaches such as opioid weaning must therefore be considered in order to establish the most appropriate course of treatment.

**The efficacy of opioid treatment**

While acute opioid administration causes analgesia, their efficacy for relieving CNCP pain is debatable (Häuser et al., 2016). The efficacy of opioid treatment is often determined by RCTs and open label trials, with more weight given to RCTs due to the comparison arm and controlled study parameters (Bialas et al., 2020). There are mixed reviews in the research literature debating the efficacy of using opioids long-term to treat symptoms of CNCP. For example, the frequently cited systematic review that includes 39 RCTs by Chou *et al.* (2015) found no studies evaluating the effect of opioids versus non-opioids or no opioid therapy long-term (>1 year) on outcomes of pain, function, or quality of life (Chou et al., 2015). Instead, Chou *et al*. (2015) assert that there is evidence for risk of harm and due to the short duration (6-16 weeks) of most study trials, long-term efficacy cannot be determined. The limitation of determining long-term efficacy has been criticised because most drug approvals from medicine agencies (e.g. European Medicines Agency and US Food and Drug Administration) require RCTs to demonstrate proof of efficacy of at least 12 weeks (Bialas et al., 2020; Häuser et al., 2016). Additionally, conducting RCTs beyond a year to determine long-term efficacy is arguably unethical, difficult to recruit and hindered by high drop-out rates (Häuser et al., 2016). There is evidence to suggest that opioids do not improve or even worsen

functionality and levels of pain in CNCP patients (Häuser et al., 2015). For example, a Danish national health survey that followed 2,354 CNCP participants out of 10,434 who completed the survey five years previously, found that rates of recovery were four times higher among those who didn't use opioids (Sjøgren et al., 2010). Comparing the two surveys (in 2000 and 2005) Sjøgren *et al* (2010) found that age, level of education, obesity, self-reported quality of life and physical job strain predicted chronic pain, so perhaps improvements in these variables should be considered in promoting pain recovery.

Conversely there is some indication from meta-analysis studies that opioids are more effective than placebo in reducing pain and improving function in some conditions *(Furlan et al*., 2006), and among patients who continue to take them for at least 6 months (Noble et al., 2008). For example, Furlan *et al*., (2006) identified 41 RCTs comparing opioids with placebo and other drugs and found that patients with nociceptive, neuropathic or fibromyalgia pain reported better improvements in pain and function with opioid treatment. Similarly, Noble *et al*., (2008) identified 17 studies (16 open label) indicating that oral opioids reduced pain scores by 63.4%, although this was among patients whose pain scores were already low at baseline. Both these studies discussed how study trials were generally too short, poorly designed and affected by high dropout rates (over 33%) due to adverse side effects or insufficient pain relief (Furlan et al., 2006; Noble et al., 2008). More recently, a systematic review and meta-analysis of 15 open label opioid trials of duration in excess of 26 weeks found that 31% of patients with lower back, osteoarthritis or neuropathic pain who completed a trial reported reduced pain and disability. However, these studies were also considered low quality and indicated that risk of dropout from trials increases with study duration (Bialas et al., 2020). Additionally, the RCT studies included in Häuser's (2016) review highlight some improvement in lowering symptoms of pain and increased function (between 37-50% of patients), involved using strong opioids such as fentanyl, buprenorphine, oxycodone or morphine (Häuser et al., 2016). Consistently, the papers discussed here acknowledge that such findings are not generalisable among all CNCP and that there remains potential risk of harm with long-term high dose opioid treatment. Equally, the authors also assert that opioids should not be entirely dismissed as they may be effective for some patients with some CNCP (Bialas et al., 2020; Furlan et al., 2006; Häuser et al., 2016). The same perception is held by the European Pain Federation (EFIC) who discussed the efficacy of using opioids for CNCP among selected and supervised patients

(O'Brien et al., 2017). Overall, the evidence determining long-term efficacy is weak and studies are restricted by trial duration, ethics, and participant retention. The risk of swinging the pendulum away from opioid prescribing may result in undertreated pain, and solely relying on non-opioid or non-pharmacological therapy may also not optimise treatment (Brennan & Gudin, 2020). It is advocated instead that perhaps there is need not to turn away from opioids but find a balance in the way they are used, by considering their indication, dosing, review and monitoring their effects (Bialas et al., 2020; Häuser et al., 2016; O'Brien et al., 2017).

**Attitudes and barriers to prescribing**

Whilst concerns over increased opioid prescribing takes precedence in more developed countries, there is an ongoing crisis at the other end of the prescribing spectrum. This is the limited or restricted patient access to opioid medication in some developing countries (e.g. Africa, Asia, Middle East, Latin and Central America) where legislation or pharmaceutical sale preferences control what pain relief is provided (Payne, 2013). Instilled beliefs, attitudes and knowledge around opioid prescribing (such as fear of dependency or diversion, cultural attitudes or onerous regulation) as well as economic restrictions have been identified as some of the impediments prohibiting the provision of opioid treatment (Berterame et al., 2016; INCB, 2019a). Barriers to opioid prescribing further limit the already narrow treatment options for people with chronic pain, whilst also sanctioning prosecution or investigation on HCPs for prescribing restricted (potentially beneficial) treatment. These approaches contradict public health recommendations set out by WHO (WHO, 2009) and the Universal Declaration of Human Rights (Assembly, 1948) and question the moral and ethical obligations to healthcare treatment. Arguments for restricting opioid prescribing in these countries may be fuelled by the fear mongering emerging from the publicised 'opioid epidemic' and lack of evidence on the efficacy of long-term opioid treatment.

Considering this, Els *et al.* (2017) argued how the perceived widespread panic of the opioid epidemic emerges from an accumulation of misperceptions, lack of alternative treatment and over reliance on low quality studies (Els et al., 2017). Specifically, Sullivan and Howe (2013) postulate that the actions of physicians (e.g. lack of knowledge or access to alternative

treatment), patients (e.g. priority of desirable outcomes, such as pain relief instead of improved function) and society (e.g. attitudes toward opioid therapy for CNCP) facilitate the crisis (Sullivan & Howe, 2013). Conversely, Häuser aruges that the ongoing crisis in the US is not comparable to events happening across Europe and as such different responses are needed (Häuser et al., 2016). Häuser also notes that over critical attidues toward long-term opioid therapy for CNCP may infulence 'opioid phobia' where the consequences will not benefit patients, physicans or society. For example, negative views and misunderstanding about opioids, risks patients who are being successfully treated with opioids having their medication reduced or discontinued, and those who might benefit from it, refused treatment (Brennan & Gudin, 2020). The current prescribing practices described in this section of the literature cannot continue (Sullivan, 2018; Vowles et al., 2015). Opioids remain an effective analgesic and do work well for some patients and some conditions to reduce or manage pain. Rieder (2010) discussed the ethical and moral responsibility associated with opioid prescribing, concluding that clinicians should not be anti-opioid as the alternative option risks creating another crisis, a pain crisis (Rieder, 2010).

## 2.5 Living with and treating Chronic Non-Cancer Pain

The therapeutic relationship between HCPs and patients is widely recognised to play an important role in the overall patient-HCP treatment experience. Yet despite common reports of having a well-developed therapeutic relationship, there are experiences of difficult or unsatisfying clinical visits, particularly in regard to opioid prescribing (Henry et al., 2018). This section will summarise literature investigating the lived experiences of patient-HCP interactions and how this relationship could be optimised to improve the management of opioid weaning in UK primary care settings.

Cross-national research carried out by the WHO established that chronic pain is among the most commonly reported health complaint in primary care (Gureje et al., 1998). This finding is supported by research investigating the epidemiology of chronic pain across Europe, which identified that patients with CNCP are five times more likely to consult a primary care HCP than patients without pain (Breivik et al., 2006; Von Korff et al., 1990). Furthermore, Henschke and colleagues recently (2015) published findings reviewing epidemiological studies of pain,

and identified that the number of CNCP patients seeking care from their HCP is increasing; 93% of CNCP patients sought health care visits compared to 84% of non CNCP patients during a six month period (Henschke et al., 2015). The combined impact of the increasing number of patients presenting with CNCP and the frequency with which they attend healthcare services is putting additional strain on the Health Care System (HCS). This not only affects individuals and how the HCS operates, but it also has a wider economic impact too. For example, the accumulated cost of loss of work, caring for those in pain and health care has been estimated to vary between $34.3 billion in Australia, to $560 billion in the US per year, compared with 3.0% of annual GDP across Europe (Henschke et al., 2015). The cost of opioid treatment in England for chronic pain (both CNCP and cancer) is estimated at around £300 million per annum (BMA, 2017). Evidence suggesting that opioid prescribing is influenced by patient expectation (SIGN, 2013), lack of consensus on appropriate use and difficulty stopping or reducing treatment (Lyapustina & Alexander, 2015), as well as emotionally charged consultations (McCrorie et al., 2015), highlights the importance of understanding these facets to establish ways to reduce prescribing. The interplay of what happens across the HCS contributes to how the patient-HCP therapeutic relationship develops and thus the subsequent behavioural response toward treatment. It is therefore important to understand the mechanisms that help support and maintain a well-defined patient-HCP relationship that both patients and HCP can confidently invest in.

To further investigate what is currently understood about the therapeutic relationship and how such findings can be used to deliver best practice of patient care, Toye *et al*., (2018, 2013) conducted a series of meta-ethnographies of HCP and CNCP patient treatment experiences (Toye et al., 2018; Toye et al., 2013). Toye et al., (2018) identified adversarial tensions that arise between HCPs and patients that are thought to occur due to the shift from a biomedical to a biopsychosocial model of healthcare. Toye explains how this shift involves moving from a solely objective (biological) approach of treating and managing chronic pain, to an embodied subjective approach (biopsychosocial) (Toye et al., 2018). This relates back to the discussion in section 2.3 supporting the concept that the psychosocial experiences of pain should not be overlooked and that there is more to managing pain than simply prescribing an opioid. This also implies that the advocated biopsychosocial model is perhaps not well

implemented into community care and rather treatment often defaults to the biomedical model instead.

**The patient experience**

Toye (2013) postulates that patient perceptions of struggling with pain and living with pain contribute to adversarial tensions that develop within themselves, and with their HCP (Toye et al., 2013). For example, Toye (2013) discusses how there is a cultural notion of finding a cure deep rooted in patients' experience of pain that is reflected in their need to prove legitimacy and affirm their own identity. This often involves aspects of navigating through the HCS, seeking trust and feeling believed by HCPs, which sometimes is symbolised by getting a referral or being issued an opioid prescription. The misdirected problem solving model refers to this experience as a 'perseverance loop' driven by patients' underlaying worry about their pain and motivation to find a solution (Eccleston & Crombez, 2007). The theory behind the model implies that until patients reframe their problem in order to identify new solutions, they will preserve with previous failed solutions, which might also explain increases of healthcare use. Simultaneously, treatment seeking has also been found to provoke paradoxical responses, whereby patients' need to continuously defend their request for and use of opioids is due to a perceived stigma attached to the use of these substances (Brooks et al., 2015; Ljungvall et al., 2020). For example, in one study patients discussed how stigmatising perceptions are often exacerbated by the media's negative depiction of opioids and have at some point felt stigmatised and judged rather than supported by their HCP (Brooks et al., 2015). Validating patients' pain and establishing a sense of trust has been found to improve treatment adherence and a way of better managing patients' emotions (Ljungvall et al., 2020). These characteristics may be established though means of affective (i.e., conveying empathy) or cognitive reassurance (i.e., educational explanations), and although good clinical practice recommends a combination of approaches, they have been found to vary in their effectiveness (Pincus et al., 2013). For example, Pincus et al., (2013) conducted a systematic review of 16 high quality studies investigating affective and cognitive reassurance in GP consultations and patient outcomes. The review concludes that affective reassurance was not as impactful as cognitive reassurance which was linked to, improvements in treatment satisfaction and pain symptoms and reduced patient concerns and healthcare use

(Pincus et al., 2013). Such findings are useful as it may help inform what approaches to consider in an intervention aimed at improving treatment engagement and positive patient outcomes.

**The HCP experience**

Later in work, Toye (2018) found that the need of finding a cure or diagnosis is reciprocated among HCPs, particularly where a more traditional biomedical model of healthcare is followed (Toye et al., 2018). This circle of reciprocation was reported in an earlier systematic review investigating the influence of patient and primary care HCP beliefs and expectations of the HCS (Parsons et al., 2007). Based on the findings of 15 studies, Parsons and colleagues (2007) identified that the continuous cycle of patients seeking a cure or treatment overlapped with HCPs obligation and moral dispute to "do something" i.e., to provide health care. The focus of this transactional behaviour was found to lead onto disappointment and conflict in efforts of trying to achieve positive treatment outcomes. For example, negative healthcare experiences have been further described in video analysis of patient-physician clinic visits in primary care and were conflict was exacerbated when patients report greater pain severity and requests for increased opioid medication were denied (Henry et al., 2018). The imbalance therefore of the patient-HCP expectation and pressure for the HCP to be seen to be doing something may manifest in itself in the search for diagnoses or cure and perhaps lead to treatment dissatisfaction and a precursor to mistrust. The findings reported by Parsons *et al*., (2007) compliment the work of Toye *et al*., (2018) who ultimately conclude that moving away from a biomedical model to embodying a biopsychosocial model of healthcare may help reduce the adversarial tensions that arise in the patient-HCP relationship.

Collectively, the experiences reported by HCPs and patients have highlighted the multi-faceted issues that occur when treating CNCP and indicate the need for a multi-dimensional approach to treatment, which fits with a biopsychosocial model. The descriptions of HCP and patient experiences suggest that for long-standing improvements healthcare must become more than just treating the physical symptoms of pain and should consider the psychological and sociological impact too (Brooks et al., 2015). In practice however, as the majority of CNCP is managed in primary care where resources, time and skills are limited it may be more resourceful to optimise patients' care with integrated services (BMA, 2017). The need for

better interdisciplinary collaboration between levels of care has been described in a series of 10 interviews with nurses in pain clinics across Norway (Gjesdal et al., 2019). Gjesdal et al. (2019) found that nurses in specialist care often experienced a breakdown in communication with primary care HCPs that resulted in unnecessary referrals and contributed to challenges of prioritising new and existing patients. The breakdown in communication between HCPs can in part be explained by the effect of dual advocacy which Toye *et al*. (2018) identify as a common adversarial tension that HCPs find difficult to balance (Toye et al., 2018). Due to the need to maintain a good therapeutic relationship (encompassing patient trust and agency) Toye describes how HCPs have to navigate a "give and take approach" between what the patient wants and what the HCS advises. Resultantly, concessions are sometimes made meaning the work of other HCPs is undone or not followed in order maintain a trusting relationship with a patient (Toye et al., 2018). These concessions may therefore feed into the HCP inconsistencies that patients often report in their treatment (McCrorie et al., 2015), as well as contribute to the increase of opioid prescribing due to the difficulty of finding a balance between doing something, managing patient expectations and professional rapport.

**Improving the patient and HCP experience**

Due to the losses described by patients as a result of their chronic pain (e.g., loss of self, quality of life, employment, control, independence (Brooks et al., 2015), instilling a sense of control (or agency) over their treatment is essential in order to improve their treatment experience (Ljungvall et al., 2020). However, to optimise this dynamic, Ljungvall *et al*. (2020) emphasise the need for close cooperation and trust between a patient and their HCP. The interplay of these behaviours (between patients and HCPs) has also identified a specific need for better collaboration between HCPs, who ideally should share a common goal and work in unison in order to improve efficacy of pain care (Gjesdal et al., 2019). Operating a more congruent network may help to reduce the contradictory advice that patients report receiving, which is often found to fuel their scepticism toward HCP advice (McCrorie et al., 2015). There are clearly a number of behavioural mechanisms that underpin the patient-HCP relationship including: cultural scepticism of pain (regarding the drive for diagnosis and cure), dual advocacy (representing the HCS and the patient), personal costs (e.g. experiencing a sense of loss), and the trust and negotiation of treatment (Toye et al., 2017). Thus, in order

to facilitate improvements in healthcare there is a clear need to target change in the beliefs and attitudes that influence these behaviours. Parsons *et al*. (2007) argues this point well, stating that changing patients' motivation is likely to be more difficult without also changing and improving HCPs skills in pain management (Parsons et al., 2007).

In efforts to mitigate potential adversarial tensions and facilitate improvements in CNCP healthcare, the literature has consistently identified the need for better education and improved communication among HCPs and patients. Improved knowledge on treating and managing CNCP involves understanding the therapeutic relationship and is considered a fundamental part of the biopsychosocial model of healthcare (Gjesdal et al., 2019; Toye et al., 2018). The need for improved communication was highlighted as a skill to help HCPs better negotiate treatment, as repeated consultations are likely to lead to inappropriate prescribing (Currow et al., 2016; Henry et al., 2018). As awareness is heightened on the increase of opioid prescribing and lack of evidence for their long-term efficacy (Bedson et al., 2019), HCPs have commonly expressed uncertainty and decreased confidence in prescribing opioids for CNCP (Currow et al., 2016; Johnson et al., 2013; McCrorie et al., 2015; Seamark et al., 2013). It is therefore, unsurprising to learn that in a Pan European survey involving ,309 primary care HCPs across 13 European countries identified CNCP as the most challenging health condition to treat, exacerbated by HCPs lack of confidence in using opioids and insufficient training and education on chronic pain (Johnson et al., 2013). Similar findings have also been reported in the US among 56 General Practitioners (GPs) which indicated that GPs were increasingly concerned about opioid misuse (89%) and did not feel sufficiently trained in managing opioid treatment (54%) (Jamison et al., 2014). McCrorie et al., (2015) draws on the complexity of this in regard to the transactional relationship that develops between GPs and patients during the journey of prescribing of opioids long-term. Linking discussions from focus groups with GPs, McCrorie (2015) describes how GPs have awareness of the limitations of opioids, however they often find it difficult to deliver coherent opioid management plans. This was further hindered by GPs lacking the capacity (due to e.g., time constraints) to review opioid medication, and was notably linked to escalating doses until either patient or GP recognised poor treatment outcomes (McCrorie et al., 2015). The need for more patient education around chronic pain management and specifically opioids has also been reported (Brooks et al., 2015). Conversely, Parsons *et al*. (2007) highlighted that although GPs understood the

importance of patient education there was often little time to deliver it during a consultation and patients' lack motivation to act on the information provided. Parsons also reported that patients found clinical information to be impractical, vague and unclear (Parsons et al., 2007). These findings highlight a need to review how HCPs communicate and educate their patients and establish ways to ensure patients comprehend the information being shared with them. The British Medical Association (BMA) published a report in 2017 recommending practices for the safer prescribing of opioids, which highlighted the need to improve adequate training within medical schools and for post graduates. The recommendation was supported by another report that identified only 4% of UK medical schools offer compulsory modules dedicated to pain, with an additional 11% offering optional modules (BMA, 2017). Although there have since been positive developments in improving the medical curriculum (IASP, 2017a) there are still many practicing HCPs in need of short courses to improve or update their competencies and skills for managing chronic pain.

Current UK guidelines advise that if patients are receiving no benefit in terms of pain reduction from their opioid treatment then discontinuation should be considered (FPM, 2020). However, advising patients that they have to stop their opioid treatment (in the absence of other alternatives) is a difficult challenge for HCPs to manage (Tong et al., 2019). Considering that most of chronic pain management is provided in primary care, the BMA recommends that HCPs are equipped with the skills, knowledge and provisions to adequately support patients at this stage of their treatment journey (BMA, 2017). Encompassing the key aspects of what makes a therapeutic relationship discussed here may help identify the direction that behavioural interventions should follow to aid opioid weaning in primary care. Practical approaches to facilitate behaviour change and ways to better support patients weaning off their opioid medication is discussed in depth in Chapter 5.

## 2.6 Chapter summary

Evidence from the literature presented here depicts the complexity of treating and managing CNCP. Over the centuries, theoretical constructs aiming to explain the physiological causes of pain have evolved, unveiling that the intricacy of pain is more than just treating a sensation (Melzack, 1969). The ascending and descending neural activity activated during pain indicates

that an evaluative process takes place etching meaning and reactive responses to sensory, affective, and cognitive cues (Melzack & Casey, 1968). It is these processes that are believed to attribute to the measure of pain that is subjectively felt and experienced and subsequently implicates the role of psychology. The emergence of this wider understanding of pain complemented the shift of healthcare in the 1970's from a purely biomedical approach to a biopsychosocial approach (Engel, 1977). The essence of which encourages HCPs to consider the biological, psychological, and sociological aspects of patient's health conditions, allowing for improved holistic healthcare. The assertion that pain could be managed by influencing motivational, affective, and cognitive factors, imply that psychological therapies such as CBT and ACT may be useful strategies in modulating sensory input and evaluation of pain (Keefe et al., 2004). The potential benefits including reduced pain intensity, improved physical functioning and quality of life of these therapies are advocated by NICE and are recommended to replace opioid therapy for CNCP (NICE, 2020c).

The strong analgesic properties of opioids meant that they have been heavily relied upon for managing CNCP over the years and until recently prescription use has been increasing across the globe (Chen et al., 2019; Häuser et al., 2016). It is now clear that opioids prescribed for CNCP may not be as effective or safe for managing long-term pain (Els et al., 2017). Patient's risk of harm is correlated with dose dependent use, exposing them to potential overdose, death, falls and factures as well as ineffective pain relief at higher MEDs, exacerbating their overall pain problem (Dunn et al., 2010). Specifically, the UK FPM assert that opioid doses above 120mg MED are ineffective and as there is an increased risk of harm recommend an opioid reduction or discontinuation in these patients (FPM, 2020). Furthermore, as of 2020 the UK NICE recommend that opioids are not prescribed at all in the management of chronic primary pain (NICE, 2020a). There is currently however no evidence based guidance to support HCPs in safely reducing patients' opioids whilst also effectively managing their pain (Eccleston et al., 2017). With almost 20% of the UK's population experiencing CNCP it imposes a magnitude of economic burden on society through indirect (e.g., unemployment) and direct (e.g., healthcare) costs (Goldberg & McGee, 2011). Although prevalence reports indicate only a small proportion of patients are in receipt of opioids above 120mg MED, there is a public health priority to reduce the risk of harm and optimise pain management in these patients (Jani et al., 2020). Reducing or discontinuing opioids will be challenging and require a change

in behaviour from both the patient and the HCP involved in their treatment. Such behaviours may be influenced by individual (e.g., knowledge, emotional distress, HCP-patient relationship), organisational (e.g., access and availability to alternative pain management), and environmental (e.g., social support) factors and should be considered when targeting change (Glanz & Bishop, 2010). First however, there is need to understand the prescribing practices at a local level and stratify patients at risk of harm, in turn this will help identify those in immediate need of opioid weaning. This need supports the basis for carrying out the first study for this programme of research, where an investigation of opioid prescribing across Liverpool CCG was carried out.

# Chapter 3: Investigating opioid prescribing in primary care General Practitioners (GPs) across Liverpool Clinical Commissioning Group (CCG)

## 3.1 Chapter overview

This chapter presents the findings of an audit of opioid prescribing data extracted from Liverpool CCG, and focuses only on CNCP patients, who received at least one opioid prescription between August 2016 and August 2018. The purpose of this study was to investigate two key aims:

1. To assess the extent of opioid prescribing among CNCP patients within the Liverpool CCG area.
2. To identify patients and GP surgeries who are receiving and prescribing opioids above the recommended daily threshold of 120mg Morphine Equivalent Dose (MED).

To address these aims, the objectives for this chapter were to:

1. Investigate the demographic profile of patients prescribed an opioid across the two-year period (August 2016-2018).
2. Identify which opioids are commonly prescribed, which opioids are linked to daily doses <120mg MED/day and those >120mg MED/day, and what duration patients receive them for.
3. Identify high prescribing GP practices and localities across Liverpool.

An introduction to the opioid prescribing phenomenon is discussed first, followed by the study methods, the results of the audit and finally a brief discussion of the findings. The results section is reported in two parts. The first part provides an overview of all opioid prescribing across Liverpool during 2016-2018. The second part specifically looks at opioid prescribing above 120mg MED/day during the same time period.

## 3.2 Introduction

Over the last 25 years, the US has seen exponential growth in opioid prescribing, resulting in them declaring an opioid crisis (Bonnie et al., 2017). Figuratively, the US prescribing frequencies and increase of serious adverse events (such as overdose and death), do not compare to those described across Europe and specifically the UK where the current study is based. For example, since the year 2000, opioid consumption in America has increased by 400% compared to 65% in the UK (Häuser et al., 2016), subsequently tripling the number of reported overdoses and deaths, as a result of the increase of opioid prescriptions (Bonnie et al., 2017). More recently, the International Narcotics Control Board (INCB) who estimate the world's consumption of narcotic drugs, identified North America as the world's highest consumer of opioids, having been responsible for consuming 79.7% of the world's morphine in 2017 (INCB, 2019a). The second largest consumer identified was Europe (32.6%) in which the UK ranks 10th highest out of 31 EU countries. In order to reduce the likelihood of serious adverse events, there is a need to investigate opioid prescribing among CNCP and identify where patients might be at risk of harm. The design of the UK health system provides a level of prevention from reaching escalated prescribing as reported in the US. The UK system uses a synchronicity of operations including strict control over licensing, scheduling and advertising as well as advocating a hierarchy of paternalism, whereby patients are prevented from seeing multiple practitioners for prescriptions, methods which are not as stringently employed in the US (McCall, 2020). Overall, the increase of opioid prescribing worldwide, has raised concern among medical professionals, specifically regarding the applicability of using opioids to treat CNCP long-term. As a result, there has been an increase in published literature highlighting regional, national, and international prescribing trends and debate on the efficacy of long-term opioid treatment for CNCP (Chou et al., 2015; Manchikanti et al., 2012; Mordecai et al., 2018).

Country-specific cross-sectional retrospective studies have been used to investigate national opioid prescribing practices. For example, Ruscitto and colleagues compared prescription dispensary data between 1995 and 2010 identifying an 18-fold increase in strong opioid prescriptions across Scotland (Ruscitto et al., 2015). Moreover, they report that tramadol was the main contributor to the surge in prescriptions. Since 2014, tramadol has been rescheduled

following advice from the Advisory Council on the Misuse of Drugs (ACMD, 2013), placing more stringent restrictions on prescribing. Ruscitto (2015) also reported that morphine, oxycodone, buprenorphine, and fentanyl increased 5-fold. In comparison, Foy *et al*., (2016) analysed primary care prescription data from the North of England during a seven year period (between 2005-2012) and found that weaker opioid prescriptions doubled, and strong opioids increased 6-fold (Foy et al., 2016). Foy also found an increase in number of patients stepping up to stronger opioids, a trend associated with increased polypharmacy, increased medical appointments and number of referrals to specialist services. Liverpool is located in the North West of England and is likely to fall among these prescribing practices. It would be worthy therefore, to investigate opioid prescribing at practice level in order to identify additional support that might be needed to help manage CNCP patients.

The increase of strong opioid prescribing has been the focus of much attention; Zin and colleagues (2014) specifically investigated UK prescribing trends by extracting data from a national prescribing database during 2000-2010 (Zin et al., 2014). Among the increase of strong opioid prescriptions, their analysis indicated that morphine was the most frequently prescribed opioid and contributor to higher daily doses (above 50mg MED). Oxycodone, buprenorphine, and fentanyl also increased over time, however oxycodone and to a lesser extent fentanyl were specifically linked to doses exceeding 200mg MED/day. Prior to 2014, Tramadol appeared to be the most commonly prescribed opioid in the UK in proportion to the total mg MED prescribed among seven other opioids during a 43-month study period (2010-2014) (Mordecai et al., 2018). Calculating the MED of opioids provides a common reference point to compare opioids with difference strengths and potencies. Using this method, Zin *et al*., (2014) were able to conclude that most CNCP patients (50.3%) prescribed an opioid received low daily MEDs (<50mg) compared to 26.2% who were prescribed doses between, 51-100mg, followed by 15.1% prescribed doses between 101-200mg and, 8.25% prescribed >200mg (Zin et al., 2014). Such findings indicate that only a small minority of patients are prescribed high dose opioids. This is evident in Torrance *et al*., (2018) study who found that despite the number of strong opioid prescriptions doubling, over 50% of people reporting severe pain were not prescribed an opioid analgesic (Torrance et al., 2018). In support of this, pooled prescribing data from a review of 42 studies estimated that around 31% of CNCP patients will be prescribed an opioid (Mathieson *et al.,* 2020a). Contrary to Zin

*et al* (2014), Mathieson *et al.,* (2020) also found that CNCP patients were more likely to be prescribed a strong opioid (18.4%) than a weak opioid (8.5%).

Patient characteristics taken from these prescription analyses commonly identify that over 60% of those prescribed an opioid medication are female, and often aged 65 or older (Chen et al., 2019; Foy et al., 2016; Zin et al., 2014). Chronic pain has been reported to be more common in females than in males, and is more prevalent in older populations (Breivik et al., 2006). The National Health Survey for England in 2017 provided context to this, highlighting that 57% of respondents with chronic pain complaints were female, 52% of whom were aged 55 or older (Digital, 2019). This is reiterated in a recent UK national review by Public Health England (PHE), who report that prescribing rate for prescription drugs were 1.5 times higher for women than men (Taylor et al., 2019). An increase of opioid prescriptions is also evident in areas with higher deprivation; data from the 2017 National Health Survey indicate more pain respondents (47%) came from the 4th and 5th lowest quintile of household income. Analysis of prescribing practices in primary care, have also found national differences in socioeconomic status (SES) and receipt of opioid medication. For example, Torrance et al., (2018) reported that patients living in more deprived areas of Scotland were 3.5 times more likely to receive a strong opioid than those in the least deprived areas (Torrance et al., 2018). Investigating this further, Mordecai and colleagues (2018) analysed data of eight commonly prescribed opioids across 209 CCGs in England during 2010-2014 (Mordecai et al., 2018). Using calculated MED, their research identified a north/south divide in opioid prescribing, specifically indicating a 31% increased variance in the number of opioid prescriptions issued in the north where there are higher localities of social deprivation (Mordecai et al., 2018). Similar disparities have also been reported by Chen *et al*., (2019); however, Chen used prescription dispensary data and calculated the total dose of opioids dispensed per 1000 registrants (Chen et al., 2019). Stratifying their data across four key areas in England (London, Birmingham, Manchester and Newcastle), Chen identified a significant association between increased prescriptions and areas of lower SES, namely Manchester and Birmingham. Their findings also linked increased prescribing to age (patients over the age of 65), gender (female), being a smoker, obesity, and reported depression. This concurs with local level prescription analysis by Foy *et al*., (2016) who found a strong association between increased opioid prescriptions and lower SES across Leeds and Bradford, cities in the North of England (Foy et

al., 2016). In addition to these studies, the recent report of English Indices of Deprivation (2019) highlight that Liverpool is among the top 5 local authorities with the highest number of deprived neighbourhoods in England (Government, 2019), indicating why it is important to investigate prescribing practices occurring around this area.

Opioid medication causes a range of mild side effects (e.g., nausea, constipation, vomiting) to serious adverse events (e.g., dependency, overdose, death) that pose a level of harm to patients, as well as a proportionate impact on society too. For example, the chronic pain that patients experience in addition to the negative effects from opioid treatment have been found to impact patients' quality of life, ability to function, ability to work, use of healthcare services and to a lesser extent the aberrant behaviours linked to the misuse of these drugs (Eriksen et al., 2006; Foy et al., 2016). It is important to note that the majority of patients prescribed opioids to treat their pain do not misuse them (Fishbain et al., 2008; Higgins et al., 2018; Vowles et al., 2015), though the pain reliving qualities and increased tolerance to opioids may lead to over reliance (Bonnie et al., 2017). Furthermore, patients who are prescribed high dose opioids for long periods of time are more likely to be at risk of falls, accidental poisoning, iron deficiency and anaemia (Bedson et al., 2019).

As a result of these unintended outcomes, long-term efficacy and safety of opioid treatment has been under much scrutiny. Reviews of opioid therapy studies have consistently reported poor quality evidence determining long-term effectiveness, whereas there is good quality evidence indicating dose-dependent risk of serious harm (Chou et al., 2015; Els et al., 2017). For example, a large scale cohort study of 98,140 CNCP patients in the UK receiving long-term opioid prescriptions were found at higher risk of adverse events such as major trauma, addiction or overdose; the risk of which increases as doses exceed 50mg MED/day (Bedson et al., 2019). This research is supported by earlier findings by Dunn *et al*., (2010) who established a significant increased risk of overdose among patients receiving long-term opioid prescriptions over 50mg MED day; patients' risk of harm however more than doubled when daily MEDs exceeded 100mg or more (3.7% compared to 8.9% respectively) (Dunn *et al*., 2010). Exposure to these potential risks are concerning particularly when there is evidence to suggest that the longer patients are prescribed an opioid, the greater the likelihood of it increasing in strength or dose (Foy et al., 2016). Contrary to this, Häuser *et al*., (2016) argue

that there is some evidence of short-term and long-term efficacy of opioid treatment. The studies included in Häuser's review that warrant this conclusion highlight improvements where strong opioids such as fentanyl, oxycodone, morphine or buprenorphine were used but also report high participant withdrawal due to adverse effects, lack of efficacy or no change in pain intensity (Häuser et al., 2016). Whilst new clinical guidelines for the treatment of chronic pain are being developed in the UK (NICE, 2017a), other UK professional resources reiterate that there are no beneficial outcomes for patients prescribed opioids beyond 120mg MED/day (FPM, 2020). Collectively, this provides a rationale for why intervention designs should focus on discontinuing or weaning patients from these harmful high doses and the importance of identifying patients before they exceed the daily threshold in order to prevent harm occurring.

HCPs are faced with the double-edged sword of both reducing the burden of pain whilst limiting the extent of potential harmful effects of opioid treatment. The trend of opioid prescribing evident from the US has prompted other countries across the globe to investigate their own prescribing practices and encouraged countries to learn from the severity of consequences that have emerged. The evidence presented here highlights the need to conduct studies at a local level in order to identify, review and intervene where patients are receiving opioid prescriptions that exceed the advised prescribing guidelines putting them at risk of potential harm. Simultaneously, investigating local prescribing practices may also identify at risk patients who could be on a trajectory of developing opioid problems arising from their treatment. Furthermore, given that high rates of opioid prescribing are strongly associated with areas of higher deprivation, and as Liverpool is identified as one of the most deprived areas in England, it gives reason to investigate prescribing practices here.

## 3.3 Methods

### Design, setting and participants

A retrospective observational research design was implemented to establish an understanding of patient and practice level opioid prescribing for CNCP patients across LCCG. Conducting an audit of local opioid prescribing was considered the most practical and pragmatic way of establishing relevant and up to date information. A quantitative statistical analysis of prescribing data was performed.

Ethical approval for this study was granted by LJMU research ethics committee (ref number: 18/NSP/050) (appendix 1). Liverpool CCG was approached and invited to collaborate on the audit (appendix 2), mutual interest was established and a data sharing agreement in accordance with the Data Protection Act 2018 was drawn up between Liverpool CCG and LJMU. This agreement outlined the extraction parameters, the extraction process and data management (appendix 3). The inclusion criteria for the audit requested data on patients who were aged over 18 years, with CNCP and in receipt of any opioid prescription between August 2016 and August 2018. The exclusion criteria excluded patients with a history of drug or alcohol dependence, and those being prescribed opioids to manage cancer pain.

Anonymity

Patients' identities were protected by assigning a unique 32-character anonymised identifier generated in EMIS during the extraction process. GP practices were identified by their unique NHS GP practice code.

Patient case studies

While average prescribing levels provide some insight into the overall pattern in Liverpool CCG, individual patient case studies highlight the complex nature of reporting opioid prescribing. To provide a general overview of prescribing within "safe" limits and prescribing over the "safe" limit (i.e., >120mg) a range of individual patient case studies were selected to highlight the patterns of prescribing in individuals receiving total daily MEDs of <120mg, =120mg and >120mg. To do this the database was filtered for current prescriptions only. Using the variable that reported patients total daily MED, another variable was created

grouping patients into >120mg, =120mg and <120mg. The random case selection function in SPSS was then used to identify random cases from each of the identified groups. As most patients fell into the <120mg group, this cohort was split into two further groups identifying the lowest and highest MED so that an accurate random selection could be made that would be representative of usual prescribing.

**Materials**

The following data was extracted from patient records: anonymised ID, age, ethnic origin, gender, GP practice code, GP partial postcode, name of opioid, dose and quantity prescribed, date prescription was added to patient record, most recent issue date, course status (past or current) and reported problem linked to the opioid prescription. Liverpool CCG acted as the gatekeeper within the data sharing process and obtained verbal consent from GP practices to share patient information. Sixty-two of the 88 GP practices located across the area agreed to share patient data. Using Egton Medical Information Systems (EMIS), the extract report was uploaded onto EMIS web, which provided the facility to select and extract the data requested from the system and then download the data into a excel spreadsheet. Once the data was extracted, the spreadsheet was transferred to a secure NHS.net email address belonging to one of the supervisory team (BF), where the researchers were able to download and save the data onto a secure network.

**Procedure**

The data was initially pre-processed using Microsoft excel. The raw dataset contained 100,003 prescriptions for 32,016 patients. After checking for missing data (no prescription data provided), duplicate cases, linked cancer pain or history of dependence (alcohol or drugs), and prescriptions extracted outside of the parameter dates, 93,236 prescriptions written for 30,474 patients remained.

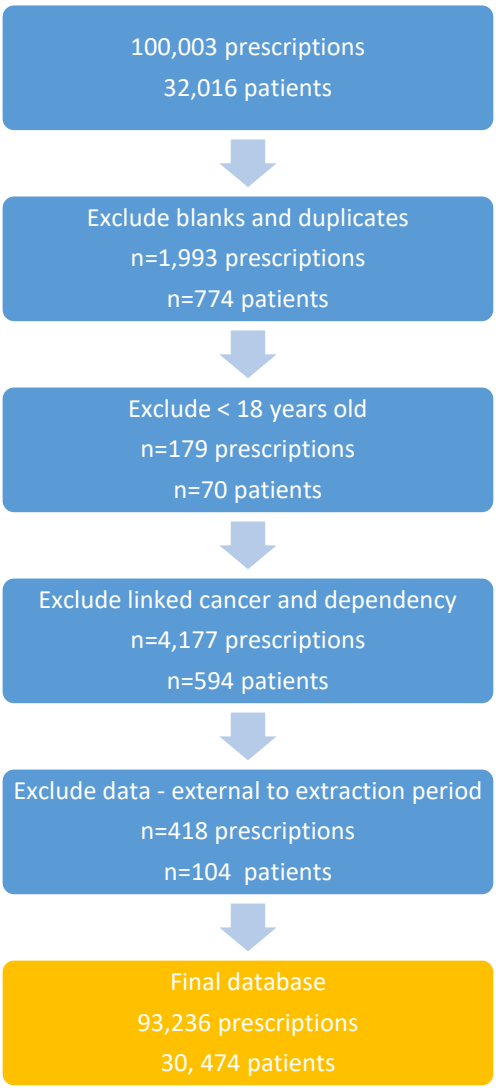


**Figure 3:1 Stages of processing and filtering prescription data.**

There was inconsistency among GP data recording for several variables including, ethnicity, linked problems, drug names and dose instructions. To have the dataset in a coherent and consistent format that would allow for a more accurate data analysis, each of these variables were re-coded. The ethnicity field was re-coded to categorise those recognised by the official UK and Wales list of 18 ethnicity groups (UKGovernment, 2011) and are listed in table 2 of the results section below. There was a great deal of heterogeneity in the coding of linked problems, providing reason why an opioid prescription was issued with over 60,000 distinct reported problems, making it difficult to reduce these into specific categories to allow for accurate analysis. As a result, a new variable was created, comprised of 78 broad categories.

Categories were created by grouping together similar conditions and conferring with a consultant anaesthetist (BF) to develop typologies. The most common linked problem for which opioids were prescribed was for musculoskeletal pain (n=16,137) specifically back pain (n=10,974) and arthritis (n=7,154). Although back pain is considered one of the most common musculoskeletal complaints, it was counted separately to provide some insight into the frequency of opioids often prescribed for this condition. For a full list of the 78 categories and frequency of linked prescriptions see appendix 4. Additionally, see appendix 5 for a full list of linked problems assigned to each category. Upon further investigation of the linked problems, it was evident that many GPs may not accurately report reasons for prescribing an opioid or the reason provided may be linked to another problem that patients present to clinic with, rendering these somewhat unreliable. Examples of these linked problems include consultation matters, requested/reviewed medication, memory or issues not medically related (such as signatory of statutory forms).

Some opioid prescriptions were reported by their brand names (examples given in brackets below), therefore all prescriptions were cross-referenced with the British National Formulary (BNF) and re-coded according to their active opioid ingredient. This resulted in 12 groups including: oxycodone (e.g. Longtec), tramadol (e.g. Tramquel), matazinol (no reported brand), methadone (e.g. Physeptone), morphine (e.g. Zormorph), tapentadol (e.g. Palexia), pethidine (no reported brand), fentanyl (e.g. Fencino), codeine (e.g. Co-Codamol), buprenorphine (e.g. Butec), dihydrocodeine (e.g. DHCcontinus) and hydromorphine (no reported brand) (see appendix 6 for full list of medication brands prescribed). A number of opioids were excluded as they were identified to be commonly indicated for cancer or drug dependence, these were Dextropropoxphene, Diamorphine, Alfentanil, Coproxomol, Galenphol, Oxylan and Pavacol. Additionally, prescription dose instructions were also re-coded in order to have a more consistent way of calculating patients' daily dose per prescription. Where this information was missing, the maximum advised dose instructions provided by the BNF was used.

Calculating Morphine Equivalent Doses (MED)

A potential Defined Daily Dose (DDD) for each prescription was calculated using the drug name and administration instructions. As mentioned above, where this information was missing the maximum daily dose advised by the BNF was used to compute the DDD. Once this

was calculated patients' DDDs were computed into a potential MED. Calculations for MEDs varied depending on the type of opioid prescribed and were advised by a Consultant Anaesthetist with extensive experience in opioid prescribing for CNCP (BF) (see appendix 7). The calculations needed to account for multiple daily opioid prescriptions that patients may take. As a result, once MEDs were calculated for every prescription a new variable was created to calculate patient's combined daily MED (MED sum). The purpose of this variable was to establish one potential total of MED for each patient, specifically for those with more than one prescription that may contributed to their daily morphine intake. However, it is clear that not all prescribed medication may be taken simultaneously, with patients choosing from a range of their prescribed medication according to the current severity of their pain. The MED sum variable was used to create an average MED variable, by dividing the MED sum by the total number of prescriptions for that patient, thus accounting for the multiple prescriptions that patients may receive. Table 1 below highlights some of the key parameters used in this section of the report.

| Variable Name | Explanation |
|---|---|
| Defined Daily Dose (DDD) | Patients' maximum daily dose from each of their prescriptions. |
| Morphine Equivalent Dose (MED) | Patients' DDD converted into a morphine equivalent dose. |
| MED sum | Patients' total daily MED, the sum of MED for all current prescriptions. |
| MED average | An average of total daily MED (MED sum/number of prescriptions). |

**Table 1. Parameters for calculating MED**

**Analysis**

Section 1 – overview of all prescriptions

The processed Excel spreadsheet was imported into an IBM Statistical Package for the Social Sciences (SPSS) v26 file to conduct the analysis. To begin with, descriptive analysis was used to provide an overview of the whole prescription database. This included establishing the total number of patients and number of prescriptions issued and patient demographic data (sex, age and ethnicity). As noted above, patients may receive more than one opioid; initially each individual prescription was displayed on a row in the dataset, and patient ID was then

used to aggregate data for each patient and provide a single transposed row for a single patient. The data was tested for normality using the Kolmorogov-Smirnoff test. This was reported for the following variables: age (KS= .039 (df, 30474), p= .001), duration of opioid episodes (KS= .243, (df, 56402), p= .001), number of prescriptions (KS= .265 (df, 30474), p= .001), number of prescriptions >120mg (KS=.244, (df, 1069), p= .001), duration of opioid episode for all prescriptions (KS= .243, (df 56401), p= .001), duration of opioid episodes for doses >120mg (KS= .170 (df, 2692), p=.001), daily doses >120mg (KS= .273, (df 1069), p= .001). The distribution for all variables was found to be significantly different from normal, and the mode was chosen as a measure of central tendency.

To identify which GP practice prescribed the highest daily opioid doses per patient, the proportion of patients prescribed an opioid, and multiple opioids were calculated separately in relation to the total number of patients at each practice. Using unique codes linked to each GP practice these proportions were calculated using the most recent data of number of registered patients at each GP practice (Healthwatch, 2018; NHS, 2018, 2019). The data extracted from these sources was also used to develop two new variables distinguishing the neighbourhood and locality of each GP practice. Using these new variables and data for currently active prescriptions, the rate of prescribing was identified and reported in proportion to total registered patients within each locality and neighbourhood.

Duration of prescription was calculated by subtracting the number of days since an opioid was first added to a patient's record from the number of days since the most recent issue. A number of prescriptions had a duration of zero days, indicating that they had only been prescribed once (n=36,839) or less than zero (n=43) indicating an anomaly in reporting to EMIS; these cases were excluded from this part of the analysis. A frequency cross-tabulation was created to establish the number of prescriptions for each of the 12 opioids. Separately, the number of times each opioid was prescribed is reported as a percentage of the total number of included prescriptions (N=93, 326), alongside the total number of patients. Additionally, the duration of prescription for each opioid was analysed; minimum, maximum, and modal durations are reported as the data was not normally distributed.

Section 2 – prescriptions above 120mg MED and average does

Analysis for section 2 followed the same format as section 1 but focussed on prescriptions above 120mg MED/day. This included analysing any prescription in combination or standalone that exceeded 120mg MED/day and separately where MED average doses also exceeded 120mg/MED. As the data extracted from patient records spanned two years, there were a number of past (no longer being issued) and current (actively receiving) prescriptions, these were identified and coded accordingly. The data analysed in this section was filtered for current prescriptions only as it allowed us to identify and calculate the daily doses patients potentially currently take.

A descriptive analysis of patient and GP data was conducted to provide an overview of GP prescribing (by GP practice), types of opioids prescribed, number of patients and patient demographic linked to prescriptions exceeding 120mg/MED day. Following this, using the MED converted from the prescribed DDD, the data was interrogated for standalone (singular) prescriptions exceeding the 120mg/MED threshold. The opioids linked to these criteria were reported and analysed further to identify the frequency which they were prescribed in combination with other opioids. Additionally, patients who received prescriptions (either standalone or in combination) above the daily threshold were identified and the opioids contributing to their total dose selected for analysis. Similar to section one, a cross tabulation was created to establish how many patients had high daily doses, and which opioids were contributed to their intake. The frequency of opioids found is reported as a percentage of the total number of prescriptions associated with doses exceeding 120mg/MED (N=2,999). This procedure was repeated for patients who were identified as receiving prescriptions with a total average daily dose above 120mg MED. The frequency of opioids found is also reported as a percentage of the total number of prescriptions associated with this dose (N=601). Lastly, to identify where these high doses are being prescribed and the number of patients in receipt of them, we analysed the locality and neighbourhood of GP practices (using their GP organisation code) linked to prescribing average daily doses above 120mg/MED.

## 3.4 Results Section 1: Overview of all prescriptions from August 2016-August 2018

A total of 93,236 opioid prescriptions were issued to 30,474 patients in primary care between 2016-2018. The highest proportion of patients (40%) received only 1 prescription during this time, however the number of prescriptions ranged from 1 to 82. Females represented 61% of this patient population (n=18,580) and on average were slightly older than males (61 years ± 16.10 and 60 ± 14.77 years respectively). Overall, patient ages ranged from 18 to 103 years old for females and from 18 to 102 years old for males. Most of the patients identified as being from a white ethnic origin (78.58%), in comparison the lowest number of patients identified as being from mixed/multiple ethic groups (0.81%). See table 2 below for full breakdown. This was not representative of the whole patient sample as a proportion of patients either preferred not to disclose their ethnicity (3.89%, reported as 'not stated' on their patient record) or the patient data was missing from the extracted data file (12.40%).

| **Ethnicity** | **N (%)** |
|---|---|
| White | 23,953 (78.60%) |
| British | 23,125 (75.88%) |
| Irish | 246 (0.81%) |
| Gypsy or Irish Traveller | 10 (0.03%) |
| Any other White Background | 572 (1.87%) |
| | |
| Mixed/Multiple ethnic groups | 245 (0.81%) |
| White and Black Caribbean | 48 (0.16%) |
| White and Black African | 59 (0.20%) |
| White and Asian | 14 (0.05%) |
| Any other Mixed/ Multiple ethnic background | 124 (0.41%) |
| | |
| Asian/ Asian British | 487 (1.60%) |
| Indian | 61 (0.20%) |
| Pakistani | 59 (0.19%) |
| Bangladeshi | 30 (0.10%) |
| Chinese | 127 (0.42%) |
| Any other Asian background | 210 (0.69%) |
| | |
| Black/ African/ Caribbean/ Black British | 446 (1.46%) |
| African | 240 (0.78%) |
| Caribbean | 51 (0.17%) |

| | |
|---|---|
| Any other black/African/Caribbean background | 155 (0.51%) |
| | |
| Other ethnic group | 386 (1.27%) |
| Arab | 90 (0.30%) |
| Any other ethnic group | 296 (0.97%) |
| | |
| Not disclosed | 1,183 (3.88%) |
| Not reported | 3,774 (12.38%) |

**Table 2. Patient demographic breakdown by Ethnicity**

Table 3 describes the number of prescriptions issued per surgery, the number of patients prescribed an opioid per surgery, and the proportion of each based on the total number of patients registered at each practise. The number of prescriptions issued ranged from 207 to 4,510, but proportions per patient varied greatly between practises. For example, the table highlights that although GP surgery GPC01 and GPC02 issued different numbers of prescriptions (3,169 and 1,453 respectively); they prescribed the highest number of opioids in proportion to their overall registered patient population. Furthermore, GP surgery GPC03 also appears to issue a high proportion of opioid prescriptions (0.44%), enough to prescribe 50% of all patients an opioid, proportionately however they prescribed to fewer patients (0.10%). There were other outliers identified in the prescribing practices: GP surgery GPC62 had the highest number of registered patients (N=44,226) yet the lowest proportion of opioid prescriptions (0.05). This is likely to reflect the patient demographic in that area, which includes a large university, and may indicate that a many of the registered patients are students. Perhaps more comparable therefore are the number of prescriptions issued between the lowest prescribers: GP surgery GPC60 and GPC61 and the highest prescribers GPC01 and GPC02. Despite having a similar number of registered patients, the bottom two surgeries prescribe opioids to fewer patients; n=127 and n=174 compared with the highest prescribing surgeries, n=907 and n=443 respectively.

| GP practice code | Number of registered patients at GP surgery[2] | Number of patients prescribed an opioid | Total number of opioid prescriptions issued | Proportion of total registered patients prescribed an opioid | Proportion of opioid prescriptions per patients registered |
|---|---|---|---|---|---|
| GPC01 | 6,680 | 907 | 3,169 | 0.14 | 0.47 |
| GPC02 | 3,271 | 443 | 1,453 | 0.14 | 0.44 |
| GPC 03 | 5,112 | 487 | 2,255 | 0.10 | 0.44 |
| GPC 04 | 3,807 | 428 | 1,403 | 0.11 | 0.37 |
| GPC 05 | 13,029 | 1,343 | 4,510 | 0.10 | 0.35 |
| GPC 06 | 3,452 | 441 | 1,144 | 0.13 | 0.33 |
| GPC 07 | 7,734 | 912 | 2,533 | 0.12 | 0.33 |
| GPC 08 | 3,344 | 421 | 1,083 | 0.13 | 0.32 |
| GPC 09 | 5,599 | 653 | 1,783 | 0.12 | 0.32 |
| GPC 10 | 3,720 | 304 | 1,177 | 0.08 | 0.32 |
| GPC 11 | 6,587 | 694 | 2,038 | 0.11 | 0.31 |
| GPC 12 | 9,998 | 909 | 3,051 | 0.09 | 0.31 |
| GPC 13 | 2,394 | 216 | 706 | 0.09 | 0.29 |
| GPC 14 | 4,103 | 412 | 1,196 | 0.10 | 0.29 |
| GPC 15 | 2,817 | 293 | 816 | 0.10 | 0.29 |
| GPC 16 | 7,921 | 793 | 2,284 | 0.10 | 0.29 |
| GPC 17 | 10,907 | 760 | 3,111 | 0.07 | 0.29 |
| GPC 18 | 11,256 | 1,258 | 3,146 | 0.11 | 0.28 |
| GPC 19 | 7,397 | 786 | 2,063 | 0.11 | 0.28 |
| GPC 20 | 4,900 | 501 | 1,351 | 0.10 | 0.28 |
| GPC 21 | 3,395 | 223 | 927 | 0.07 | 0.27 |
| GPC 22 | 2,022 | 145 | 550 | 0.07 | 0.27 |
| GPC 23 | 6,138 | 551 | 1,657 | 0.09 | 0.27 |
| GPC 24 | 4,594 | 421 | 1,240 | 0.09 | 0.27 |
| GPC 25 | 2,643 | 240 | 703 | 0.09 | 0.27 |
| GPC 26 | 2,518 | 220 | 660 | 0.09 | 0.26 |
| GPC 27 | 3,221 | 322 | 844 | 0.10 | 0.26 |
| GPC 28 | 8,537 | 754 | 2,224 | 0.09 | 0.26 |
| GPC 29 | 8,366 | 700 | 2,162 | 0.08 | 0.26 |
| GPC 30 | 2,535 | 185 | 644 | 0.07 | 0.25 |
| GPC 31 | 2,540 | 234 | 643 | 0.09 | 0.25 |
| GPC 32 | 5,644 | 434 | 1,418 | 0.08 | 0.25 |
| GPC 33 | 9,222 | 793 | 2,311 | 0.09 | 0.25 |
| GPC 34 | 16,086 | 1,199 | 4,000 | 0.07 | 0.25 |
| GPC 35 | 4,401 | 417 | 1,082 | 0.09 | 0.25 |
| GPC 36 | 7,009 | 635 | 1,715 | 0.09 | 0.24 |
| GPC 37 | 3,668 | 366 | 893 | 0.10 | 0.24 |

[2] This data was extracted in January 2019 from Liverpool CCG Primary Care Network List 2019, Liverpool CCG Neighbourhood Pack Summer 2018 and from Health Watch Liverpool GP report 2018.

| GP practice code | Number of registered patients at GP surgery[3] | Number of patients prescribed an opioid | Total number of opioid prescriptions issued | Proportion of total registered patients prescribed an opioid | Proportion of opioid prescriptions per patients registered |
|---|---|---|---|---|---|
| GPC 38 | 4,297 | 255 | 1,042 | 0.06 | 0.24 |
| GPC 39 | 8,955 | 614 | 2,129 | 0.07 | 0.24 |
| GPC 40 | 6,744 | 418 | 1,515 | 0.06 | 0.22 |
| GPC 41 | 5,426 | 319 | 1,183 | 0.06 | 0.22 |
| GPC 42 | 9,583 | 727 | 2,076 | 0.08 | 0.22 |
| GPC 43 | 2,511 | 177 | 530 | 0.07 | 0.21 |
| GPC 44 | 12,908 | 980 | 2,702 | 0.08 | 0.21 |
| GPC 45 | 8,160 | 689 | 1,706 | 0.08 | 0.21 |
| GPC 46 | 6,812 | 440 | 1,374 | 0.06 | 0.20 |
| GPC 47 | 2,545 | 207 | 510 | 0.08 | 0.20 |
| GPC 48 | 3,526 | 228 | 681 | 0.06 | 0.19 |
| GPC 49 | 5,241 | 306 | 1,001 | 0.06 | 0.19 |
| GPC 50 | 3,699 | 244 | 675 | 0.07 | 0.18 |
| GPC 51 | 9,237 | 601 | 1,675 | 0.07 | 0.18 |
| GPC 52 | 8,550 | 473 | 1,478 | 0.06 | 0.17 |
| GPC 53 | 8,175 | 496 | 1,338 | 0.06 | 0.16 |
| GPC 54 | 8,937 | 589 | 1,420 | 0.07 | 0.16 |
| GPC 55 | 7,062 | 290 | 1,084 | 0.04 | 0.15 |
| GPC 56 | 1,480 | 82 | 207 | 0.06 | 0.14 |
| GPC 57 | 5,276 | 175 | 605 | 0.03 | 0.11 |
| GPC 58 | 6,443 | 244 | 718 | 0.04 | 0.11 |
| GPC 59 | 7,544 | 248 | 799 | 0.03 | 0.11 |
| GPC 60 | 3,228 | 127 | 292 | 0.04 | 0.09 |
| GPC 61 | 6,598 | 174 | 519 | 0.03 | 0.08 |
| GPC 62 | 44,226 | 571 | 2,032 | 0.01 | 0.05 |

**Table 3. Proportions of opioid prescriptions issued by GP surgeries**

Table 4 below highlights the prescribing patterns within specific localities of GP practices across Liverpool CCG. There is a total of 413,730 patients registered at the GP practices included in this data set, of these 7.39% have been prescribed an opioid and of those a fifth (21%) have been issued more than one opioid. The highest rate of opioid prescribing as a percentage of practice population (cross referencing with table 3) was found in the North Locality with GP practice GPC01 at 0.47% (Walton neighbourhood). In South and Central Liverpool, the highest prescribing rates were found with GP practice GPC GPC04 at 0.37%

[3] This data was extracted in January 2019 from Liverpool CCG Primary Care Network List 2019, Liverpool CCG Neighbourhood Pack Summer 2018 and from Health Watch Liverpool GP report 2018.

(Speke and Belle Vale neighbourhood) and with GP practice GPC03 at 0.44% (Riverside neighbourhood), respectively. The lowest rate of opioid prescribing in relation to the proportion of registered patients was identified in the City Centre (Central neighbourhood) by GP practice GPC62 who prescribed 0.05%, which could be explained by the high student population residing in this area.

| | Locality | % no. of patients in a practice on an opioid (from practice population)[4] | % no. of patients on >1 opioid (from practice population) | Of the patients currently prescribed an opioid what % are prescribed >1 |
|---|---|---|---|---|
| Citywide | - | 7% | 1.5% | 21% |
| | | | | |
| North | - | 9% | 1.8% | 20% |
| Central | - | 5% | 1.2% | 23% |
| South | - | 7% | 1.4% | 21% |
| **Per neighbourhood:** | | | | |
| Aintree | North | 8% | 1.8% | 22% |
| Croxteth & Norris Green | North | 8% | 1.9% | 23% |
| Everton & Anfield | North | 10% | 1.6% | 16% |
| Walton | North | 11% | 2.3% | 22% |
| West Derby | North | 8% | 1.6% | 19% |
| | | | | |
| City Centre | Central | 3% | .07% | 21% |
| Kensington | Central | 9% | 1.9% | 22% |
| Picton | Central | 8% | 2% | 27% |
| Riverside | Central | 9% | 2.4% | 27% |
| | | | | |
| Speke & Belle Vale | South | 8% | 1.4% | 19% |
| WAGGA | South | 8% | 1.8% | 21% |
| Childwall & Wavertree | South | 5% | 1.1% | 21% |

**Table 4. Percentage of patients 'currently' prescribed an opioid across localities and neighbourhoods during 2016-2018.**

[4] Percentages are calculated using the total number of patients prescribed any opioid divided by the total number of registered patients in that GP locality. Percentage of patients on more than one opioid is calculated in the same manner. Patients prescribed more than one opioid as a percentage of those receiving any opioid is calculated as such: (patients prescribed >1 opioid/patients prescribed 1 opioid)*100.

Table 5 reports the frequencies that each opioid was prescribed in each GP practice. This table should be reviewed in conjunction with table 3 (the proportion of prescriptions) to help identify which opioids are frequently prescribed within each GP practice. To enable easy comparisons with the data in table 3, the rows highlighted in table 5 below identify the top 3 GP practices who prescribed the most opioids (see the total column). When compared with table 3, once the number of prescriptions were considered with the proportion of patients registered, the prescribing outlook changes. For example, only one of the three highest prescribing GP practices highlighted in table 3 (that identifies the proportion of opioids prescribed per registered patient), is also identified in table 5 as prescribing the highest number of opioids (GPC01). Table 3 highlighted that GP practice GPC01 was proportionally one of the highest prescribing practices, however it is clear from table 5 that they prescribe fewer high strength opioids in comparison to other GP practices. The totals for each of these opioids also informs the percentages reported in table 6.

| GP practice code/ Drug | Oxycodone | Tramadol | Matazinol | Methadone | Morphine | Tapentadol | Pethidine | Fentanyl | Codeine | Buprenorphine | Dihydrocodeine | Hydromorphone | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| GPC09 | 29 | 368 | 0 | 3 | 129 | 4 | 0 | 7 | 1,159 | 26 | 58 | 0 | 1,783 |
| GPC14 | 42 | 234 | 0 | 0 | 104 | 1 | 0 | 2 | 727 | 59 | 27 | 0 | 1,196 |
| GPC10 | 66 | 177 | 0 | 3 | 108 | 1 | 0 | 19 | 681 | 43 | 79 | 0 | 1,177 |
| GPC48 | 3 | 120 | 0 | 0 | 26 | 0 | 0 | 1 | 492 | 26 | 13 | 0 | 681 |
| GPC53 | 48 | 220 | 4 | 0 | 113 | 2 | 3 | 29 | 773 | 85 | 61 | 0 | 1,338 |
| GPC19 | 95 | 531 | 0 | 8 | 293 | 17 | 0 | 54 | 1,819 | 222 | 107 | 0 | 3,146 |
| GPC05 | 216 | 740 | 17 | 38 | 636 | 13 | 0 | 22 | 2,252 | 221 | 355 | 0 | 4,510 |
| GPC33 | 45 | 666 | 0 | 1 | 108 | 14 | 0 | 9 | 1,292 | 148 | 28 | 0 | 2,311 |
| GPC44 | 82 | 355 | 1 | 21 | 273 | 18 | 0 | 37 | 1,687 | 106 | 122 | 0 | 2,702 |
| GPC03 | 26 | 366 | 1 | 29 | 95 | 21 | 0 | 9 | 1,472 | 34 | 202 | 0 | 2,255 |
| GPC51 | 54 | 234 | 2 | 10 | 119 | 4 | 0 | 10 | 1,120 | 67 | 55 | 0 | 1,675 |
| GPC04 | 22 | 190 | 0 | 21 | 79 | 0 | 0 | 44 | 896 | 102 | 49 | 0 | 1,403 |
| GPC17 | 68 | 620 | 0 | 2 | 294 | 9 | 0 | 21 | 1,754 | 202 | 140 | 1 | 3,111 |
| GPC52 | 50 | 267 | 1 | 0 | 174 | 12 | 0 | 15 | 875 | 32 | 52 | 0 | 1,478 |
| GPC01 | 69 | 502 | 0 | 0 | 213 | 3 | 0 | 9 | 2,131 | 97 | 145 | 0 | 3,169 |
| GPC13 | 23 | 139 | 0 | 0 | 41 | 4 | 0 | 15 | 412 | 43 | 29 | 0 | 706 |
| GPC24 | 37 | 182 | 0 | 0 | 77 | 6 | 0 | 2 | 770 | 64 | 102 | 0 | 1,240 |
| GPC34 | 180 | 553 | 1 | 14 | 361 | 22 | 0 | 21 | 2,469 | 242 | 137 | 0 | 4,000 |
| GPC40 | 35 | 178 | 0 | 0 | 64 | 3 | 0 | 17 | 1,133 | 23 | 62 | 0 | 1,515 |
| GPC20 | 36 | 231 | 0 | 0 | 89 | 1 | 0 | 9 | 903 | 37 | 45 | 0 | 1,351 |
| GPC57 | 9 | 77 | 0 | 0 | 7 | 0 | 0 | 0 | 452 | 39 | 21 | 0 | 605 |
| GPC55 | 47 | 177 | 1 | 0 | 68 | 3 | 0 | 22 | 655 | 77 | 34 | 0 | 1,084 |
| GPC54 | 63 | 237 | 0 | 0 | 71 | 7 | 1 | 16 | 927 | 74 | 24 | 0 | 1,420 |
| GPC28 | 53 | 394 | 0 | 22 | 129 | 9 | 0 | 11 | 1,438 | 44 | 124 | 0 | 2,224 |
| GPC12 | 47 | 539 | 0 | 14 | 185 | 24 | 18 | 14 | 1,755 | 178 | 277 | 0 | 3,051 |
| GPC46 | 27 | 230 | 0 | 43 | 51 | 4 | 0 | 7 | 834 | 71 | 107 | 0 | 1,374 |

| GP practice code/ Drug | Oxycodone | Tramadol | Matazinol | Methadone | Morphine | Tapentadol | Pethidine | Fentanyl | Codeine | Buprenorphine | Dihydrocodeine | Hydromorphone | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| GPC06 | 42 | 183 | 1 | 63 | 74 | 4 | 0 | 1 | 632 | 90 | 59 | 0 | 1,170 |
| GPC58 | 26 | 136 | 0 | 0 | 48 | 3 | 1 | 10 | 479 | 10 | 5 | 0 | 718 |
| GPC30 | 11 | 118 | 0 | 0 | 28 | 8 | 0 | 14 | 392 | 26 | 48 | 0 | 646 |
| GPC49 | 20 | 159 | 1 | 0 | 66 | 0 | 0 | 7 | 641 | 28 | 80 | 0 | 1,003 |
| GPC39 | 82 | 304 | 1 | 0 | 203 | 1 | 0 | 21 | 1,378 | 76 | 63 | 0 | 2,129 |
| GPC36 | 36 | 216 | 8 | 0 | 141 | 5 | 0 | 15 | 1,054 | 124 | 116 | 0 | 1,715 |
| GPC08 | 27 | 188 | 0 | 0 | 109 | 3 | 0 | 2 | 647 | 69 | 38 | 0 | 1,083 |
| GPC27 | 10 | 29 | 0 | 0 | 40 | 0 | 0 | 0 | 504 | 29 | 48 | 0 | 660 |
| GPC42 | 64 | 272 | 0 | 67 | 129 | 24 | 0 | 18 | 1,341 | 86 | 75 | 0 | 2,076 |
| GPC45 | 45 | 285 | 0 | 1 | 107 | 4 | 0 | 91 | 1,026 | 57 | 90 | 0 | 1,706 |
| GPC21 | 19 | 190 | 0 | 1 | 41 | 2 | 0 | 0 | 604 | 28 | 42 | 0 | 927 |
| GPC07 | 63 | 466 | 2 | 1 | 333 | 3 | 1 | 74 | 1,463 | 35 | 92 | 0 | 2,533 |
| GPC29 | 69 | 303 | 0 | 33 | 260 | 6 | 2 | 14 | 1,291 | 99 | 85 | 0 | 2,162 |
| GPC32 | 31 | 182 | 0 | 1 | 70 | 10 | 0 | 12 | 1,029 | 35 | 48 | 0 | 1,418 |
| GPC35 | 56 | 142 | 0 | 0 | 83 | 7 | 0 | 17 | 673 | 32 | 72 | 0 | 1,082 |
| GPC50 | 22 | 147 | 0 | 0 | 36 | 0 | 0 | 23 | 403 | 28 | 16 | 0 | 675 |
| GPC56 | 9 | 26 | 0 | 0 | 4 | 1 | 0 | 0 | 145 | 17 | 5 | 0 | 207 |
| GPC59 | 10 | 88 | 0 | 0 | 42 | 7 | 0 | 14 | 519 | 49 | 70 | 0 | 799 |
| GPC26 | 10 | 140 | 0 | 0 | 44 | 6 | 0 | 3 | 600 | 31 | 10 | 0 | 844 |
| GPC16 | 120 | 263 | 1 | 86 | 179 | 5 | 0 | 16 | 1,389 | 90 | 135 | 0 | 2,284 |
| GPC23 | 30 | 213 | 0 | 0 | 129 | 6 | 0 | 15 | 1,186 | 58 | 20 | 0 | 1,657 |
| GPC18 | 42 | 295 | 0 | 95 | 167 | 7 | 0 | 3 | 1,150 | 124 | 180 | 0 | 2,063 |
| GPC62 | 56 | 338 | 0 | 314 | 126 | 8 | 0 | 3 | 1,044 | 99 | 44 | 0 | 2,032 |
| GPC61 | 10 | 96 | 0 | 1 | 40 | 2 | 0 | 0 | 327 | 12 | 31 | 0 | 519 |
| GPC47 | 3 | 54 | 0 | 0 | 8 | 9 | 0 | 0 | 399 | 29 | 8 | 0 | 510 |
| GPC41 | 71 | 179 | 0 | 0 | 102 | 0 | 0 | 13 | 761 | 16 | 41 | 0 | 1,183 |

| GP practice code/ Drug | Oxycodone | Tramadol | Matazinol | Methadone | Morphine | Tapentadol | Pethidine | Fentanyl | Codeine | Buprenorphine | Dihydrocodeine | Hydromorphone | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| GPC25 | 4 | 142 | 0 | 0 | 17 | 4 | 0 | 5 | 423 | 24 | 84 | 0 | 703 |
| GPC11 | 19 | 522 | 0 | 2 | 138 | 4 | 0 | 3 | 1,101 | 107 | 142 | 0 | 2,038 |
| GPC37 | 29 | 146 | 0 | 4 | 103 | 4 | 0 | 3 | 552 | 29 | 23 | 0 | 893 |
| GPC60 | 0 | 52 | 0 | 0 | 11 | 0 | 0 | 0 | 209 | 14 | 6 | 0 | 292 |
| GPC43 | 5 | 111 | 0 | 1 | 39 | 6 | 0 | 3 | 337 | 25 | 3 | 0 | 530 |
| GPC02 | 29 | 184 | 0 | 171 | 132 | 3 | 0 | 11 | 737 | 74 | 112 | 0 | 1,453 |
| GPC31 | 20 | 100 | 0 | 1 | 22 | 19 | 0 | 4 | 396 | 52 | 29 | 0 | 643 |
| GPC38 | 38 | 218 | 1 | 0 | 82 | 1 | 0 | 30 | 630 | 25 | 17 | 0 | 1,042 |
| GPC15 | 11 | 171 | 0 | 0 | 71 | 0 | 2 | 3 | 513 | 13 | 32 | 0 | 816 |
| GPC22 | 3 | 115 | 0 | 0 | 56 | 2 | 0 | 6 | 309 | 22 | 37 | 0 | 550 |
| Total | 2,614 | 15,300 | 43 | 1,071 | 7,187 | 376 | 28 | 876 | 57,161 | 4,120 | 4,459 | 1 | 93,236 |

**Table 5. Prescribing frequencies by drug and GP practice**

**Long-term opioid prescriptions**

GPs issued a range of opioid drugs for various durations, most of which are considered long-term (i.e., continued repeat prescriptions). The data presented here highlights the duration that individual opioid prescriptions for each opioid lasted for, however it was not possible to ascertain that repeat prescriptions were always collected and dispensed during this time. This data uses the date an opioid was first ever added to a patient's record thus the duration may exceed the number of days in the data extraction period. Overall, the modal number of days an opioid prescription lasted for was 28-days. This differed for methadone and tapentadol which commonly lasted for 1 day and 84 days, respectively. It is unknown why these opioids present as outliers here, otherwise it would appear that most opioid prescriptions adhere to the 28-day prescription guideline. This presumption does not take into account the quantity of a prescription issued to a patient and the length of time it should last based on dosing instructions. For most opioids, the minimum number of days a prescription was issued for was 1 day (this may be interpreted as a one-off prescription), the maximum was 10,998 days (1,571 weeks)[5]. It is also unknown why these figures differed for Meptazinol and Pethidine with modal and minimum durations of 23 and 11 days, respectively. Prescriptions for codeine were issued for the longest period of time (a duration of 10,998 days) compared to tapentadol which had the shortest maximum of 2,156 days. It is possible tapentadol is an outlier due to the limited availability of this drug within primary care settings.

Table 6 below describes in detail the number and duration of prescriptions issued per drug. There were 12 main types of opioids prescribed (listed in column 1 of table 6), codeine was the most commonly prescribed opioid (n=57,161, 61.31%) followed by tramadol (n=15,300, 16.41%) and morphine (n=7,187, 7.71%). In comparison meptazinol, pethidine and hydromorphone were prescribed less frequently to fewer of patients (n=33, 0.05%; n=12, 0.03%; n=1, 0.00% respectively).

[5] Patient's records state when a drug was first added in order to calculate the total length of time a patient received a prescription. This could originate before the data extraction period of August 2016-2018.

| Drug | No. of patients (% of prescriptions out of 93,236) | Modal no. of days of an episode | Minimum no. of days of an episode | Maximum no. of days of an episode |
|---|---|---|---|---|
| Codeine | 23,590 (61.31%) | 28 | 1 | 10,998 |
| Tramadol | 8,010 (16.41%) | 28 | 1 | 8,216 |
| Morphine | 2,824 (7.71%) | 28 | 1 | 7,136 |
| Dihydrocodeine | 2,528 (4.78%) | 28 | 1 | 9,634 |
| Buprenorphine | 1,848 (4.42%) | 28 | 1 | 6,482 |
| Oxycodone | 892 (2.80%) | 28 | 1 | 4,750 |
| Methadone | 426 (1.15%) | 1 | 1 | 4,162 |
| Fentanyl | 384 (0.94%) | 21 | 1 | 4,190 |
| Tapentadol | 179 (0.40%) | 84 | 1 | 2,156 |
| Meptazinol | 33 (0.05%) | 23 | 23 | 8,483 |
| Pethidine | 12 (0.03%) | 11 | 11 | 5,378 |
| Hydromorphone | 1 (0.00%) | - | - | - |

**Table 6. Total number and duration of prescriptions by drug group.**

**Results Section 2: Overview of current prescriptions > 120mg MED per day**

The data presented here describes current prescribing practices which accumulate daily MEDs above 120mg that patients received during 2016-2018. Providing an overview of practice prescribing, table 7 below depicts the number of patients by practice locality stratified into groups receiving daily opioid doses below 120mg MED, equal to 120mg MED and more than 120mg MED. This output indicates that the majority of patients receive prescriptions within the clinical guidelines and identifies overall good prescribing practice. A number of patients (n=466) are identified as currently receiving the maximum advised dose (120mg MED).

| Location/Group | <120mg MED/day | =120mg MED/day | >120mg MED/day |
|---|---|---|---|
| North | 13,856 | 222 | 522 |
| South | 7,948 | 121 | 315 |
| Central | 6,328 | 123 | 232 |
| Total | 28,132 | 466 | 1,069 |

**Table 7. Number of patients in stratified groups by GP locality.**

A total of 1,069 patients (3.5% of the total sample) were identified as currently receiving prescriptions (N=2,999) contributing to daily doses exceeding 120mg MED/day. The majority of this subset were female (n=710; 66%) and on average were older than males (58 years ±14.50 and 56 years ±12.62 respectively). Females ranged from 20 to 98 years old; males ranged from 24 to 89 years old. The modal number of prescriptions patients were prescribed was 3, though this ranged from 1-14. The data highlighted that standalone (i.e., single) current

opioid prescriptions for fentanyl, oxycodone, buprenorphine, and morphine, were the only single drugs issued in doses above the advised daily maximum dose (120mg MED). In addition, these drugs were also commonly prescribed simultaneously with other opioids, yielding a daily dose above 120mg MED. Table 8 below displays the number of single prescriptions issued above 120mg MED and the number of times they are co-prescribed contributing to high daily doses. A quarter (n=760) of the combination prescriptions these patients received included a prescription for morphine. Morphine is the drug most commonly prescribed in conjunction with other drugs that contribute to patients exceeding the recommended dose threshold. In contrast, fentanyl is the least prescribed in conjunction with other opioids; on its own fentanyl was prescribed above 120mg MED, on 243 occasions but in combination with other opioids prescribing increases to 290 occasions. There is also clear indication that oxycodone and buprenorphine are commonly prescribed in combination with other opioids contributing to these increased daily doses.

| Drug | No. of single prescriptions >120mg MED | No. of combination prescriptions equalling >120mg MED |
|---|---|---|
| Fentanyl | 243 | 290 |
| Oxycodone | 148 | 525 |
| Buprenorphine | 121 | 282 |
| Morphine | 52 | 760 |

**Table 8. Single Opioid prescriptions compared with combination prescriptions >120mg MED**

Patients whose prescriptions exceed the 120mg MED threshold, either as single prescriptions or as a combination of prescriptions are included in table 9 below. This table also reports the modal, minimum and maximum number of days that each drug was prescribed highlighting the range of time that these prescriptions were issued for. Despite being the weakest opioid, codeine continues to feature as a frequently prescribed drug that contributes to patient's daily high doses (15%). Methadone, tapentadol, pethidine and hydromorphone were least likely to contribute to patient's high doses. Collectively these drugs represented less than 1% of prescriptions that contributed to exceeding the daily 120mg MED threshold. Meptazinol was not prescribed above nor contributed to daily doses exceeding 120mg MED. The modal number of days was higher for prescriptions exceeding doses of 120mg MED compared to prescriptions in general (as discussed in table 6). Here, the shortest modal average was for methadone which spanned 4 days (compared to 1 day for all doses). The longest was 3,777

days for tramadol (compared to 28 days for all doses). Unlike the data in table 6, there was no consistency between the different opioids and modal duration. This indicates that opioids contributing to doses above 120mg MED are often prescribed for longer durations and therefore have greater variance in the number of days they are commonly prescribed. It should be noted that meptazinol, tapentadol and hydromorphone were not prescribed as single prescriptions above 120mg MED to anyone in this subset of the analysis. Tapentadol and hydromorphone feature in table 9 below as they have been identified as part of the combination of prescriptions patients receive contributing to doses exceeding 120mg MED. For example, although hydromorphone was not prescribed above 120mg MED, the patient receiving this prescription was also issued a prescription for fentanyl patches and oxycodone generating a daily total of 362mg MED.

| Drug | No. of patients (% of prescriptions out of 2,999) | Modal duration (days) | Minimum duration (days) | Maximum duration (days) |
|---|---|---|---|---|
| Morphine | 357 (25%) | 127 | 2 | 7,136 |
| Tramadol | 276 (19%) | 3,777 | 7 | 6,335 |
| Oxycodone | 246 (18%) | 287 | 13 | 4,740 |
| Codeine | 244 (15%) | 2,279 | 8 | 7,546 |
| Fentanyl | 234 (10%) | 21 | 2 | 3,979 |
| Buprenorphine | 187 (9%) | 141 | 11 | 6,300 |
| Dihydrocodeine | 46 (3%) | 698 | 8 | 7,450 |
| Methadone | 7 (0.63%) | 4 | 1 | 1,796 |
| Tapentadol | 6 (0.23%) | 437 | 437 | 824 |
| Pethidine | 2 (0.10%) | 446 | 446 | 1995 |
| Hydromorphone | 1 (0.03%) | - | - | - |

**Table 9. Opioids contributing to daily morphine intake >120mg**

With the exception of one surgery (GPC56), all GP practices had at least one patient in receipt of prescriptions above a daily MED of 120mg (see table 10). In total, 1,069 patients are in receipt of daily prescriptions above 120mg MED. GP practice GPC05 (highlighted below) prescribed >120mg to the largest number of patients (n=82), this is consistent with the reporting of prescription frequency in table 5, however proportionally (using data in table 3) GPC05 is the 5$^{th}$ the highest prescriber. Of the GP practices prescribing opioids in doses >120mg, almost a fifth (19%) prescribed an average of 180mg MED, doses above 120mg MED range between 124mg and 640mg MED. Practice GPC18 prescribed the highest daily dose

equalling 3840mg MED. Upon investigating this further, it appears that the patient receiving this prescription was prescribed two courses of Subutex (8mg x3 daily = MED 1,920mg), one was a long-term repeat prescription from April 2013 – August 2018, and another was a brief one-off prescription made during July 2018. In this specific case, it would appear that this patient is receiving particularly high daily doses when in fact the usual dose would only be one course of this. As such, this calls for some caution when interpreting the maximum doses indicated in table 10 below.

| GP practice code (total no. of registered patients at GP practice) | Number of patients prescribed >120mg MED | Modal MED prescribed within a practice | Maximum daily MED prescribed within a practice |
|---|---|---|---|
| GPC09 (5,599) | 21 | 140 | 650.00 |
| GPC14 (4,103) | 9 | 140 | 360.00 |
| GPC10 (3,720) | 14 | 128 | 400.00 |
| GPC48 (3,526) | 4 | 180 | 644.00 |
| GPC53 (8,175) | 22 | 144 | 810.00 |
| GPC19 (11,256) | 42 | 160 | 1824.00 |
| GPC05 (13,029) | 82 | 180 | 760.00 |
| GPC33 (9,222) | 21 | 150 | 1240.00 |
| GPC44 (12,908) | 43 | 180 | 1140.00 |
| GPC03 (5,112) | 21 | 180 | 1600.00 |
| GPC51 (9,237) | 13 | 144 | 504.00 |
| GPC04 (3,807) | 24 | 180 | 1110.00 |
| GPC17 (10,907) | 43 | 180 | 630.00 |
| GPC52 (8,550) | 16 | 160 | 424.00 |
| GPC01 (6,680) | 47 | 180 | 800.00 |
| GPC13 (2,394) | 7 | 140 | 240.00 |
| GPC24 (4,594) | 9 | 180 | 220.00 |
| GPC34 (16,086) | 42 | 160 | 1840.00 |
| GPC40 (6,744) | 13 | 160 | 1140.00 |
| GPC20 (4,900) | 7 | 140 | 744.00 |
| GPC57 (5,276) | 2 | 132 | 192.00 |
| GPC55 (7,062) | 11 | 440 | 1443.90 |
| GPC54 (8,937) | 21 | 128 | 1440.00 |
| GPC28 (8,537) | 26 | 130 | 744.00 |
| GPC12 (9,998) | 25 | 200 | 1500.00 |
| GPC46 (6,812) | 5 | 140 | 890.40 |
| GPC06 (3,452) | 12 | 130 | 800.00 |
| GPC58 (6,443) | 7 | 140 | 368.00 |
| GPC30 (2,535) | 1 | 234 | 234.00 |
| GPC49 (5,241) | 7 | 124 | 1320.00 |
| GPC39 (8,955) | 20 | 240 | 720.00 |
| GPC36 (7,009) | 24 | 180 | 1027.50 |
| GPC08 (3,344) | 7 | 124 | 960.00 |

| GP practice code (total no. of registered patients at GP practice) | Number of patients prescribed >120mg MED | Modal MED prescribed within a practice | Maximum daily MED prescribed within a practice |
|---|---|---|---|
| GPC27 (2,518) | 2 | 140 | 210.00 |
| GPC42 (9,583) | 18 | 187.50 | 1280.00 |
| GPC45 (8,160) | 33 | 360 | 967.50 |
| GPC21 (3,395) | 3 | 240 | 500.00 |
| GPC07 (7,734) | 47 | 180 | 1500.00 |
| GPC29 (8,366) | 30 | 160 | 2600.00 |
| GPC32 (5,644) | 4 | 135 | 548.00 |
| GPC35 (4,401) | 18 | 125 | 800.00 |
| GPC50 (3,699) | 13 | 187.50 | 440.00 |
| GPC59 (7,544) | 8 | 144 | 940.00 |
| GPC26 (3,221) | 2 | 140 | 240.00 |
| GPC16 (7,921) | 36 | 180 | 1280.00 |
| GPC23 (6,138) | 9 | 144 | 624.00 |
| GPC18 (7,397) | 23 | 160 | 3840.00 |
| GPC62 (44,226) | 25 | 180 | 2560.00 |
| GPC61 (6,598) | 2 | 180 | 300.00 |
| GPC47 (2,545) | 1 | 248 | 248.00 |
| GPC41 (5,426) | 23 | 140 | 2180.00 |
| GPC25 (2,643) | 3 | 160 | 720.00 |
| GPC11 (6,587) | 33 | 180 | 412.00 |
| GPC37 (3,668) | 17 | 200 | 520.00 |
| GPC60 (3,228) | 1 | 640 | 640.00 |
| GPC43 (2,511) | 1 | 127.50 | 127.50 |
| GPC02 (3,271) | 20 | 144 | 1440.00 |
| GPC31 (2,540) | 8 | 140 | 449.00 |
| GPC38 (4,297) | 9 | 187.50 | 1001.60 |
| GPC15 (2,817) | 4 | 124 | 440.00 |
| GPC22 (2,817) | 8 | 160 | 560.00 |

**Table 10. Commonly prescribed doses above a daily MED of 120mg and number of patients per practice**

It is important to bear in mind that patients often receive more than one opioid and may not simultaneously take them, which is why average daily MEDs were calculated. Using the data from MED average we found 340 patients and 601 prescriptions, from 53 practices that prescribed average daily dose of opioids above 120mg MED. Females continue to represent the majority at 64% (n=216) and remain on average slightly older than males (61 years ±13.94 and 56 years ±12.23 respectively). Females ranged from 20 to 96 years and males from 24 to 88 years. Using the MED average, GP practice GPC44 prescribed the highest number of opioids. GPC44 prescribes average daily doses above 120mg MED to n=18 patients with a

modal dose of 188mg MED. Overall, GP practices prescribing an average daily dose above the daily threshold often prescribe between 124mg and 1,120mg MED. The highest average daily dose was prescribed by GP practice GPC18, who reportedly prescribed a maximum average MED of 1,920mg. See table 11 for a full description on the number of patients per practice prescribed an average daily dose, modal dose, and maximum average doses above 120mg MED.

| GP Practice Code (total no. of registered patients at GP practice) | No. of patients prescribed mean MED >120mg | Modal MED >120mg | Maximum average daily dose |
|---|---|---|---|
| GPC09 (5,599) | 6 | 128 | 325 |
| GPC14 (4,103) | 1 | 180 | 180 |
| GPC10 (3,720) | 7 | 128 | 220 |
| GPC48 (3,526) | 1 | 215 | 215 |
| GPC53 (8,175) | 6 | 147 | 720 |
| GPC19 (11,256) | 17 | 150 | 1280 |
| GPC05 (13,029) | 17 | 160 | 380 |
| GPC33 (9,222) | 4 | 137 | 311 |
| GPC44 (12,908) | 18 | 188 | 640 |
| GPC03 (5,112) | 5 | 188 | 800 |
| GPC51 (9,237) | 1 | 252 | 252 |
| GPC04 (3,807) | 15 | 192 | 720 |
| GPC17 (10,907) | 8 | 210 | 210 |
| GPC52 (8,550) | 5 | 136 | 360 |
| GPC01 (6,680) | 7 | 180 | 400 |
| GPC24 (4,594) | 1 | 188 | 188 |
| GPC34 (16,086) | 11 | 200 | 613 |
| GPC40 (6,744) | 7 | 160 | 380 |
| GPC20 (4,900) | 3 | 210 | 540 |
| GPC55 (7,062) | 7 | 147 | 720 |
| GPC54 (8,937) | 4 | 128 | 1440 |
| GPC28 (8,537) | 8 | 130 | 372 |
| GPC12 (9,998) | 10 | 800 | 1280 |
| GPC46 (6,812) | 1 | 223 | 223 |
| GPC06 (3,452) | 2 | 133 | 400 |
| GPC58 (6,443) | 2 | 184 | 188 |
| GPC49 (5,241) | 2 | 360 | 440 |
| GPC39 (8,955) | 7 | 360 | 720 |
| GPC26 (7,009) | 7 | 128 | 390 |
| GPC08 (3,344) | 2 | 289 | 960 |
| GPC42 (9,583) | 9 | 188 | 640 |
| GPC45 (8,160) | 15 | 360 | 360 |
| GPC21 (3,395) | 3 | 167 | 240 |
| GPC07 (7,734) | 17 | 188 | 540 |

| GP Practice Code (total no. of registered patients at GP practice) | No. of patients prescribed mean MED >120mg | Modal MED >120mg | Maximum average daily dose |
|---|---|---|---|
| GPC29 (8,366) | 8 | 150 | 720 |
| GPC32 (5,644) | 2 | 160 | 274 |
| GPC35 (4,401) | 7 | 188 | 540 |
| GPC50 (3,699) | 6 | 188 | 220 |
| GPC59 (7,544) | 2 | 188 | 540 |
| GPC16 (7,921) | 13 | 1120 | 1280 |
| GPC23 (6,138) | 4 | 125 | 540 |
| GPC18 (7,397) | 7 | 160 | 1920 |
| GPC62 (44,226) | 13 | 480 | 1280 |
| GPC41 (5,426) | 9 | 360 | 1090 |
| GPC25 (2,643) | 2 | 188 | 720 |
| GPC11 (6,587) | 5 | 128 | 320 |
| GPC37 (3,668) | 4 | 125 | 260 |
| GPC60 (3,228) | 1 | 640 | 640 |
| GPC02 (3,271) | 9 | 160 | 1440 |
| GPC31 (2,540) | 1 | 150 | 150 |
| GPC38 (4,297) | 6 | 188 | 290 |
| GPC15 (2,817) | 1 | 147 | 147 |
| GPC22 (2,817) | 4 | 124 | 560 |

**Table 11. Number of patients prescribed a daily average above 120mg MED by practice**

Those patients in receipt of an average daily dose above 120mg MED are most commonly prescribed fentanyl (n=171 patients, 35% (n=209) prescriptions) followed closely by oxycodone (n=83 patients, 26% (n=155) prescriptions), buprenorphine (n=74 patients, 16% (n=96) prescriptions) and morphine (n=48 patients, 11% (n=69) prescriptions). It is not surprising that the top four opioids presented in table 12 below are in the same order in which they emerged for opioids prescription >120mg described in table 8. Metazinol, pethidine, tapentadol, dihydrocodeine and hydromorphone were not prescribed above daily averages of 120mg MED. However, dihydrocodeine, pethidine and hydromorphone appear in table 12 as they were identified as part of a combination of opioids contributing to a daily average dose above 120mg MED.

The daily average doses exceeding 120mg/MED revealed that morphine was most commonly prescribed for the longest duration. In comparison buprenorphine was prescribed for the shortest duration but had the highest maximum number of days in a prescription, N=6,300. This implies there are outliers in the maximum number of days in a prescription. These figures

differ from the modal number of days reported in table 9, where tramadol and methadone presented as the highest (n=3,777) and lowest (n=4), respectively.

| Drug | No. of patients (% of prescriptions out of 601) | Modal no. of days in an episode | Minimum no. of days in an episode | Maximum no. of days in an episode |
|---|---|---|---|---|
| Fentanyl | 171 (35%) | 21 | 2 | 3,591 |
| Oxycodone | 83 (26%) | 676 | 21 | 4,740 |
| Buprenorphine | 74 (16%) | 11 | 13 | 6,300 |
| Morphine | 48 (11%) | 3,644 | 7 | 4,804 |
| Tramadol | 19 (3%) | 469 | 37 | 4,716 |
| Codeine | 42 (7%) | 930 | 19 | 1,948 |
| Dihydrocodeine | 7 (1%) | 113 | | |
| Pethidine | 1 (0.17%) | 1,995 | 1602 | 1,995 |
| Hydromorphone | 1 (0.17%) | - | -- | - |

**Table 12. Prescription frequency and number of days prescribed for opioids with an average daily MED above 120mg.**

**Geographical differences in prescribing of high dose opioids across Liverpool**

Figure 3.2 below highlights areas across the Liverpool CCG region where patients are in receipt of opioids prescribed above a daily average of 120mg MED. GP practices located in the North of Liverpool were identified as prescribing to the highest number of patients (primarily 9 GP practices around West Derby). Neighbourhoods across South Liverpool had relatively similar prescribing practices to those in North Liverpool and within this locality practices in the Speke and Belle Vale area (n=6 GP practices) prescribed to the highest number of patients. In comparison prescribing practices located in Central Liverpool were lower, with the exception of 6 practices located in the city centre.

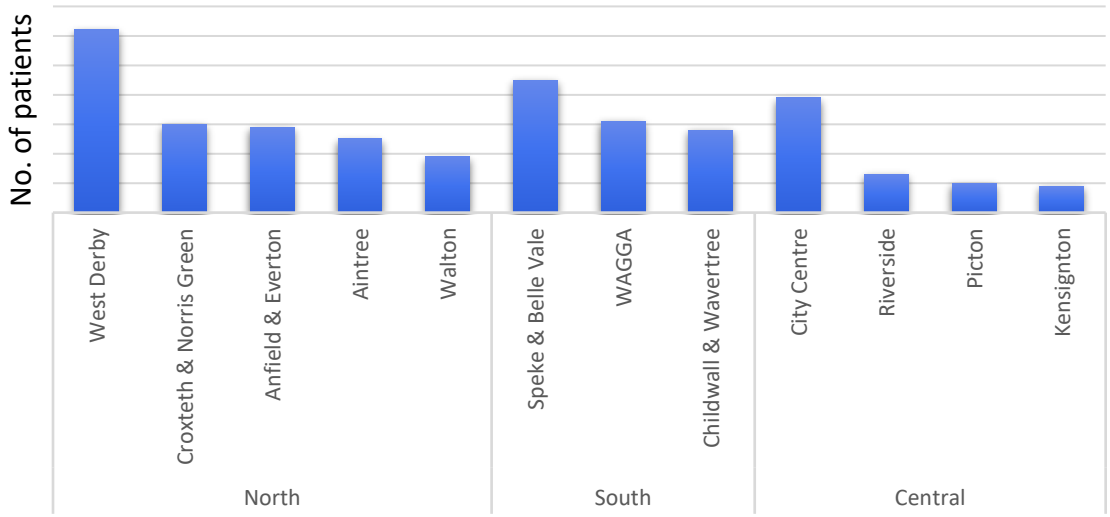


**Figure 3:2: Locality and frequency of patients prescribed a daily average above 120mg MED**

## 3.5 Case study examples

To provide some insight to the complexity of prescribing practices, case studies have been extracted from stratified groups in the dataset. These include patients prescribed daily opioids below 120mg MED, equal to 120mg MED and above 120mg MED. The cases examples presented in figure 3.3 below have been selected at random and provide details of patients prescribing history for opioid drugs they received during 2016-2018. As most patients are stratified into the below threshold group (<120mg MED/day) the first two case examples provided depict the minimum and maximum doses prescribed within this group. This is followed by one case example of doses equal to 120mg and one case example above 120mg MED, respectively.

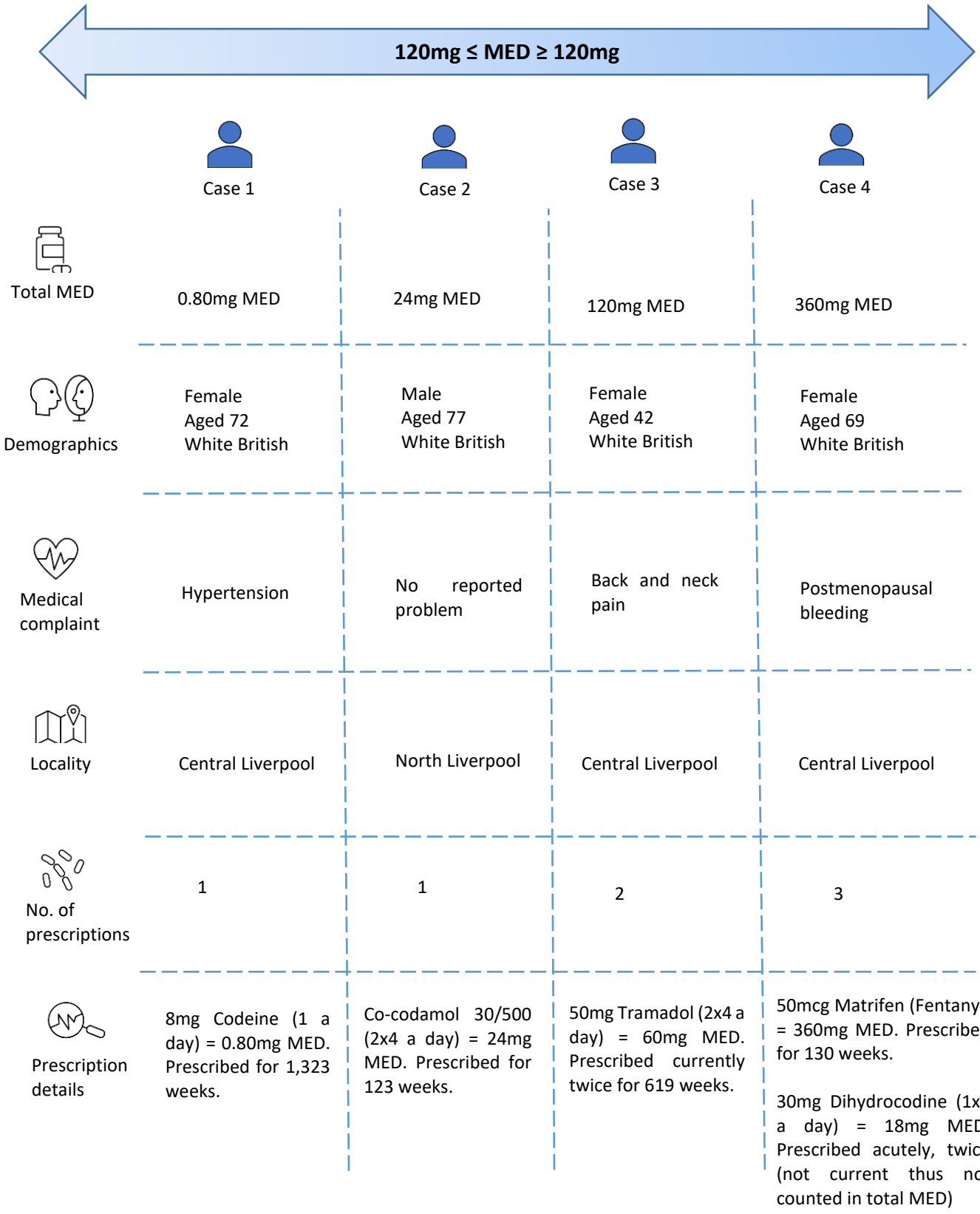


**Figure 3:3. Case study examples**

The analysis of this audit provides some insight of the opioid prescribing practices carried out among GP surgeries across Liverpool. In summary, the majority of GP surgeries demonstrate safe prescribing practice where most patients do not exceed the advised threshold of 120mg MED/day. It is clear that a number of variables are associated with the minority of patients exceeding 120mg/MED, including prescribing strong opioids, multiple opioids, longer episodes, older age groups and female patients. The implications of these finding are discussed in detail below with regard to what it means for practice and further research.

## 3.6 Discussion

The aim of this study was to investigate the aetiology of opioid prescribing among chronic non-cancer pain patients in primary care across Liverpool, and to identify areas and patients prescribed opioid doses above 120mg MED/day. Systematic reviews (Baldini et al., 2012; Chou et al., 2015), empirical research studies (Bedson et al., 2019) and national clinical guidance (NICE, 2017a) have all reiterated the lack of efficacy and increased risk of harm of long-term opioid use, particularly when daily doses are above 120mg MED (Dillie et al., 2008; Hauser et al., 2017). Many research studies from around the globe have already published national trends on the prevalence of opioid prescribing in primary care (Degenhardt et al., 2016; Hamunen et al., 2009; McDonald et al., 2012), and concur an increase in opioid prescribing and sequential risk of harm among CNCP patients that warrant public health attention. Along with these studies, regional and national research in the UK have also identified consistent patterns of opioid prescribing that correlate with patient socio-demographics such as, gender, age, ethnicity and SES and link to the prevalence of higher strength opioids (Chen et al., 2019; Mordecai et al., 2018; Torrance et al., 2018; Zin et al., 2014). The key findings of these studies will be discussed alongside the findings reported here, however this study focused on local level prescribing, reflecting recommendations from a recent national prescription database study (Mordecai et al., 2018).

This current study analysed opioid prescription data extracted from 62 (out of 83) GP practices across LCGG during August 2016 – August 2018. During this period, 93,236 opioid prescriptions were issued to 30,474 patients. Aggregated data demonstrated that most patients were female (61%), patients had a mean age of 60-years, identified as white British

(75%) and were commonly prescribed one opioid, most of which were below 120mg MED/day (96.5%). These findings are consistent with other national cross-sectional studies that highlight increased prevalence for weaker opioids (Torrance et al., 2018), higher percentage of low daily doses (Zin et al., 2014), mostly female (Foy et al., 2016; Sjøgren et al., 2010) and generally older adults (Chen et al., 2019). This suggests that the data here reflects current trends and that there is only a small subset of patients receiving high dose opioids. It also implicitly implies that either patients can be successfully treated with weaker opioids or that most GPs prescribe within the recommended limits. Additionally, it also indicates that the patients already established on high doses may require support and interventions to reduce their opioid use and optimise their treatment.

Results show that codeine was the most commonly prescribed opioid, representing over half of the prescriptions issued, it was also prescribed for the longest duration. This was followed by tramadol and then morphine which mirrors prescribing trends in Scotland during 2018 (Torrance et al., 2018); however, the data which Torrance et al., (2018) report on represent the number of patients prescribed common opioids and not the frequency each opioid was prescribed. Conversely, between 2010-2014 Mordecai and colleagues (2018) found that tramadol was the most prescribed opioid in England, although they measured total mg of morphine from dispensed prescriptions (Mordecai et al., 2018). The reduction in tramadol prescriptions in the current study may be explained by its reclassification in 2014 (ACMD, 2013). The different methods used to describe prescribing frequencies can make it difficult to accurately compare trends across studies. This study highlighted findings for both number of prescriptions and number of patients for all doses prescribed and specifically those over 120mg/MED, enabling us to compare with other prevalence reports. Mordecai *et al* (2018) argues that quantifying total mg of morphine equivalent is more informative than just counting number of prescriptions. More consistent or standardised methods of reporting would make study comparisons easier, particularly when comparing local and national prescribing practices.

For the past six years morphine has remained the most frequently prescribed high strength opioid (Mordecai et al., 2018; Torrance et al., 2018; Zin et al., 2014), and is also supported in the present study. This indicates that morphine is a key drug in a patients CNCP treatment

regime and perhaps a key indicator for monitoring or reviewing its efficacy in patients who are prescribed it. Prescribing trends across the UK have consistently found that although stronger opioids such as fentanyl, oxycodone or buprenorphine are generally less frequently prescribed than weaker opioids, such as, codeine or tramadol, trends of strong opioid prescribing are increasing year on year (Foy et al., 2016; Ruscitto et al., 2015; Torrance et al., 2018; Zin et al., 2014). Although this study did not conduct a time-trend analysis, it did find that strong opioids (primarily fentanyl, oxycodone, buprenorphine, and morphine) are less frequently prescribed and most likely to contribute to patients exceeding 120mg MED/day. While only 3.5% of the patients in this cohort were issued opioids above this amount, this also reflects national prescribing trends indicating that a minority of CNCP patients are prescribed opioids above 120mg MED/day, (Taylor et al., 2019).

Whilst carrying out the analysis for this study it became clear that prescribing data must be interpreted cautiously. For example, patients may be issued brief prescriptions or exceptions to their usual prescription (reasons for which are unknown). As a result, on record this would appear to increase a patient's daily dose even though they may not take all prescriptions simultaneously. While these could be excluded as outliers, the nature of treating chronic pain means that patients do frequently receive multiple prescriptions, as such, an average MED was calculated and patients still exceeding 120mg MED/day reviewed. The number of patients in this group substantially reduced compared to those prescribed any dose over 120mg (1,069 to 340 patients). At a local level, this identifies a small cohort of patients who should be prioritised for treatment review. The characteristics around the prescribing practices of these patients could be used to identify other potential patients at risk of inappropriate prescribing and facilitate intervening before it occurs or perhaps worsen. This study found that patients receiving prescriptions above 120mg MED/day, commonly received an average of three opioids. Interestingly, when dosing data was controlled for average daily doses above 120mg, this reduced to one opioid. The difference in number of prescriptions reported here could be explained by the large number of fentanyl prescriptions, as fentanyl was unlikely to be prescribed in combination with other opioids. Prevalence studies on opioid prescribing commonly report that patients with CNCP are usually prescribed multiple opioids. For example, Zin et al., (2014) found that the number of strong opioids patients received annually that attributed to MEDs above 88.9 mg increased from six in 2000 to 9.5 per 2010

(Zin et al., 2014). It is difficult to directly compare these findings with this study as Zin and colleagues had a much bigger patient database over a longer period of time and quantified number of patients receiving prescriptions into dose ranks rather than the number of opioids at each dose rank. It does however highlight the complexity and importance of carefully interpreting multiple combination of opioids prescribed that attribute to overall daily doses.

When opioids were filtered for MEDs above 120mg, this study found that fentanyl, oxycodone, buprenorphine, and morphine were the only drugs prescribed on their own above 120mg/MED. Although fentanyl attributed to the most number of prescriptions above 120mg MED, it represented less than 1% of all the opioids prescribed during 2016-2018, consistent with national 2018 trends across England (Mordecai et al., 2018). Furthermore, fewer patients were prescribed high dose fentanyl compared to patients receiving prescriptions for morphine and oxycodone. This helps indicate what kind of opioids and case management load HCPs might have to deal with when considering weaning patients at most risk of harm. Many prevalence studies also focus their analysis on these stronger opioids (Mordecai et al., 2018; Ruscitto et al., 2015; Zin et al., 2014) except they commonly frame their findings in categories such as strong versus weak or long-term versus short term or as single versus multiple prescriptions. As such, there is a gap in the literature investigating specific combination of opioids contributing to doses above 120mg MED/day despite recognising that patients receiving high doses are often prescribed more than one opioid. Mathieson *et al.,* (2020a) considered the likelihood of receiving a combination of opioids, however they also use the categorisation of strong verses weak opioids identifying increased likelihood of receiving strong combinations (24.1%) than weak combinations (11%) (Mathieson *et al.,* 2020a). Taking this into account, it is therefore worthwhile to reflect on combinations prescribed as it may help identify where in a patient's treatment journey inappropriate prescribing occurs. This may be particularly important in terms of reducing harm, including overdose and death. Both Dunn (2010) and Bedson (2019) found that doses exceeding 100mg MED/day was attributed to at least three opioids and significantly increased patients' risk of fracture, falls, overdose, and death (Bedson et al., 2019; Dunn et al., 2010). It is equally important however, that risk of harm doesn't deter prescribers from issuing opioids altogether, as at lower doses they are arguably effective for CNCP among some patients groups (e.g. those who experience fewer side effects (Bialas et al., 2020). To strike this balance of minimising risk and maximising

benefit, a pro-active approach to prescribing is recommended, requiring prescribers to closely monitor, review and risk assess patients throughout their opioid treatment (Brennan & Gudin, 2020).

It is concerning that this study found morphine, prescribed on its own as being least likely to exceed 120mg MED, yet in combination with other opioids it was almost 14 times more likely to attribute to doses above this. It is possible that patients are prescribed morphine and over time are prescribed additional opioids due to tolerance and uncontrolled pain and without realising that summatively, these result in riskier daily doses. For example, the data reported here also found that morphine was the 3rd most prescribed opioid and that the higher the daily dose of morphine the longer the duration of the prescription. Foy *et al* (2016) reported similar findings, indicating that with time opioids increased in strength and dose and that patients were less likely to reduce their dose (Foy et al., 2016). In addition, oxycodone and buprenorphine were also linked to multiple opioid prescriptions contributing to doses above 120mg MED/day. Without further in-depth analysis of individual GP practice prescribing and qualitative data, it is difficult to ascertain the nature of these prescribing practices. It does indicate the need to review patients in receipt of morphine prescriptions more regularly, particularly those prescribed it long-term.

Duration of prescription was usually around 28 days. When prescriptions were filtered for doses above 120mg MED/day the modal duration increased. This pattern was evident using MED average, suggesting that patients who are prescribed high daily doses (above 120mg MED/day) are prescribed them for longer periods of time. Fentanyl had a relatively short duration throughout all levels of the analysis (regardless of dose) indicating that GPs are already more cautious about the length of time these prescriptions are issued for. Patients prescribed long-term high opioid doses have a higher use of health care services, are more likely to be obese and have a poorer quality of life (Chen et al., 2019; Sjøgren et al., 2010). It is likely that these attributes are reciprocal in nature and changes need to be made to provide better treatment; opioids however appear to be the common denominator.

With the exception of one GP practice, all practices included in the analysis prescribed opioids or a combination of opioids to at least one patient that exceeded 120mg MED/day. Practices in the in the North of Liverpool prescribed the most opioids above 120mg MED/day to the

highest number of patients, followed by South Liverpool then Central Liverpool. Socioeconomic disparities have been linked to regional differences in opioid prescribing, where levels of prescribing are higher in areas with greater social deprivation (Chen et al., 2019; Mordecai et al., 2018). For example, Mordecai et al (2018) reported a general north/south prescribing divide across England, indicating significant increases in the north (Mordecai et al., 2018). Specifically, Chen et al (2019) reported higher prescribing rates in the North West of England (Manchester) compared to localities in the North East (Newcastle), Midlands (Birmingham) and the South (London) having the lowest prescribing rate (Chen et al., 2019). Using Index of Multiple Deprivation (IMD) both studies associated high rates of prescribing to areas of greater social deprivation. These findings could be generalised to those reported here as Liverpool resides in the North West of England and this study found the highest number of opioids prescribed in areas of North Liverpool. Specifically, patients in North Liverpool were more likely to receive more than 1 opioid, compared to patients from practices located in South and Central Liverpool (1.8%, 1.2% and 1.4%, respectively). Although certain areas in South and Central Liverpool also had particularly high rates of opioid prescribing. IMD scores for 2019 ranked Liverpool the 3$^{rd}$ most deprived local authority out of 317 across in England, specifically neighbourhoods in the North of Liverpool, inner core and South Liverpool were identified as being the most deprived in the city (LiverpoolCityCouncil, 2020). This would indicate that on a local level, the areas of high prescribing reported here are likely to be linked to areas of higher deprivation.

When looking at practice level prescribing further, this study found that the top two prescribers (from North Liverpool) had similar number of registered patients to the bottom two prescribers (from South and Central Liverpool) yet prescribed a much higher number of opioids. It is unknown what drives such differences, further investigation is needed into individual practice prescribing to understand why. Mordecai et al (2018) suggest that it is perhaps due to the higher prevalence of chronic pain reported in people with lower socioeconomic status (Mordecai et al., 2018). Although it is useful to identify areas prescribing high numbers of opioids in order to set context and compare neighbourhoods, the frequency of prescriptions does not necessarily mean that practices are prescribing high doses. For example, one GP practice located in North Liverpool was identified as being the 5$^{th}$ highest prescriber in proportion to the number of prescriptions prescribed per patient registered,

even though per item they issued the most opioids (the majority of which were high strength opioids including buprenorphine, oxycodone, and morphine). This practice also prescribed the highest number of morphine prescriptions and as discussed previously; patients are more likely to exceed the daily morphine threshold if they are in receipt of combined opioids that include a morphine prescription. Collectively, areas of high social deprivation, long-term morphine prescriptions, female, adults aged 61 or older may be key indicators to identify GP practices more likely to be prescribing opioids inappropriately.

**Strengths**

A key strength of this study is the use of individual practice and patient level prescribing data analysed to depict an understanding of localised prescribing. Currently the majority of UK prevalence data shows prescribing trends at national and regional levels therefore it is advantageous to establish insight at a local level so to inform areas to place an intervention. Another strength of this study is that it is representative of patients registered at GP practices across Liverpool CCG, with 62 out of 83 practices agreeing to share their data.

**Limitations**

This study has identified a number of different prescribing trends and common practices which corresponds and complements the published literature. There are however a number of limitations that should be highlighted in order to provide complete transparency of the study findings. Most limitations are due to the way in which patient data is collected and recorded which has restricted some sections of the data analysis. For example, the recorded linked problems associated with an opioid prescription did not always logically justify a prescription, such as: malaise, Asperger's, blackouts, issues with memory and driving licence application. Querying this information further, it was understood that patients may present to clinical appointments with numerous problems; therefore, GPs may record one of these problems as the reason for a patient's visit and may not be the exact reason for the opioid prescription. Additionally, some patient record information were either incomplete or missing such as their recorded ethnicity, linked problem or advised dosing instructions. The latter variable was compensated by presuming the highest dosing instruction advised from the BNF and may account for an over or under estimation in some of the calculated MED's. Limitations of the study design meant that the time frame of data extraction is much shorter than some

of the published literature therefore it restricts comparing a time trend analysis. The timeframe of project delivery also meant that we could not calculate an exact duration each prescription should last based on the quantity prescribed and dose instructions provided (in addition to missing dose instructions). Lastly, the data does not provide a reason for differences in practice prescribing patterns and what happens at patient-doctor level. More understanding of this would require in-depth qualitative research to investigate the experiences of doctor-patient prescribing practices. There is no way of confirming that prescriptions in this data set were dispensed and used throughout the duration of an episode or confirming how often a patient collected a prescription. As a result, the data implies that a medication was continuously prescribed across a certain time period. It is known that around 5.6 million opioid prescriptions were dispensed in 2017-2018 for CNCP (Taylor et al., 2019). However, without further evidence linking prescriptions to dispensaries and feedback from patients; it is difficult to know for sure if and how many times an opioid is issued between the date they are first added and last prescribed on a patient record.

## Conclusion

The prescription database analysed in this study included a substantial number of GP practices across Liverpool and is representative of the majority of primary care patients prescribed opioids. The key characteristics associated with high dose prescribing that were identified here (and should be considered as risk factors) include: females, patients over 58 years, white British, reside in North Liverpool and prescribed a long-term prescription of morphine. The British Pain Society (BPS) recommends that patients prescribed doses above 120mg MED/day should be referred to specialist pain clinics for additional support (BPS, 2013a). However, the capacity in specialist pain clinics is already limited and this calls for more accessible interventions within the community. In light of these findings and established knowledge around the risks of high dose opioid prescribing, there is a clear need to develop an approach applicable for primary care practitioners to discontinue or reduce inappropriate opioid prescribing. Future research should consider stratifying patients at a community level who are receiving high dose opioids and in need of interventions designed to optimise their chronic pain treatment.

# Chapter 4: The views and lived experiences of Chronic Non-Cancer Pain (CNCP) patients and Health Care Professionals (HCP). Study 2a and 2b

## 4.1 Chapter Overview

This chapter presents the findings of semi-structured interviews conducted with 16 Health Care Professionals (HCP) and 13 patients with Chronic Non-Cancer Pain (CNCP). This study address objectives 3 and 4 of the research design (discussed in section 1.2) and aims to explore the behaviours of patients and HCPs concerning the process of using and discontinuing opioid treatment for CNCP, so to identify potential facilitators or barriers to opioid weaning. To address this, interviews were conducted to understand the decision-making process around opioid treatment; how opioid reduction or discontinuation plans are negotiated and managed; what treatment concerns and barriers arise during an opioid weaning; and what support mechanisms are considered helpful to facilitate opioid weaning, from both a practitioner and a patient perspective. The chapter begins with an introduction to the professional relationship between HCP and patients during the course of opioid treatment for CNCP. The study methods are outlined, before presenting the findings from HCP and patient interviews, respectively. Following this, the results from study 2a and 2b are integrated to provide an overall view of opioid management in CNCP before finally being discussed in the context of extant literature.

## 4.2 Introduction

Chronic pain affects between one third and one half of people in the UK, a condition which inherently remains for long periods of time (Fayaz et al., 2016). Historically it has not been viewed as a healthcare priority but rather a secondary symptom of other diseases (Goldberg & McGee, 2011). In 2004, chronic pain was recognised by the WHO and the IASP as a global health priority in its own right (IASP, 2004; WHO, 2004). Since then, there has been a focus in the UK, driven by various health professional organisations (e.g., The British Pain Society, Chronic Pain Policy Coalition, Faculty of Pain Medicine, and the Royal College of General Practitioners) to reform the approach taken by the National Health Service (NHS) to manage chronic pain. The three levels of care (primary, secondary, and tertiary) which the UK NHS

operate provide various points of care that individuals can access depending on their health needs. Primary care is usually the first point of contact for individual healthcare needs (NHSProviders, 2020) and where a large majority of CNCP patients are managed by their GP (Ernstzen et al., 2017; Gureje et al., 1998). For more specialist services or emergency care, patients are referred onto secondary or tertiary care. In 2013, a support document addressing the needs of chronic pain services across the UK was developed to help facilitate collaboration between local commissioning groups and HCPs, to improve pain services (RCGP, 2013). This resonates with statistics indicating that people with chronic pain consult their GP five times more frequently than those without and presents in around 22% of all primary care consultations (Johnson et al., 2013). As the number of people developing chronic pain increases (currently estimated at ~5 million a year in the UK, of whom two thirds recover), it places a substantial burden on individuals who suffer the pain, their families, HCPs who deliver their care and society as a whole (RCGP, 2013).

Frequently CNCP patients are prescribed opioid analgesics to help manage their pain. The observed increase in opioid prescribing and subsequent concern for their long-term safety in CNCP management has prompted more research (Chou et al., 2009). This has resulted in growing consensus from the literature indicating opioids lack of effectiveness in CNCP as well as links to increased risk of harm, particularly when prescribed at higher doses (Bedson et al., 2019; Dunn et al., 2010). Such findings have led to calls to reduce or discontinue opioids, where there is no perceived benefit but potential risk of harm (FPM, 2015b). This in turn may reduce the already limited treatment options for CNCP, but also paves an opportunity to improve patient care and ensure that where benefit is obtained that it is maximised in best practice. As discussed in Chapter 2 and 3, there is a significant number of people with CNCP in the UK (and around the globe) who are on chronic regimens of high dose opioids with limited benefit and exposure to potential harm. There is need therefore to monitor and respond to the inappropriate use of prescription opioids and enhance HCPs competencies and guidance for standards of care and best prescribing practice. Combining commentary from two UK expert sources, Stannard (2018) and NICE (2019), inappropriate prescribing is described as continued "*dose escalation in the face of poor pain relief*" and prescribing "*without considering the complexity of individual needs*" including preference for treatment, health priorities and lifestyle (Stannard, 2018) (pg.119) and (NICE, 2017b) (pg.3), respectively.

Stannard (2018) discusses the future of using opioids in CNCP treatment, highlighting that rather than establishing more awareness of their associated risks and efficacy, it is now a matter of what to do instead. As a result HCPs are calling for modification of the original analgesic ladder (Vargas-Schaffer, 2010) and direction from newly developed guidance specifically for the treatment of CNCP (Cheung et al., 2014). Although emerging guidelines are often welcomed among HCPs, Ljungvall (2020) argue that in practice they don't always identify the most appropriate opioid treatment and advocates the need for tailored treatment built around a first person perspective (Ljungvall et al., 2020). Exploring varying perspectives of the lived experiences of both HCPs and patients, will provide insight into what best practice should look like and identify the needs to better support HCPs and patients.

There is no doubt that chronic pain is a complex condition for HCPs to adequately treat, whereby the balance of ensuring optimal pain management whilst also minimising risk of harm is difficult to achieve. Prescribers do not often consider the inter-individual variability of patients in receipt of opioids, and combined with their associated adverse effects can result in ineffective treatment (Morrone et al., 2017). The biopsychosocial model provides a framework for treatment that considers chronic pain as a multi-faceted condition which ideally requires interdisciplinary care (Ljungvall et al., 2020; NICE, 2019). This level of care advocates the co-location of various skilled HCPs which is thought to enhance the integration and communication associated with improved treatment outcomes (Gjesdal et al., 2019). Where the co-location of HCPs is not available or possible, multidisciplinary care is recommended, albeit this potentially risks causing problems with communication. For example, a content analysis of interviews with 10 nurses from a pain clinic in Norway found that the breakdown in communication, between specialist services and primary care was a barrier to optimising care (Gjesdal et al., 2019). Nurses reported how it caused problems prioritising limited resources for newly referred and existing pain patients, and that better integration between levels of care would help overcome and optimise patients care.

With a large proportion of CNCP patients long-term treatment being delivered in primary care, it would be logical to consider the potential mechanisms of treatment within this setting. A survey among primary care practitioners across 13 countries in Europe found that physicians reported CNCP as one of the most challenging health complaints to treat and they

were less confident in prescribing opioids due to their associated risk of dependency and misuse (Johnson et al., 2013). The issue that HCPs face is that symptom reporting from CNCP patients seldom improves to the point where patients no longer need treatment. This is particularly problematic for primary care as is where most patients seek healthcare and where both patients and GPs report the management of pain as unsatisfactory (Henry et al., 2018; McCrorie et al., 2015; Morrone et al., 2017). GP responses to chronic pain management are often driven by available and accessible treatments and their level of expertise in the area (McCrorie et al., 2015), yet most primary care physicians report insufficient training and a need for more education (Johnson et al., 2013). This interplay of reported GP experience combined with patient experience is investigated further in a qualitative study of long-term opioid prescribing in 15 UK primary care practices (McCrorie et al., 2015). The qualitative findings depicted four main themes considered influential to opioid prescribing: lack of clarity in treatment strategy, lack of confidence in decision making, continuity of HCP and established mutuality and trust. McCrorie *et al*., (2015) concluded that problematic opioid prescribing was more likely to occur among patients who experienced repeated consultations due to their unmet needs and when GPs were unable to negotiate alternative treatment (McCrorie et al., 2015). The impasse that patients and HCPs are often met with is that patients present to clinical appointments with a sense of desperation to cure their pain and desire for a "quick fix" (Gjesdal et al., 2019) and HCPs feel pressurised to "do something" with limited clinical appointment time (McCrorie et al., 2015). Dissatisfaction with clinical consultations was explored further by Henry and colleagues (2018) who conducted descriptive analysis on video recorded consultations combined with pre and post questionnaires with patients and primary care GPs (Henry et al., 2018). They found that when patients were seeking increased pain medication, it was more likely to result in patient-doctor disagreement, a worse patient experience and increased doctor-reported visit difficulty. Although requests for increased medication only occurred in 42% of patients who were video recorded, these led to two further confrontational clinical appointments (per patient). The approach taken to manage such difficult consultations should be carefully considered as it may risk poor patient engagement in future treatment recommendations as rapport and trust with HCPs breakdown (Ljungvall et al., 2020). Furthermore, accounts of patients lived experience of being treated with opioids uncovered that they perceive opioids to be both a salvation and a curse (Ljungvall et al., 2020). Ljungvall et al., (2020) highlight that patients don't particularly

like taking opioids and that the stigma attached to them make them feel that they are a nuisance or drug seeking when they discuss with their HCP that treatment is not working. The outcome of Ljungvall's study suggests that patients perceive good treatment as feeling believing by a HCP and a relationship that encompasses trust, empathy and compassion. These factors may be difficult to achieve when there is a lack of consistency in the HCP a patient sees and equally difficult for HCPs to deliver during limited consultation times.

The RCGP guidelines (2013) recommend that the management of chronic pain is best delivered by a team of multidisciplinary HCPs, which at a minimum should involve the collaboration between a doctor, physiotherapist and psychologist (RCGP, 2013). As primary care manages the majority of long-term chronic pain patients, this places a substantial burden on GPs given their already limited time, resources, and knowledge of chronic pain. Furthermore, it is clear that the development of patients and HCP therapeutic relationship plays a key role in the overall treatment experience and likelihood of positive treatment outcomes. Investigating the lived experiences of patients and HCPs involved in CNCP treatment will therefore help us understand what is helpful and promote a positive outcome for both. In establishing this it will help identify ways in which patients and HCPs may be better supported during the process of prescribing, reducing, or discontinuing opioids in the management of CNCP.

## 4.3 Methods

**Design**

This research took a pragmatic approach to inform the research design. The nature of this provided flexibility in choosing a methodology best suited to address the research problem. In this case, qualitative methods were used to investigate differing perspectives of HCP and patient experiences using opioids to treat CNCP. Thematic analysis (Braun & Clarke, 2006) was chosen to analyse the data because of its theoretical flexibility that suited the pragmatic stance adopted for this thesis. Thematic analysis is commonly used in wider health research, recommended for novice qualitative researchers (Braun & Clarke, 2006) and lends itself well to conducting in-depth qualitative research. Conversely, other alternative analytic methods such as discourse analysis, grounded theory or interpretative phenomenology were not

suited to achieve the research aims as these methods are often tied to a specific theoretical or epistemological position. The study was approved by the NHS Research Ethics Committee (REC) granting Health Research Authority (HRA) 18/NW/0217 (appendix 8). It was also registered on the National Institute of Health Research (NIHR) Clinical Research Network (CRN) which provided a platform to share the study and support recruitment if needed (CPMS ID 38137).

**Setting**

A tertiary care pain clinic in the North West of England was used as the main recruitment site to invite HCPs and patients to take part in this study. Additionally, to ensure experiences from the community were also captured, HCPs (namely GPs and community pharmacists) were recruited via LCCG. All CNCP patients were recruited from a tertiary care pain clinic.

**Participants**

A lead consultant anaesthetist (BF) at the affiliated tertiary care pain clinic helped to facilitate initial recruitment of HCPs and patients.

HCPs

HCPs included those involved in the prescribing of medication for patients with CNCP (e.g., GPs, consultants, nurse prescribers) and those concerned with medicine or pain management (e.g., psychologists, physiotherapists, pharmacists). HCP's who met the inclusion criteria (see figure 4.1) were recruited using snowball sampling. Invitation emails (see appendix 9) were initially sent by the lead consultant (BF) to colleagues in the pain management field. Once HCPs responded with interest in taking part, the lead researcher (EB) emailed a copy of the participant information sheet and consent form; hard copies were also provided where face-to-face interviews were conducted (see appendix 10 and 11). Participating HCPs were asked to share the email invitation with other colleagues who they thought might be interested. Of the 16 HCPs invited to take part, all agreed to opt into the study.

Patients

Patients included adults being treated with opioids for CNCP. Patients were screened by the lead consultant (BF) to identify those who met the inclusion criteria (see figure 4.1); once identified, the lead researcher (EB) attended the clinic and invited these patients to take part (N=25). Patients were asked to share their contact details to allow for a follow up phone call to discuss and answer any queries they had about the study. This also ensured that the recruitment procedure did not consume their clinical appointment time. All patients were provided with a hard copy of the participant information sheet and consent form during their clinic appointment, as well as a prepaid envelope to return their consent form should they wish to opt in (see appendix 11 and 12). Fifteen patients opted into the study however two patients did not answer the pre-arranged telephone call. A final total of 13 patients were interviewed. The main reasons for patients opting out of the study were due to feeling unwell, experiencing high levels of pain, generally not being interested or no response given.

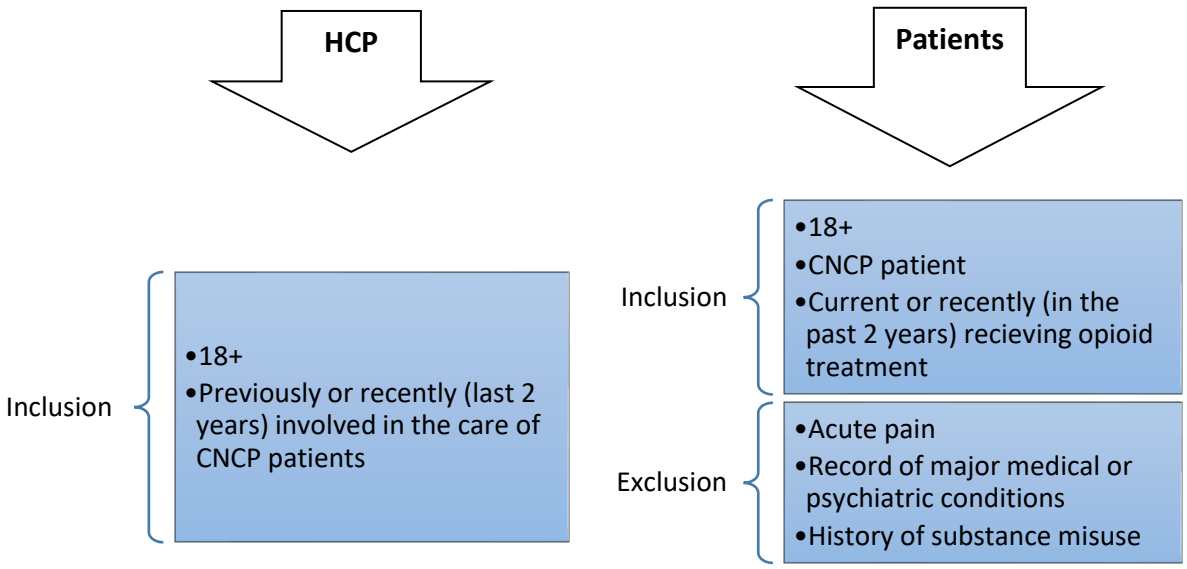


**Figure 4:1: Study 2 inclusion and exclusion criteria**

Participant recruitment and interviews ran simultaneously between May 2018 – March 2019 where a total of 29 interviews were conducted with 16 HCPs and 13 patients. See table 13 below for a breakdown of participant characteristics and data collection method.

| Patient Group | No. of male/female | Age range | Employment status | Interview style |
|---|---|---|---|---|
| HCP | Female n=9<br>Male n=7 | 31-46[6] | Pain consultant n=2<br>Pain specialist nurse n=3<br>Pharmacist n=3<br>Psychologist n=3<br>Physiotherapist n=2<br>GP n=3 | Face to face, n= 10<br>Telephone, n= 6 |
| Patients | Female n=4<br>Male n = 9 | 37-72 | Employed n=2<br>Unemployed n=7<br>Retired n=2<br>on long-term sick n=1<br>No answer n=1 | Face to face, n= 2<br>Telephone, n= 11 |

**Table 13. Study 2 participant characteristics**

**Materials**

Two separate interview guides were developed: one for HCPs and one for patients. Questions were devised to specifically reflect the study aim and objectives and consulted with the supervisory team for consensus.

HCPs

The interview guide for healthcare professionals included questions regarding their experience of medication management of opioids in patients with CNCP, their views on opioid prescribing, managing problematic use of opioids, and supporting patients wishing to reduce or discontinue use of opioids (appendix 13).

Patients

Similarly, a separate but related interview guide was developed for patients that focussed on their experience of using opioids (appendix 14). This considered the impact of opioids, barriers to reducing or discontinuing opioid treatment and consideration of what support they found helpful or needed to facilitate their weaning plan. Patients were also asked to rate their health care experience on a scale of 1 (unsatisfactory) to 10 (satisfactory). This was used to probe patients further about why they chose their rating and how it could be improved.

[6] 9 out of 16 participants agreed to share their age.

**Procedure**

All participants were given the option of returning their consent forms via post, email or completing it face-to-face prior to interview. Once consent was obtained, a mutually agreed time for interview was arranged. Participants were given the choice of conducting the interview face-to-face or over the telephone. Altogether, this study recruited 29 participants, 17 of whom opted to conduct their interview by telephone (6 HCPs and 11 patients) and 12 participants opted for face-to-face interviews (10 HCPs and 2 patients). Two MSc students (HR and AM[7]) were trained by the lead researcher (EB) to help conduct interviews with HCPs and patients using the developed interview guide (HR conducted four interviews and AM conducted five interviews). Training involved carrying out role play and practice of using the HCP and patient interview guides until both MSc students demonstrated competency.

All interviews were digitally recorded, stored onto a secure password protected network and deleted from the recording device. The duration of interviews ranged between 31 minutes to 1 hour 38 minutes for patients and 21 minutes to 58 minutes for HCPs. Interviews were transcribed verbatim by the interviewer, and MSc student transcriptions were checked for accuracy by EB. Transcripts were then imported into Nvivo version 12 for analysis.

**Analysis**

Data analysis was conducted solely by the lead researcher (EB). Using Nvivo version 12; interviews transcripts for HCPs and patients were analysed separately and followed the 6 phased approach of Braun and Clarke's (2006) framework for thematic analysis: data familiarisation, generating initial codes, identifying themes, reviewing themes, defining and naming themes and lastly producing the report (Braun & Clarke, 2006). See appendix 15-18 for detailed process.

[7] HR refers to Hannah Riley and AM refers to Alison Moffat.

Step one: familiarisation

Approaching the dataset having transcribed the interviews verbatim provided early exposure to some initial analytic interests. However, to ensure the depth and scope of the interviews were fully understood, the data was re-read in an 'active way' (i.e., critically looking for areas of relevance) documenting ideas or commentary in this initial data familiarisation stage.

Step two: generating initial codes

The notes made during data familiarisation were reviewed and implicitly feature throughout this initial coding phase. Each dataset (HCPs and patients) was coded systematically using a combination of inductive and deductive approaches. Using Nvivo, a long list of nodes were created using the first transcript as a framework for the others, whilst allowing for further interesting impressions to be discovered and tentatively coded. Any new codes identified in subsequent transcripts were also checked for in earlier transcripts. Additionally, MSc students' interpretations of the data were compared independently by a second supervisor (HP) with the lead researcher's (EB) coding to ensure rigor and quality of the emerging codes.

Step three: searching for themes

Once both datasets were coded, each code was then reviewed with the purpose of establishing patterns and sorting them into meaningful groups. New codes termed sub-themes were created in Nvivo to facilitate the sorting and organisation of these patterns.

Step four: reviewing themes

The coded data assigned to each sub-theme was reviewed for suitability and collapsed into new overarching themes that reflected their properties. A thematic map was developed to illustrate the refined properties of each of the themes identified for HCPs and patients (see Figure 4.2 and 4.3).

Step five: defining and naming themes

Once refined, each theme was defined and theme names established. During the refining process the extracted and coded data was reviewed to ensure each theme told a story that addressed the research objectives.

Step six: producing the report

The results of the thematic analysis are presented in two separate written narratives addressing the experiences of HCPs and patients who use opioids to treat CNCP. Verbatim quotes are used to depict the essence of each theme and are labelled according to interview group (i.e. HCP or P(atient)) and participant number (e.g. HCP1 or P2). The thematic analysis for HCPs is presented first and subsequently lead by the patients.

## Quality and rigour

Quality and trustworthiness are key concepts in legitimatising the standard of qualitative research. To depict this, Yardley's (2000) four point criteria was used to demonstrate, 1) sensitivity to context, 2) commitment to rigour, 3) transparency and coherence and 4) impact and importance (Yardley, 2000). The criteria developed by Yardley was chosen as she draws on standards of qualitative research specific to health psychology, similar to the context of this study. The steps taken to demonstrate the consideration of Yardley's criteria are outlined in table 14 below.

| **Criterion** | **Steps taken in research** |
|---|---|
| Sensitivity to context | *Theory and literature:* a review of the literature provided insight and understanding into the theories of pain and how its complex nature requires a biopsychosocial approach to treatment. This helped inform questions for the interview guide.<br><br>*Sociocultural factors:* data largely reflects questions from the interview guides thus might limit certain insights, but participants were probed to elaborate on discussion points to help clarify their subjective experiences. There was need to be sensitive toward the varying contexts of HCPs and CNCP patient's perspectives where insights on the same topic was shared.<br><br>*Participant's perspective:* a semi-structured interview guide was developed constructing open-ended questions allowing participants to elaborate on their experiences subjectively.<br><br>*Ethical issues:* participants identity and any identifiably information exposed during interviews was concealed throughout. The balance of power was ensured by identifying the participant as the expert and how their experience would improve existing knowledge. Reflective summaries were also used to establish clarity in participants meaning. |
| Commitment to rigour | *Engagement with topic:* the researcher was fully immersed in the data having conducted and transcribed verbatim the interviews and iteratively coded and interpreted the data. Participants also had extensive experience as either CNCP patients or HCPs.<br><br>*Methodological competence:* the thematic analysis framework of Braun and Clarke (2006) was systematically followed. Coding and themes were reviewed by a member of the supervisory team (HP) who has extensive experience in qualitative |

| | |
|---|---|
| | research methods and compared with interpretations of the data conducted separately by two MSc students.<br><br>*Data collection:* interview guides (one for HCPs and one for patients) ensured a flow of topic consistency throughout participant interview. Recruitment ceased when no new information emerged from the interviews, indicating data saturation.<br><br>*Depth/breadth of analysis:* varying insights from HCPs with different expertise and patients at different stages of weaning were gathered. This helped determine a collective representation and triangulation of differing perspectives. |
| Transparency and coherence | *Clarity and power:* themes identified were data driven and supported by participant quotes throughout. A paper trail of this development is depicted across appendices 15-18. Establishing perspectives from a range of participants provides clarity around reoccurring issues and potential ways to overcome them.<br><br>*Transparency of methods and data:* a detailed description of the data collection process is described, followed by a dense presentation of the data that is supported by participant quotes. Also see the paper tail in appendices 15-18.<br><br>*Theory and method:* using thematic analysis facilitated an exploration of the subjective lived experiences of living with and treating CNCP with opioids. This pragmatic approach suited the philosophical position of the researcher and facilitated mixing data from differing perspectives to uncover in depth knowledge about opioid weaning.<br><br>*Reflexivity:* the position of the researcher was clearly set out at the beginning of this thesis (see Chapter 1, section 1.4). Briefly, the researcher had limited prior knowledge on the issues that surround CNCP before initiating this research. Mainstream media influenced early perceptions of the severity of using opioids to manage CNCP and subsequent need to reduce them.<br><br>This research changed that perspective, demonstrating a broader view of the topic from perspectives of participants, literature, and scientific meetings. A more thorough understanding has been obtained indicating a small but significant CNCP population at risk of harm from opioid treatment; and although opioids may still be beneficial at small doses, there is need to reduce the risk of harm and optimise pain management among patients who are not benefiting from their use. |
| Impact and importance | *Theory:* the research findings support the need to follow the biopsychosocial framework to improve the treatment and management of CNCP. It also indicates it is not currently well implemented in primary care and the need to establish ways to better integrate the psychosocial element of the biopsychosocial model to early pain management.<br><br>*Socio-cultural:* barriers and enabling behaviours were identified that might hinder or facilitate opioid weaning in primary care. The insights learned have been used to theoretically inform a behavioural change intervention aimed at reducing opioids with the potential of reducing risk of harm and optimising pain management.<br><br>*Practicality:* understanding the behaviours of end-users involved in an opioid weaning intervention will help advance research and help identify practical solutions to arising problems. Involving end-users is crucial to development of services including behaviour change interventions, as well as their success. |

**Table 14. Strategies for ensuring quality and rigour in qualitative research**

## 4.4 Results: Study 2a – insights to Health Care Professional's experiences of treating CNCP patients

The interviews with HCPs highlighted the diverse and complex nature of treating CNCP patients, there is no absolute treatment applicable for all patients, and this inevitably results in the trial and error of various treatment plans. There is consensus among HCPs thatnon-opioid treatments are initially trialled and often encouraged throughout a patient's treatment journey. However more often opioids feature as a main component of patients' treatment package and the longevity of their condition and its treatment, often sees patients transitioning through the health care system consulting with different HCPs. The HCP interview analysis resulted in three common themes 1) **Initiating treatment**: explored different treatment approaches including pharmacological and non-pharmacological options and discussion around the efficacy of using opioids and managing an opioid weaning plan. 2) **Working with patients**: uncovered what it is like to treat CNCP patients, the difficulty of managing their co-morbidities and how patient knowledge contributes to understanding treatment plans. 3) **Health Care System**: explored the transitional movement of patients through the HCS, barriers that arise during this process and role and responsibility of HCPs involved in patient's treatment. Collectively these themes provide insight into HCPs experiences and identify the barriers, challenges, and successes of treating CNCP patients. Figure 4.2 below illustrates key themes and subsequent sub-themes that encompass the HCP

experience.

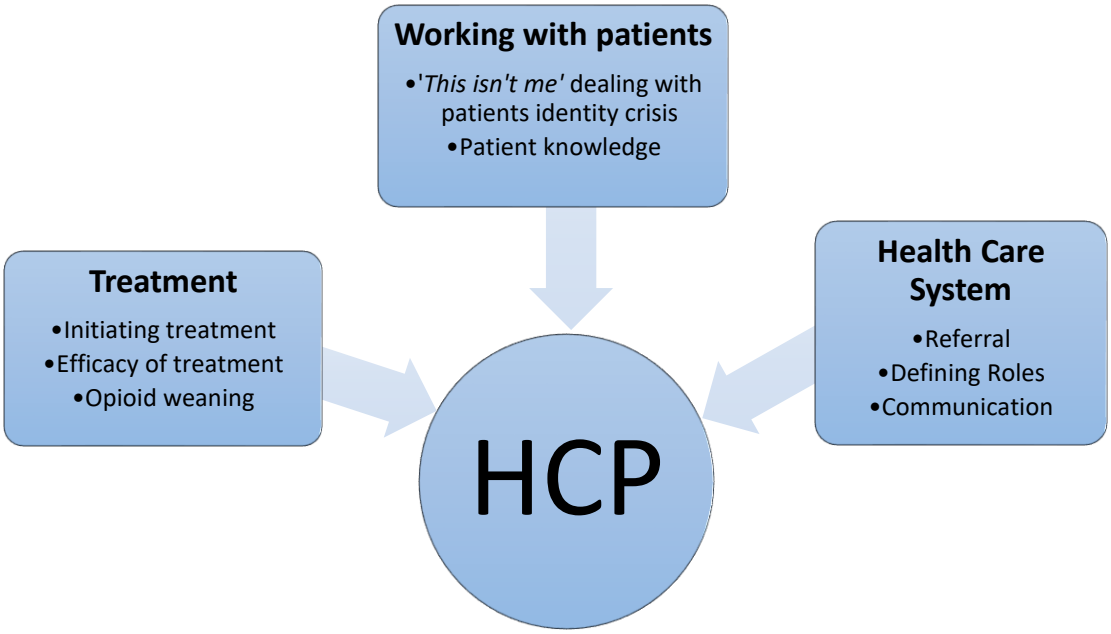


**Figure 4:2: Thematic map of interview analysis with Health Care Professionals (HCP)**

### 4.4.1 Treatment

CNCP is treated with pharmacological and non-pharmacological methods or a combination of both. The synergy between these two treatment options is discussed here. Specifically, the efficacy of opioid treatment for CNCP and the difficulties HCPs report when initiating and maintaining opioid weaning regimes with patients. Treatment outcomes may include a measure of pain relief as well as improved daily wellbeing and functioning therefore, multicomponent pharmacological and non-pharmacological treatment plans are often required. To ensure patients are benefiting from treatment it is important to review and monitor progress and consider ways to optimise treatment where needed. The insight gained from HCPs experiences provides an overview to inform how treatment may be optimised.

<u>Initiating treatment</u>

The most common pharmacological treatment prescribed for CNCP and main focus of this research is opioids. Initially, HCPs highlighted that non-pharmacological therapies (e.g., physio or acupuncture) should be prioritised before opioid treatment. Although in practice such options may not always be available, particularly in the community.

*"Oh most definitely, we explore non-opioids and alternative treatments and physio therapy way before we get to opioids" (HCP16, Prescribing Pharmacist)*

*"Within the health care setting in primary care there aren't really any alternative treatments, I mean people can go to the voluntary sector and get acupuncture, massage… but we aren't providing that service to them" (HCP26, GP)*

Deciding whether or not to initiate or continue prescribing opioids was something HCPs reported feeling adverse pressure about. This was due to being unsure of the indication of opioids for certain conditions, establishing optimal doses and determining whether patients were drug seeking. It was particularly challenging for GPs who reported simultaneously feeling pressurised "*do something*" (HCP24, GP) and the perception that prescribing is perhaps the most immediate and "*easiest thing to do*" (HCP16, Prescribing Pharmacist).

*"They [patients] just want someone to do something, you know they're like please help me and the GP Feels pressured… the easiest thing to do is to dispense" (HCP7, Physiotherapist)*

"*I think that's why some primary care prescribers and clinicians often will allow medications, to do something, its 'an' intervention, its whether that intervention is the appropriate one*" (HCP26, GP)

Throughout the interviews it was more common for HCPs in tertiary care to discuss initiating opioid weaning as they were often confronted with patients on high doses by the time of referral. Their capacity and access to MDT treatment, including Pain Management Programmes (PMPs) covering, pain education sessions, medication education, psychological support, and physiotherapy facilitated this.

"*My problem is that now I'm going to stop or decrease your [patient] opioid, that's a bigger problem because they're usually on high doses before they come to us*" (HCP19, Pain consultant).

*"It's an MDT programme… mostly the three main components are psychology, occupational therapy and physiotherapy… so we are tackling peoples physical functioning, fitness and rehab" (HCP10, Consultant Psychologist)*

The recurring message from HCPs was that any treatment should not be seen in isolation; rather a multi-model plan should be initiated as part of a holistic treatment approach. Specifically, HCPs suggested that patients should not solely rely on pharmacological treatments to address their pain and likewise alternative treatments should be accompanied by supportive pain management plans. This was linked to the limited efficacy of opioid treatment on its own, which is discussed in the next theme.

*"I would use it [opioids] when its appropriate… or as part of multi-modal therapy so that would not only mean medication it may mean neuromodulation, physiotherapy or rehabilitation and part of pharmacological treatment pathway" (HCP19, Pain consultant)*

<u>Efficacy of opioid treatment</u>

HCPs agreed that opioid medication for CNCP has limited efficacy, particularly for some pain conditions (e.g., "m*usculoskeletal pain and back pain painkillers are only limited in their efficacy*" (HCP7, Physiotherapist)). This makes establishing whether patients will be responsive is difficult to predict. As a result, HCPs discussed having to work through an algorithm to find the most effective treatment. The issue with this however is the time taken ("*probably give them like 2 or 3 months*" (HCP13, Nurse)) to trial each drug and then having to wean patients off the drug if it is not indicated or beneficial.

*"We've got to work through like an algorithm of what we like do and as we get so far, we can test the effectiveness of the medication and say ok that's not, that's not been effective, next" (HCP13, Nurse)*

Recognising opioids lack of efficacy, HCPs were concerned that they continue to be prescribed long-term and at increasing doses. This also linked into concerns around when an acute prescription inadvertently become long-term and determining indication for increasing the dose or strength of an opioid.

*"Opioids they only last for so long the effectiveness and we're going up and up and up on the erm doses" (HCP13, Nurse)*

"*If they* [patients] *tried the moderate strength opioids and they still don't respond to it whether they do respond to the high strength opioids" (HCP16, Prescribing Pharmacist)*

To address some issues of efficacy HCPs acknowledged that there needs to be a measure of mutual understanding and expectation of treatment outcomes from both practitioner and patient.

*"They [patients] don't want to be in pain and they want you to help them and their ideas of how you are supposed to help them isn't in keeping with what our ideas are" (HCP25, GP)*

As such, when consulting with patients, HCPs discussed the importance of conveying realistic expectations about the efficacy of any medication that is recommended. For example, HCPs reported ensuring that patients comprehend that "*medication is one part of it* [their treatment]" (HCP26, GP) and "*no matter what medication you're taking it won't get rid of the pain*" (HCP10, Consultant Psychologist).

*"We always mention from the start that any medication is probably only ever really going to give 30-50% pain reduction so it's trying to set that expectation from the start" (HCP7, Nurse)*

HCPs also reiterated that patients themselves recognised opioids lack of effectiveness, they discussed how patients claimed it only "*takes the edge off*" (HCP10, Consultant Psychologist), yet they continue to take it regardless. This instilled a perception among HCPs that patients perhaps become reliant on opioids and are often left feeling "*it's better than nothing*" (HCP10, Consultant Psychologist).

*"They [patients] rely on the medication and that's often if you speak to them it hasn't actually done that much for them in terms of pain" (HCP25, GP)*

When conversations about efficacy occurred with patients, HCPs discussed how they use this as an opportunity to encourage patients to consider an "*opioid reduction*" (HCP11, Nurse) or to "*just take the medication when the pain is bad*" (HCP25, GP). However, there comes a point in a patient's treatment journey where HCPs recognise that none of the pharmacological options are providing the patient with any benefit and only increasing risk of harm. They describe this as "*hitting a wall*" (HCP13, Nurse) and the point at which opioid weaning needs to be considered.

Weaning

Opioid weaning in CNCP patients occur in both primary and tertiary care, although some primary care practitioners preferred to refer their patients to drug services, traditionally accessed by people who use illicit opioids, crack cocaine, or other controlled drugs.

*"They [drug services] are the best people to deal with that I think, erm rather than the GP, they will be seeing them just for that reason [opioid weaning]… it's not an ideal situation for the GP to be doing it (HCP25, GP)*

A reason given for this was that GPs find it difficult to manage opioid reductions due to restricted consultation times, in which they are also treating the multitude of medical problems patients present with. It was common therefore that GPs expressed frustration that the current system does not account for these difficulties and called for more MDT support in primary care.

*"These chronic patients usually have masses of comorbidities whether that is mental health or other comorbidities or a mixture of the two…to get clarity in 10 minutes is incredibly difficult" (HCP24, GP)*

*"You need MDT support I don't think it is a discipline [opioid weaning] that can successfully work with someone who is on a higher amount of opiates and most likely psychosocial difficulties as well" (HCP26, GP)*

Prescribing pharmacists were able to reduce some of the clinical pressure from GPs as evident from their interviews. The extension of their role provided the capacity to better manage

opioid reductions, offering patents longer appointment times and being able to review and monitor opioid prescriptions. This support however is not widely available as none of the GPs interviewed had a prescribing pharmacist at their practice.

*"In this practice it probably would be myself that would take care of opioid reductions, so we do have a template and we do have a process for such people" (HCP16, Prescribing Pharmacist)*

*"The majority of them [patient referrals] either come from the GP at the practice or similarly kind of meds management colleagues" (HCP5, Prescribing Pharmacist)*

In contrast, tertiary care has the advantage of a co-located MDT who often work in synchronicity to better manage opioid weaning. For example, pain specialist nurses may focus on developing and monitoring the weaning plan but will also refer to psychology for additional support.

*"Patients can request a meeting with us to go through their medication list… we rationalise it; can we get the medications down any further?" (HCP13, Nurse)*

*"They [patients] come in scared and anxious about this plan and it's trying to coax them around or reassure them around what the plan is… how stress can increase pain and how psychology can help manage that" (HCP7, Nurse)*

Tertiary care has the resources of psychologists who employed a range of psychological therapies such as Cognitive Behavioural Therapy (CBT) and Acceptance and Commitment Therapy (ACT) to help patients live better with their chronic pain conditions. These HCPs did not specify any particular method to support opioid weaning, instead the type of therapy used would often depend on the patient and the goal of their treatment outcomes.

*"I would probably use CBT to outline some of the unhelpful cycles… we don't just use CBT we use approaches from ACT, mindfulness, sometimes motivational interviewing. I don't think we've got that far yet to know what we would use in an opiate specific group" (HCP28, Psychologist)*

Overall, HCPs understood the adversity patients face when engaging with opioid weaning and recognised the need to offer regular appointments, telephone support lines or recommend referral for psychological support.

*"I am happy to see you on a weekly basis til this is done, you know I can offer you regular appointments, you know I think its about providing that support around reducing" (HCP24, GP).*

Consistently however, opioid weaning was highlighted as the treatment HCPs needed more support with, particularly in primary care. It was clear that perhaps there is an over reliance on opioids to treat CNCP which is particularly for HCPs in primary care where resources are limited. Understanding what it is like to work with CNCP patients will help indicate what is needed to facilitate a successful opioid weaning plan. This is discussed in the next theme.

### 4.4.2 Working with patients

Treating a patient with CNCP requires more than just treating the pain symptoms and HCPs should consider the wider impact of pain on patients' wellbeing. This theme discusses content referencing HCP's experience of what it is like to work with and treat patients with CNCP. This includes unpicking the psychosocial adversities; patients' knowledge and understanding and the role this can have on positive treatment outcomes; how HCPs respond to stigma and stereotyping and patient drug seeking behaviours. This theme provides a sense of context for what clinicians deal with and have to consider when deciding on and engaging patients in treatment plans.

<u>'This isn't me' – dealing with patients' identity crisis</u>

Working with patients who experience CNCP can be challenging for HCPs. Often the difficulty that HCPs described come from the intangible adversities (e.g., "*depression, anxiety, anger, guilt, injustice*" (HCP10, Consultant Psychologist)) that followed patient's inability to live a normal life due to their chronic pain.

*"People can go from being quite successful… have a good family structure and a good relationship… good group of friends and over time they can become gradually more isolated… can't socialise, they can't carry on with leisure activities and sometimes there could be relationship problems" (HCP5, Prescribing Pharmacist)*

The psychosocial impact of chronic pain meant that HCPs had to sometimes "*struggle with getting patients on board*" (HCP13, Nurse) and unravel patient's conflict around accepting a new self.

*"This isn't me, you know I was never like this, this is not my life you know, I've changed completely, even my personality has changed" (HCP10, Consultant Psychologist describing a patients experience)*

Alongside this HCPs discussed having to manage the non-communicable aspect (i.e., the invisibility) of patients' chronic pain. This was believed to attribute to patient's psychological distress increasing their fear and anxiety about making their pain worse. A combination of these factors was enough to provoke disengagement with treatment and HCPs often found patients would "*back lash*" (HCP24, GP) making challenging conversations about treatment difficult to have.

*"The intensity of their pain has led them to believe there must be something significantly wrong" (HCP7, Physiotherapist)*

It was more common for HCPs in tertiary care (where patients presented much later in their pain treatment journey), to explore and unpick these behaviours. For example, psychologists discussed how they focus part of their therapy on patients "*Identity… self-esteem… self-efficacy… around acceptance and adjusting of pain*" (HCP10, Consultant Psychologist). Additionally, the negative connotations linked to opioids implicitly contributed to patient's identity crisis. HCPs often recalled how patients would get defensive about their opioid prescription and feel the need to distinguish themselves from people who experience problems with drug use.

*"It's empowered I'm not a drug addict'…and it's their [patients] belief that actually they're fundamentally different from the people who are just drug seeking in a counter way" (HCP26, GP)*

To help ease patient's anxiety surrounding this stigma one HCP shared how she advised her patients to use different terminology (e.g., "*Physeptone instead of Methadone*" (HCP11, Nurse) when collecting their prescription. At the same time, HCPs were also aware that they needed to stay alert toward potential drug seeking behaviours. For example, some HCPs reported how patients who were more intellectually articulate would manipulate the system to get what they want "*she always talked the talk and was aware of strategies*" (HCP5, Prescribing Pharmacist). Identifying these behaviours was challenging for HCPs, as it was equally important they did not "*judge or stereotype patients*" (HCP25, GP).

*"If you've been in the practice for a number of years you know your patients… and you've a sort of idea as to whether they might run into problems… its not an objective risk assessment its sort subjective and a sense of whether it [to prescribe] is the right thing to do"*
*(HCP26, GP)*

<u>Patient Knowledge</u>

To some degree all HCPs either directly linked or insinuated that patient's lack of knowledge and understanding of CNCP and its treatment impacted on their response to treatment. For example, the discussion around treatment expectations (as reported in the treatment theme above) implies that due to a lack of knowledge, expectations of treatment outcomes can be misaligned. Subsequently this may impact on issues of trust, disappointment, and engagement when certain expectations are not met. The discussion in this theme expands upon this, identifying issues around the delivery and receipt of information on patient's knowledge.

*"I don't think anybody is given enough information. We certainly don't give them leaflets"*
*(HCP24, GP)*

There were inconsistencies among HCP perceptions about who should be responsible for educating patients before initiating opioid treatment. Mostly, when it came to providing information to patients HCPs defaulted to the information leaflets provided inside prescriptions which placed the onus on the patient to inform themselves.

*"It depends on their capacity and level of education, all patients are given sufficient information out of the packaging" (HCP16, Prescribing Pharmacist)*

This seems counterintuitive when HCPs highlighted how patients "*aren't particularly diligent at reading the information*" (HCP1, Pharmacist) and how they would "*underplay*" (HCP10, Consultant Psychologist) or do not comprehend the information provided. For example, HCPs described how medication would impair patient's cognitive ability or how they would misinterpret the long-term implications of their treatment.

*"I think they do read it, but I don't think they are able to associate the long-term implications of it… particularly with the tolerance and dependency" (HCP11, Nurse)*

*"I think patients are given information but how much they can absorb and retain it's a problem because they are on amitriptyline, pregabalin, gabapentin, they all make you cognitively impaired" (HCP19, Pain consultant)*

It was predominantly HCPs from tertiary care who discussed delivering education sessions to patients as part of PMPs. Generally, HCPs recognised the need for the education provider (i.e., the HCP) to be "*updated on the latest evidence base and guidance*" (HCP5, Prescribing Pharmacist) and for specific pain modules to be implemented within the medical training curriculum.

"*I do regular talk with patients about the long-term use of meds and one of the topics which bothers my patients most is the opioids and I would be discussing that on a regular basis*" (*HCP19, Pain consultant*)

"*It's an education thing… this should be getting done right from medical training and the chronic pain curriculum in medical training*" (*HCP10, Consultant Psychologist*)

Furthermore, HCPs also felt that there was a sense of complacency in patients who simply took HCPs word rather than query any treatment recommendations.

*"I think they have this inherent belief that well the GP would never have given it to me if it was gonna be that harmful" (HCP10, Consultant Psychologist)*

*"It tends to be the older patients who, they'll see the clinician as the font of all knowledge and they just… I trust you" (HCP26, GP)*

As a result, HCPs noticed more patient disengagement and frustration when changes were made to treatment plans, particularly from HCPs who were unsure or less confident in prescribing opioids for CNCP.

"*If they're not necessarily completely understanding the plan… they just simply won't turn up for their appointment*" (HCP11, Nurse)

"*I think fear is often driven by a lack of understanding and that's in the patients and the clinicians, which is why we want local guidance*" (HCP26, GP)

HCPs have highlighted here that their role involves a lot more than simply treating pain symptoms and they perceive patients need a much more guided approach and education around treatment. This may be particularly challenging for primary care HCPs who have limited capacity and access to alternative treatments, e.g., psychoeducation and support. An understanding of how the Health Care System (HCS) operates will provide further insight into the challenges of optimising patients treatment.

### 4.4.3 Health Care System (HCS)

Patients with CNCP are likely to be treated by one or more of the three levels of care (primary secondary and/or tertiary care) offered by the UK NHS. Differences between health care pathways at the various levels of care are generally bound by specific areas of expertise, knowledge, and availability of specialised treatment. This theme describes HCP's experiences of integrating tertiary and primary care services via the referral system, perceived job role responsibilities and highlights the challenges of communicating across levels of care.

<u>Referral</u>

Whilst discussing the context of patient's treatment with HCPs, the process of referral often emerged. There was noticeable disparity between primary and tertiary care HCPs regarding when a patient is referred to specialist care. In primary care, HCPs suggested that it is usually after a "*couple of treatment failures*" (HCP16, Prescribing Pharmacist) or when patients reach

a prescribing threshold whereby HCPs did not feel comfortable prescribing higher doses. In contrast, tertiary care discussed how it could be years before patients are referred to them from primary care.

*"We would refer at 60 [mg of morphine or MED] or you would get help and advice from someone with specialist interest in pain" (HCP26, GP)*

*"By the time we see people who you know we have people who are twenty-five years plus in pain" (HCP10, Consultant Psychologist)*

The issue for HCPs in tertiary care was that often by the time they usually see patients a series of unhelpful behaviours have already developed and are difficult to undo or change. This can make it challenging for HCPs to engage patients into treatment, exacerbated by experiences or misconceptions that may shape negative perceptions and subsequent intentions to engage.

*"I think if you were to see people a lot earlier on, hopefully we would have prevented some of those disability cycles" (HCP10, Consultant Psychologist)*

*"Some people might not want to come to a group, they might you know not see the benefits so we might not be able to engage them in that" (HCP28, Psychologist)*

The nature of the referral system means that HCPs see patients "*go through the medical roundabout for quite some time*" (HCP10, Consultant Psychologist), transitioning back and forth between a range of HCPs such as, "*orthopaedics, neurosurgeon or neurologist*" (HCP19, Pain consultant). This inherently brings about additional issues associated with referral waiting times, e.g., "*two to three months for a consultant appointment*" (HCP11, Nurse) and risk of fragmenting care as more HCPs become involved.

*"It can become really easily fragmented care, so you know if patients under a physio and a consultant potentially under neuro as well pain management, you know someone like me, and then they don't generally see the same GP within the practice… they can become lost in the system" (HCP5, Prescribing Pharmacist)*

This demonstrates that the HCS is not always linear and sometimes HCPs have no option but to refer the patient back to community care or another pain consultant, where the process may start again.

*"If patients don't want to do what you've suggested or recommended, its back to the GP or back to the consultant" (HCP7, Nurse)*

Defining Roles

Tertiary care has specialist staff with expertise in treating CNCP, whereas for many HCPs in the community it falls within their wider job role (e.g., GPs). This sub-theme highlights the crossover of patient responsibility when multiple HCPs become involved in patients care and identifies where issues arise in delivering optimal levels of care.

HCPs described a sense of hierarchy of patient responsibility that existed alongside other members of the healthcare team. This hierarchy placed more accountability and decision making onto pain consultants or specialist trained nurses. Aligned with this was also an assumption about what HCPs roles entailed, for example, it was presumed that HCPs developing opioid weaning plans would simultaneously counsel patients in preparation of weaning. This assumption potentially risks overlooking important elements of care and places disproportionate responsibility onto unskilled HCPs.

*"I think the work is done by the kind of pain consultants and nurses, they're the ones who kind of do the reduction plan and im sure they do a lot of counsel of that you know and prepping people for that" (HCP10, Consultant Psychologist)*

The impact of making assumptions was evident from discussions with specialist pain nurses, who described inheriting job role responsibility that sits outside of their remit. Here nurses highlighted the need for more psychological support as they felt ill-equipped to adequately deal with patient's mental health.

*"In our opioid team we don't have any psychological support… I'm no psychologist, I'm no mental health nurse none of us are, we get phone calls and you know a lot of these patients are very suicidal… that's not something that's ever really been trained with us" (HCP13, Nurse)*

HCPs recognised the need to improve ways in which CNCP patient care is currently being managed such as, monitoring and reviewing prescriptions, scheduling MDT meetings, and providing education. However, many felt that in the current climate their job role capacity has already reached its limit restricting their ability to do what is needed.

"*You actually have to try and set up multi professional meetings to try and contain the situation but that's rare and people don't have time for that*" *(HCP10, Consultant Psychologist)*

"*To be honest there just isn't the time erm to do that at the moment* [review patient medication], *erm I don't think there is ever going to be the time to do that" (HCP25, GP)*

Only two HCPs from primary care discussed being able to adequately manage CNCP patients. This seemed to only occur when there was a small number of patients or a where a prescribing pharmacist was involved to offer support.

*"As a practice we've set up a template for chronic pain… we also have resources in the practice formulary that with chronic pain non-cancer pain we tend to assess quite prudently in response to opioids" (HCP16, Prescribing Pharmacist)*

*"The majority of people won't be using very strong opioid medication, so we, you know certainly in our practice we are aware who is and what we try and do is monitor that" (HCP26, GP)*

To help overcome some of these barriers and better manage patient care, HCPs proposed having a "*nominated prescribing clinician*" (HCP16, Prescribing Pharmacist) to take responsibility of opioid prescribing. This was also considered useful to target issues around patients who 'doctor shop'; an approach that involves patients seeking out lenient doctors they consider more likely to prescribe a particular medication.

*"Employ a specialist Dr to just go round every surgery and try and take people off these medications, I think that is something that could be good for the future" (HCP25, GP)*

*"We find that patients will kind of go to different Drs in the same practice and then stick with the Dr who they feel is the most lenient Dr in terms of prescribing" (HCP25, GP)*

Facilitating HCPs in delivering treatment of best practice depends largely on the interconnectivity between them. Understanding HCPs communication network may help identify weaknesses and where improvements are needed to ensure everyone involved in patient's treatment are delivering what is expected from their individual role. This is further expanded on in the next theme, communication.

Communication

Communication is a central theme. It is evident throughout every theme in this analysis as it is an intricate part of the treatment journey. It includes dialogue between a patient, patients' relatives, and HCPs or between HCPs themselves. Whichever way information is communicated, HCPs report many instances where it has worked well and where it gets lost or breaks down. This theme encompasses content from HCPs perspective about communication, issues and methods of communication and risk communication. Lines of communication were considered satisfactory "*we have pretty good lines of communication*" (HCP11, Nurse) when HCPs were co-located. Often this principle operated an open-door policy to encourage dialogue between HCPs.

*"Usually if I have a concern, I usually walk down and, and try to find the person whom I need to discuss the case" (HCP19, Pain consultant)*

*"I've got the two consultants that I can kinda pick their brains and ask for their help with something" (HCP5, Prescribing Pharmacist)*

It was apparent however that when dialogue is extended outside of an internal infrastructure that the lines of communication become blurred. For example, tertiary care nurses explained how the shortage and high turnover of GPs meant that there was no consistent community representative to refer patients back to.

*"A massive shortage of GPs the turnover is so high that we're not consistently able to get communication with the same person" (HCP13, Nurse)*

Furthermore, tensions as a result of communication breakdown was visible between tertiary and primary care HCPs, particularly where there was disagreement around following treatment recommendations. For example, HCPs in tertiary care expressed concern that primary care do not always adhere to treatment plans. However, GP interviews indicate this is because they have often already been unsuccessful in trialling treatment approaches suggested by tertiary.

*"I think communicating with the GP's is particularly difficult at times, erm they don't always act on what we ask them to do…. or they will not be willing to take over prescribing of something" (HCP11, Nurse)*

*"A lot of the stuff they say we have already done, we have already been down that pathway and there is nothing new erm so yeah I don't think I've received much communication" (HCP24, GP)*

The method and fluidity of how information is shared between HCPs was another commonly identified issue. It was often the case the HCPs did not have the most relevant and up-to-date patient information due to the fact they "*don't have a combined, joined up system*" (HCP10, Consultant Psychologist). Instead, HCPs discussed how they rely on letters or past patient notes, which can cause a "*bit of disconnect*" (HCP1, Pharmacist) in contextualising a patient's treatment history and previous treatment.

"*Information should be shared more readily and people, there will be information on the EMIS that you know will be helpful for other care Dr's to know*" *(HCP25, GP)*

"*All we do is write letters to each other and I think that's where things fail as well you know, primary, secondary and tertiary care we don't have a very clear communication network*" *(HCP10, Consultant Psychologist)*

The risk of relying on letters is that there is no systematic way of confirming the right people received the relevant information. Equally HCPs find that liaising with patients this way may not always be reliable.

*"They'll [patients] say this Dr said I can increase the dose to this amount and its not what is written on the prescription … they just play Dr's off each other" (HCP25, GP)*

*"I'd initially send them [patients] a letter saying please make an appointment… I would send out about 20 letters and 4 would make an appointment" (HCP5, Prescribing Pharmacist)*

In effort to mitigate the breakdown of communication, HCPs identified the need for regular MDT meetings, combined forms, specialised hotlines, or email accounts. These provisions where considered as potential developments in improving the interconnectivity of those involved in a patient's treatment.

*"I think a forum or a, I don't know erm so for instance the same way radiology has a GP hotline, something like that maybe erm or maybe an email service" (HCP24, GP)*

*"I think we would like to encourage more phone calls and if possible, occasionally we have invited the GP to come in and have an MDT alongside the patient as well" (HCP28, Psychologist)*

The overall consensus among HCPs indicate a clear need for improved lines of communication throughout different levels of the health care system. It is important that communication is timely, accurate and shared with the right people. HCPs have identified the need for a better information sharing platforms for HCPs and opportunities to develop dialogue with patients (i.e., via the pharmacist) which should be considered in future developments.

## 4.5 Summary

The experiences of HCPs treating CNCP patients have been captured and depicted across three main themes: treatment, working with patients and the Health Care System (HCS). These themes interlink in a way that the treatment theme outlines different treatment approaches that HCPs use, this feeds into the complexity of actually delivering treatment to patients (working with patients) and the interplay of the HCS in providing the network to operate within. Communication was common across all these themes, this included how well

HCPs communicated with patients as well as restricted network access between levels of care within the HCS. The themes are summarised here.

**Treatment**

CNCP patients are often recommended two lines of treatment by HCPs; pharmacological and non-pharmacological, yet ultimately HCPs acknowledge that the best line of treatment is a multi-modal approach combining these two options. Due to the limited treatment provisions available in primary care, non-pharmacological treatment such as PMPs are not accessible until patients are referred to tertiary care; by which point patients have been on a "*medical roundabout*" (HCP10) for a substantial period of time. As a result, GPs are often pressurised to "*do something*" (HCP24) and often default to prescribing opioids. HCPs discussed the importance of ensuring patients understand the limited effectiveness of opioids in eradicating their pain and emphasised the need to set realistic expectations of patient treatment outcomes. GPs appeared to be less confident in managing opioid treatment than HCPs in tertiary care and called for more clarity on indication of use and guidance on when to increase doses. This also applied to managing opioid weaning plans whereby GPs were aware of the techniques used (i.e., reducing doses slowly) but they found it difficult to manage due to the variability of health complaints that CNCP patients present to clinical appointments with. As a result, GPs strived to provide the optimal level of care needed thus preferred to refer to specialist services.

**Working with patients**

The main issue that GPs reported experiencing when treating CNCP patients is their incapacity to adequately support the interplay of wider health and well-being adversities that accompany chronic pain (e.g., psychological, sociological, physical and economic impact). These encompassing factors make it challenging to treat patients as they struggle accepting a different, potentially life-limiting identity. Furthermore, the inherent stigmatisation surrounding opioid use meant that patients felt the need to justify requesting them, but equally created heightened caution amongst some prescribing HCPs. Simultaneously, HCPs had to manage multiple problems whilst also being alert to potential drug seeking behaviours i.e., unreasonable requests for more medication. Consistently, HCPs highlighted the lack of

patient knowledge on opioid treatment and chronic pain as a health issue, which they considered to negatively impact on patient's treatment engagement. Difficulties occurred in providing information to patients, including a lack of HCPs (namely GPs) confidence in delivering information, and HCPs concerns regarding patient's cognitive capacity to comprehend the information provided.

**Health Care System**

The nature of long-term treatment for CNCP often sees patients transition through different levels of care in the NHS, mostly facilitated by primary care and referrals to specialist services in tertiary or secondary care. The disadvantage of referrals are their inherently long waiting lists which mean that by the time patients are seen in tertiary care, they have already established unhelpful coping behaviours, which tertiary HCPs struggle to address, alongside initiating and managing opioid reductions. Other barriers inherent to the HCS that affect patient's treatment include, access to MDT support, limited consultation times and inefficient communication between HCPs involved in a patient's treatment. The involvement of HCPs from different levels of care risks fragmenting lines of communication, particularly with those who are not co-located. This is exacerbated by the inconsistency of HCPs that patients see in primary care and the turnover of staff who are considered responsible for patient cases.

## 4.6 Results: Study 2b – insights to patients experience of CNCP treatment

Analysis of patient data provided insight into the experiences of patients as they transitioned through receiving opioid treatment. The results presented here depict the lived experiences of patients who have either successfully discontinued their opioid treatment, are undergoing a weaning plan or who are considering initiating an opioid reduction. Overall, patients expressed dislike toward opioids and generally resented the accumulated side effects that accompany their use. Simultaneously, the sensation of pain without opioids was considered too overbearing, leaving patients conflicted due to limited other alternative treatment options. The interviews with patients identified three main themes, 1) **The treatment journey**: explores the series of experiences patients transition through and how well they adhere to and communicate with HCPs. 2) **Living with opioids**: explores the trials and difficulties patients experience with having to take opioids, how effective they perceive them to be and alternative ways to manage the their pain. 3) **Weaning experience**: explores the different methods used, how patients respond to weaning, and the support needed during and after completing a weaning plan.

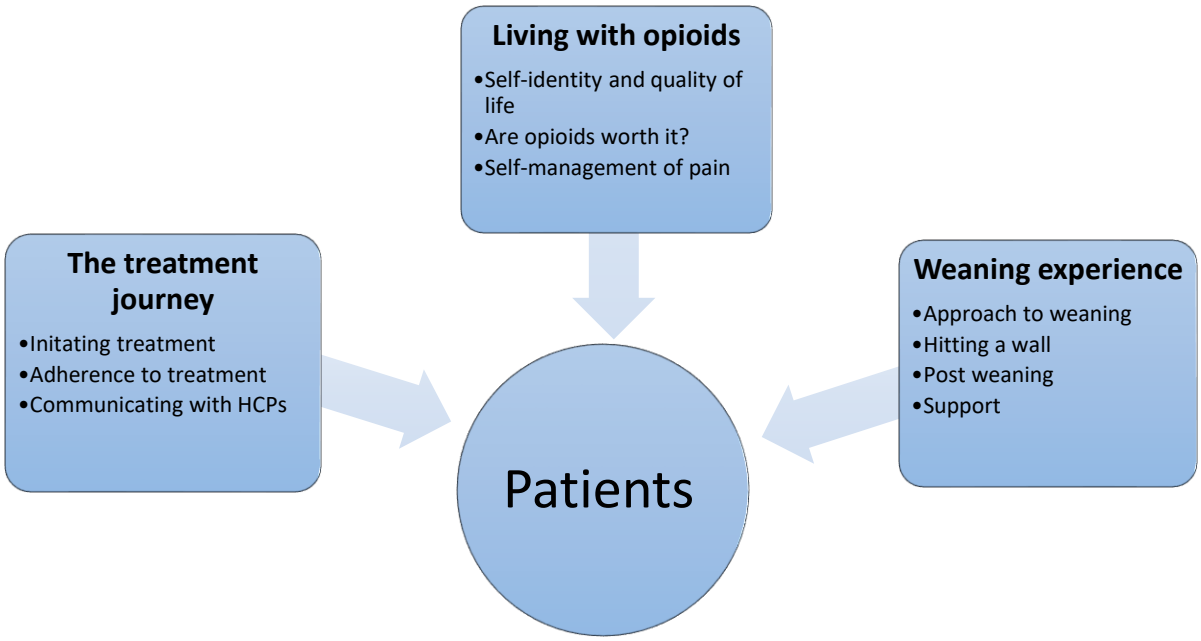


**Figure 4:3: Thematic map of interview analysis with patients**

Patient background

Table 15 below provides contextual information about the patients who were interviewed including some biographic information and self-reported encounters with opioid medication and report complaints of pain or diagnosis.

| Stage of weaning | Patient | Age | Sex | Employment status | Reported pain | Opioid medication |
|---|---|---|---|---|---|---|
| Initiating weaning | P4 | 69 | M | Unemployed | Degenerative disc disease | Previous use of ibuprofen and Buprenorphine. Currently prescribed oxycodone. |
| Initiating weaning | P23 | 43 | F | Unemployed | Shoulder pain | Previous prescriptions for morphine, oramorph and fentanyl lollipops. Current weaning using oxycodone and Oxynorm. |
| Currently weaning | P2 | 55 | F | Unemployed | Not specified | Previous prescribed fentanyl patches, fentanyl spray, Zenmorph. Currently weaning from buprenorphine. |
| Currently weaning | P3 | 72 | M | Unemployed | Knee surgery | Previous prescriptions of morphine and co-codamol. Currently prescribed oxycodone and liquid (not specified). |
| Currently weaning | P6 | 61 | M | Employed | Leg pain | Didn't specify earlier treatment, but it escalated to oxycodone. Currently prescribed Zormorph. |
| Currently weaning | P12 | 57 | F | Unemployed | Hip injury and other widespread pain | Previous prescriptions for morphine, oramorph and fentanyl patches. Currently discontinuing using ketamine. |
| Currently weaning | P14 | 39 | M | Unemployed | Lower back and leg pain | Previous prescription for morphine, oramorph and oxycodone. Currently discontinuing from Zormorph. |
| Currently weaning | P15 | 43 | M | Sick leave | Back pain and other widespread pain | Previous prescriptions for co-codamol, oramorph, Zormorph. Currently weaning using tapentadol. |
| Currently weaning | P18 | 47 | M | Home carer | Lower back pain | Previous prescriptions for tramadol, codeine, amongst others he can't recall. Currently weaning from tapentadol. |
| Currently weaning | P21 | 37 | M | Employed | Lower back pain | Previous prescriptions for Tramacet, tramadol, oramorph. Currently weaning from tapentadol. |
| Discontinued | P9 | 40 | M | NA | Back pain | Previous prescriptions of co-codamol, tramadol, morphine and oramorph. Discontinued from buprenorphine. |
| Discontinued | P17 | 51 | F | Unemployed | Back pain and other widespread pain | Previous prescriptions for tramadol, oxycodone, fentanyl patches, oramorph and ketamine. She also had lidocaine infusions. Discontinued using buprenorphine. |
| Discontinued | P22 | 49 | M | Unemployed | Lower back pain | Previous prescriptions for tramadol and fentanyl patches. Prescribed buprenorphine to aid weaning but it made him sick. Made the decision to go cold turkey. |

**Table 15. Study 2 patient characteristics**

### 4.6.1 The Treatment Journey

Patients reported trialling a number of different opioids either solely or in combination with other pharmacological and/or non-pharmacological therapies. Not all patients adhered to or engaged with treatment recommendations from their HCP. This theme provides some insight into the treatment journey from the perspective of patient's with CNCP, including accessing treatment, engaging in treatment, reviewing medication, and communicating across levels of care. A deeper understanding of the practicalities that arise throughout treatment will be helpful in devising ways to support patient engagement and behaviour in relation to opioid use and reduction.

<u>Initiating treatment</u>

Most often opioids quickly became part of patient's treatment and everyday life. Of those interviewed, the length of time taking opioids ranged between 2 and 40 years. Patients commonly discussed being prescribed a number of different opioids (as highlighted in table 14) although there was no consistency where opioids were first initiated, e.g., in secondary (post-surgery) or primary (from a GP) care. Once opioids were initiated it was common for patients to continue to receive repeat prescriptions from their GP, often without review. For example, P22 (researcher notes) discussed how he was first prescribed tramadol by his GP and after having spinal infusions was put on fentanyl by the hospital which his GP continued to prescribe for 7 years. Once established on opioids patients described their ease in obtaining more prescriptions and how their doses or strength of opioid quickly escalated.

*"They [doctors] are quite happy to dish it out and not really monitor it I know that much, I mean I got up to 60 [*mg*] really quite quickly" (P15)*

*"It was just the case of going back to the GP and very little was working to be honest and they were pilling more and more tablets on" (P9)*

Patients sought HCP advice with the hope of finding a treatment that would reduce their pain. Although patients were generally "*happy to give anything a go*" (P21), there was greater value placed on biomedical treatment methods (e.g., pharmacological, or surgical). For example, patients were generally content with continuing to take opioids as long as they were being

prescribed "*the more I was getting off them* [GPs] *the happier I was*" (P23). This is also evident in the length of time they took opioids, despite how effective in relieving pain patients reported them to be.

*"I was taking more, more morphine and it weren't killing the pain" (P3)*

In comparison, some patients were less engaging and quicker to discontinue alternative therapies such as PMPs. There were a mixture of patient experiences of PMPs with some describing them as "*a bit fluffy*" (P12) or "*rubbish*" (P23) and others who considered them "*brilliant*" (P14) and hoped to "*learn new skills, to cope better*" (P17). It was not clear why these individuals differed in their outlook, but it is possible that a lack of understanding about PMPs was a key factor.

*"I don't know what that [PMPs] would do about my pain so I never ever like that, so I never went back to it" (P23)*

Accessing treatment was not easy for some patients and was one of the factors that contributed to patients who negatively rated their treatment experience. Systematic barriers to treatment such as: referral waiting times "*it is 6 months between appointments*" (P15), correspondence informing treatment plans "*they* [GP] *can't do anything until the letter comes*" (P21), the availability of medicines on local practice formularies, funding cuts and limited local services all impacted patient's experience. For example, one patient discussed how he was caught in a cross-border debate (between Wales and Chester) which meant some facilities could not treat him because he "*wasn't on street drugs*" or "*wasn't in their catchment area*" (P9). This patient eventually received treatment in Liverpool after being cycled around different and inappropriate services.

*"Tapentadol was a big problem for me because I'm in a postcode bracket that doesn't allow doctors to prescribe it" (P15)*

*"I was on infusion every 3 weeks, but local CCG pulled the funding for it" (P17)*

Adherence to treatment

It was common for patients to adapt dosing instructions to their own required need. As a result, there was a combination of patients who strictly followed the dosing instructions "*that's an alarm to tell me I'm ready for my next medication*" (P21); those who preferred to use their medication on a "*PRN* (pre-required need)" (P2); and those who "*guesstimate*" (P15) or re-dosed early. The latter became particularly problematic for one patient when she found herself re-dosing (fentanyl lollipops) three times over the recommended amount.

*"I think I should have been taking four a day but I was taking like 14/15 a day. I'd have one and then have another one straight away" (P23)*

It is concerning that some patients described such inappropriate dosing whilst also explaining that their medication was not being monitored as frequently as they thought it should "*we never ever reviewed how effective they are*" (P15). For example, it was common for patients to report not seeing their GP for years and simply collecting their repeat prescription without review.

*"I haven't seen my main GP in years… they just doing repeat prescriptions every sort of 28 days so I haven't seen anybody about my pain meds for a long time" (P17)*

Overall, patients gave the impression that they would prefer more direct input from their HCP and wanted to feel like someone was genuinely interested in their treatment.

*"You don't really get to get a one on one relationship. You don't get to give them feedback about how it's been going, how it's not been going" (p21)*

Communicating with HCPs

Patients commonly discussed difficulties liaising with various HCPs involved in their care. This was exacerbated by having to visit multiple HCPs at different locations causing patients to not understand what HCPs were advising.

*"I go to the Y hospital, I go to X hospital, you know I go to about 5 different places, why can't they all just get together in a room, that's all I want, but it doesn't happen" (P12)*

*"As a patient you're between the devil and the deep blue see, you've got one person telling you one thing and another person telling you another" (P15)*

It was noticeable that these frustrations increased as more HCPs became involved in patients care. This was observed in the breakdown of communication between HCPs which patients described as leading to inconsistent or contrary advice. Whether this was around what dose or type of medication they should be on or what exercises they should or should not be doing, it often left patients feeling confused about what the best approach should be.

*"They [HCPs] don't always talk from the same hymn sheet… so what do I do?" (P6)*

*"You just end up agreeing with them in the end and then you're coming out and you don't know where you are going to be in 12 months' time" (P23).*

These experiences may also be influenced by the difficulty patients have recalling and understanding information their HCP provides. It was common for example, for patients to feel like their HCP "*didn't explain things very well*" (P22- researcher notes) or their medication made them feel "*foggy*" (P15). In turn this affected their level of comprehension and memory, leaving them feeling "*stupid*" (P23).

*"It can be very difficult communicating…. unless I've got a letter or something that sort of says what it is I'm supposed to be doing or what the treatment programme is, it's very hard to remember" (P15)*

*"I find it hard to relate really to the actual doctors here, with the opioid medication, they don't seem to understand" (P6)*

Conversely, patients who described having a positive experience with their HCP explained how they could "*talk quite openly*" (P12) and negotiate treatment options together. It was important for patients to feel "*heard*" (P2) and "*involved*" (P21) in their treatment.

*"If I asked for a medication there was a good reason for it, and we would discuss it and decide together whether or it was right for me" (P2).*

Further relationship barriers emerged where patients perceived their GP to be less knowledgeable compared to tertiary care experts. This led to feelings of mistrust about the treatment they were receiving and a lack of confidence in their GP's ability to adequately treat them.

*"They [GP's] don't have any specialty in certain fields" (P9)*

*"My GP's they're maybe not specialist in pain management issues so they're maybe not up to date or they're not aware of treatments and medications that can be used that aren't…as damaging as opioids" (P17)*

As a result of these experiences patients discussed that having a knowledgeable, consistent point of contact, who could communicate with HCPs on their behalf would help reduce any disparities. For example, one patient had the benefit of having a key worker which he described as a "*massive help*" (P9) during his treatment.

*"Something constant, the single point of contact that you know if you're dealing with a long-term chronic injury" (P15)*

*"If there was something in between, not necessarily the GP but someone you could go to who is knowledgeable" (P3)*

Overall, patients were happy with their treatment experience (rating it a 6 out of 10, 10 being most satisfied). The main reasons behind a positive rating usually involved the in-depth and intensive treatment received from tertiary care. It was here, that most patients reported feeling like someone was genuinely interested in helping them and were able to access pathways where they could envisage realistic outlooks into the future.

*"Brilliant because at least I can see sort of a really good outlook" (P12)*

*"They've [pain clinic] been brilliant so far" (P17)*

*"There's been more response and more interest in what I'm taking, how I'm taking it and how I feel it's been going through the pain management more than my GP" (P21)*

A number of barriers to patient's treatment exist and continue to arise throughout their treatment journey. This makes it difficult for patients to understand treatment decisions as well as causing difficulties accessing potential beneficial treatment. Patients who reported more positive experiences seem to have a better level of understanding, expectation of treatment and good communication with their HCP. Perhaps developing approaches that incorporate these aspects into care would help reduce negative experiences. At this point, it is important to consider what it is like for CNCP patients to live with opioids and the effect they have on daily life as it is related to overall treatment experience. This is discussed in the next theme.

### 4.6.2 Living with opioids

The patients interviewed for this research spoke about their experience of living with CNCP and the life changing adjustments they have had to make as a result. The sensation of pain plays a key role in this experience alongside the effects of opioid treatment. This theme illustrates how living with opioids has affected patients and considers if opioids are worth the adversity.

<u>Self-identity and quality of life</u>

Patient's pain was constant but unpredictable, they often described having "*good moments*" (P3) or "*days that are much better than others*" (P2). The long-term experience of pain impacted patient's ability to live a normal life, affecting sleep, desire to socialise, physical functioning, ability to work and how opioids revolved around these 'normal' activities.

*"I had no social life… I didn't want to be anywhere… I couldn't do anything when the pain came in, like I'd have to leave my wife if I was out anywhere, I'd have to just come home and take my tablets" (P6).*

The combination of patient's pain and awareness of their next opioid dose controlled their motivation and perception of being able to do anything. For example, the anticipation of a pain flare-up or medication wearing off filled patients with anxiety and fear of leaving their home.

*"I don't like going out, I'm scared" (P14)*

*"I wouldn't go out for ten years, because I knew after taking 7 hours I was going to be, I was going to have to go like cold turkey" (P6)*

To control this fear patients would carry around extra medication "*just in case*" (P3) or "*pre-load*" (P2) prior going out. They would logistically work out travelling so they didn't have "*far to walk*" (P17) and would plan rest days "*before and after*" (P21) an event. Alternatively, some patients weighed out the risk-benefit ratio of taking their medication, depending on their desired goal patients described choosing to either avoid participating in any events, or taking less than their prescribed dose to remain alert with the consequence of increased pain.

*"I don't want to be completely drugged up so yes I'm pain free but I can't do anything. So I accept that in order for me to do the things… there's some pain and I'd rather have the option to do those things and to deal with the pain afterwards" (P21)*

*"Yeah I'm missing out, I can't drink so I prefer not to go to somewhere where I am watching everyone around me having a drink and enjoying themselves" (P4)*

This repetitive behaviour was taxing on patients and their inability to do things often contributed to their sense of lost identity. This was often expressed through reminiscing about the things they could no longer do as they mourned the person they once were.

*"I'm not who I was 5 years ago, psychologically I'm not the same person" (P15).*

*"I used to do a lot of crafts and things, and now I struggle" (P17)*

Sometimes, patients didn't even notice how they had changed "*my speech apparently was very slurred which I didn't realise* "(P17). It was not until they started to reduce their opioids where "*all of a sudden everything felt a little bit brighter*" (P21) and they could "*operate a little bit better*" (P6). Separately, but related to patient's identity, was their need to differentiate themselves from people who use illicit opioids. Patients often felt the need to defend or justify their use of opioids and ensure they didn't become dependent like illicit drug users would. To overcome this sense of judgement, patients described how they found reassurance having their doctor affirm their opioid prescription was genuine and trusted their recommendations if any improvements were to be made.

*"I knew I was abusing them, I wasn't abusing them like a smack head abuses drugs" (P23)*

*"I'm not dependent on that and I'm not addicted to it, I can stop this whenever I need to" (P2)*

*"I've got to do whatever they [doctor] ask me to do and what they think is best for me. Because otherwise I'm, you know, things aren't going to get any better" (P17)*

Lastly, patient's mental health was another reoccurring issue whilst they were both taking opioids for their pain and weaning off them. Accumulatively patient's experience left them feeling trapped between living with pain (and its extended psychosocial impact) and taking opioids to treat the pain (which had equally undesirable effects). They often discussed experiencing feelings of depression and despair and thoughts of suicide.

*"I would say a lot of depression has come from taking the morphine" (P9)*

*"At this moment [*going through an opioid reduction*], I'm starting to have suicidal thoughts, I have had them before, and I can hear voices when I'm anxious and that seems to be happening a lot mentally at the moment" (P14)*

<u>Are opioids worth it?</u>

Patients reported experiencing a number of side effects from taking opioid medication, which on top of the pain affected their overall quality of life and well-being. As a result, patients commonly held negative views about opioids and generally did not like taking them "*I hate it*" (P14). Patients preferred not to have to take opioids but are conflicted with limited alternatives to manage their pain.

"*They're bad stuff opioids but until they think of something better…*" (P6)

This often left patients feeling caught between two equally undesirable choices where they described not being able to live with or live without opioid treatment.

*"No matter how bad side-effects the pain was even worse" (P4)*

*"It was helping me but it was my worst enemy" (P6)*

These insights often arose due to the adverse side effects and lack of pain relief patients reported experiencing. Patients often described how "*it's not doing nothing for the pain*" (P23) or "*it didn't touch me*" (P12) despite increasing opioid doses. It was for these reasons that patients self-rating of treatment satisfaction was considered a 5 out of 10.

*"I have been taking what was the maximum dose of a lot of medications, to which I was still having pain" (P21)*

*"Painkillers are the wrong name because sometimes they don't kill any pain" (P3)*

Opioid medication meant that patients couldn't always do the things they wanted, due to the varying side effects. The side effects of opioids are well known, and the patients interviewed didn't report anything new (e.g., "*nausea*" (P17), "*constipation*" (P15), "*foggy*" (P22) "*loss of motivation*" (P6)). A lot of the reasons why patients reported wanting to discontinue their opioid medication were due to the severity of the side effects and the extent to which they impaired their daily well-being and ability to function 'normally'. For example, some patients reported how opioids impacted on their ability to do their job (P21, P17), their family life and relationships (P21, P6, P9) and doing things that they enjoy (P2, P3). Generally, patients discussed how opioid medication took away part of who they were and how they wanted to get their life back.

*"I'm only 40 years old and I'm basically lying on the sofa doing nothing. I need to get my life back" (P9)*

*"It will give me back some of what was lost really" (P12)*

It was common for patients to discuss not getting the full duration of effect from their dose of opioids. As a result, patients relied on oramorph to ease their break-through pain until their next dose. Although patients found this to be effective, the preparation of oramorph (i.e., liquid form) meant there was a clear risk of misuse when patients did not follow dosing instructions.

*"You can get a really sharp drop off towards the last hour, 2 hours… I was finding the overlap quite bad so I would top up with Oramorph" (P15)*

*"I know I was on Oramorph and I was basically drinking it, erm I wasn't measuring it out to be honest with you" (14)*

In addition to these negative experiences, one patient felt strongly resentful about the lack of information provided on the risks of opioids (specifically addiction), and another patient perceived that HCPs withheld potential treatment. These additional reasons were contributing factors for both these patients rating their treatment experience 2 out of 10.

"I*f I had of thought I'd become addicted like that then I'd never have taken them*" (P22-researcher notes)

*"There seems to be a very strong unwillingness to try anything" (P15)*

The longer patients used opioids, the more they began to recognise their limited efficacy and resentment in ever using them "*I just want to get rid of the whole thing*" (P3). Conversely, two patients recognised the potential good of opioids and highlighted that they should not be completely ruled out as an anaesthetic.

*"We need to stop looking at opioids as the enemy… opioids can be a great assistant" (P2)*

*"Some of them [Doctors] won't prescribe it [opioids]… I think that is a mistake actually" (P4)*

<u>Self-management of pain</u>

Alongside the use of opioids, patients commonly discussed spending a lot of time adapting and trying to find ways to self-manage their pain. Some methods were advised by their HCP, others were self-developed (which can be problematic as discussed in the referral HCP theme, section 4.4.3). Most often patients tried to ignore their pain by distracting themselves via pacing, keeping busy or doing hobbies they enjoyed. However, this was not always possible due to reported greater levels of pain and disability.

*"I use distraction all the time…. distraction is probably one of the most powerful things that you can do" (P4)*

*"I am trying to do my hobbies, but it's difficult…. because things start going wrong because the pain starts taking over and then I get really frustrated with myself" (P14)*

There was a sense that patients were generally motivated to want to do more and feel better, it was important for them to improve their quality of life "*learn new skills, to lead a better-quality life*" (P17). Having a positive mindset and supportive network aided this motivation as was the need to take responsibility for your own health and well-being.

*"I would say we [patient and her husband] are very young minded. We are quite motivated to you know do all sorts of things" (P12)*

*"People are going to pass through there that aren't willing to do anything for themselves, they want the doctors to do it all for them and the doctors are there to help you, not to do it for you" (P2)*

Patients find themselves on long-term opioid prescriptions as the main source of treatment to manage their pain. It is not until patients are well-established on opioids that the severity of adverse effects become apparent and continue to take patients by surprise. This implies patients have a general lack of understanding about opioid therapy and subsequently the eventual approach to reduce or discontinue opioid treatment. Generally, patients portrayed the sense that taking opioids are not worth the adverse effects, unfortunately there are limited in other ways to manage their pain.

### 4.6.3 Weaning experience

A primary focus of the patient interviews was to capture their experiences of reducing opioid medication. At the time of interview there were n=8 patients on a current reduction plan, n=3 patients who recently discontinued and n=2 patients who were about to start a reduction. Patients provided valuable perspectives on the following sub-themes: approach to weaning (methods used, expectations and reasons for weaning); hitting a wall (discussion around the difficulties of weaning) and finally what it like for patients 'post weaning' and the level of 'support' they received throughout their journey. These sub-themes help identify some of the barriers patients face and what works best for them during this difficult time.

Approach to weaning

It was more common that patients made the decision to discontinue their opioid treatment themselves, than it was for their HCP to initiate it. Patients usually reached a threshold (often driven by the unbearable side effects) with their treatment which left no other option but to consider reducing or discontinuing their medication.

*"I made the decision this is basically killing me, I went back to my GP and asked what was the best way to start coming off all this" (P9)*

*"I said right push has come to shove so what are the options – 'well there are none, so you need to come off the Fentany [patient repeating her HCP]" (P17)*

Preceding the decision to wean off opioids, patients discussed initially going through a community-based weaning plan with their GP. The reduction approach for all patients was generally the same whereby they reduced their dose slowly, meaning a few mg/mcg/ml at a time every 2 – 3 weeks. The duration of an opioid weaning plan often surprised patients and once they were established on it, felt frustrated at how long the whole process took.

*"It was a long process, but I was, like I said I was gradually doing 5mg every 2-3 weeks and then if I was bad, the doctor would leave it that week"" (P14)*

*"The one [taper plan] that I'm on at the moment well you couldn't get it any slower" (P4)*

Although patients described grasping the basic concept of weaning, there were various misunderstandings of what it actually involved. This was evident in both patients who were currently weaning and those who already discontinued their opioids. Patients discussed how they weren't fully informed of what to expect or understood decisions to rotate or discontinue their treatment, they often simply agreed to it because a HCP advised them to.

*"I have no idea. That's all I know, is I'm going back in 4-5 weeks and basically take it from there, so I don't know how long I'm going to be you know like this." (P14).*

*"I mean I'm on the medication for something aren't I and I don't understand why they want to reduce it on me" (P6)*

As all patients were recruited via the same tertiary care setting, it would imply that at the time of interview there was need for specialist support and guidance in their treatment. In tertiary care patients commonly reported being rotated onto different opioids (mostly buprenorphine, tapentadol and sometime ketamine), or offered inpatient treatment to help facilitate opioid education.

*"I can either go into the hospital and come off them… or we can just do it 10mg like over so many weeks" (P23)*

*"He said he would contact my GP's and get them to reduce me over a period of sort of 6-12 months… or I could, he'd take me into the X clinic sort of detox me off the opiates in 7-10days" (P17)*

Not all patients were offered inpatient weaning. Those who were, expressed some hesitancy and anxiety because either they didn't like hospitals, could not justify the time off work or were concerned about leaving family alone. For example, P12 had previously refused inpatient treatment but later accepted it when she understood what treatment involved and could logically weigh the benefits and outcomes.

*"I think if they would have allowed me to come in and stay in hospital, it would've helped me because that's what I wanted to do" (P6)*

*"I just thought it would be sort of a day or two [*inpatient treatment*] and then I'd be home again. But it is what it is and if it will give us back what we want then erm it's done, it's sorted and for the better really" (P12)*

The three patients who successfully discontinued opioid medication were rotated onto a buprenorphine weaning plan and reported responding well to the medication (e.g., less side effects). This worked by ensuring patients daily morphine dose matched that of the rotated opioid with the purpose of minimising withdrawal in order to make the reduction somewhat easier.

*"The Buprenorphine or Subutex is a much safer drug… it is also a good painkiller with very few side effects. Or from what I found, there were very few side effects" (P9)*

*"They had to match that dosage what I was having with something else so I didn't get no withdrawals" (P23)*

Hitting a wall

Going through an opioid weaning regime was difficult and challenging for patients. It commonly took them several attempts to come off their medication and would often waver between their planned reductions.

*"I've tried to come off them several times… to no avail really" (P12)*

*"I have to go up to 40 sometimes 50, sometimes i touch 60, simply the combination of the pain but I think more importantly it's because I can't get myself off the side effects" (P3)*

Patients currently going through an opioid reduction talked about how they would reach a point in their reduction plan where they felt they could not get any lower with it. When this occurred, there was a sense of disappointment, frustration, and uncertainty as they described that despite having "*the best will in the world*" (P15) they just couldn't get the reduction down any further.

*"I couldn't get off the oxy, no matter what I'd done, I couldn't get off the oxycontin… I think I got to 65mg from 80mg" (P6)*

*"Once I got to the 75, going down to the 50 that was it, I just couldn't get down that far" (P12)*

Reasons for 'hitting a wall' were mostly due to the intensity of the withdrawal symptoms (namely "*sweating*" (P4) "*nausea*" (P14), "*lethargy*" (P12), "*shaking*" (P23)) which accumulatively left patients feeling like a "*zombie*" (P3). Three patients, each taking different opioid medication also reported experiencing sound and visual withdrawal effects. All of whom either reduced too quickly (P21), recently lowered a dose (P3) or had vomited after taking their medication (P14). Symptoms of vomiting was particularly difficult for patients as intensified their withdrawal experience and they likened it to going "*cold turkey*" (P2).

*"When you take your tablets in a morning and then you vomit an hour later and you see your tablets you know in there and then like I'm stuck for the rest of the day" (P14)*

More than any other withdrawal effect, patients discussed how their increased level of pain was the recurring symptom that made their reduction most difficult, and they didn't understand how their HCP expected them to cope.

*"They want me to come off the medication, but I'm on the medication because I'm in pain, I'm in pain now. I mean how do they want me to function" (P6)*

*"Being stuck with the increase of pain because I haven't had any medication. It's, I just don't think it should have been done like that" (P14)*

Additionally, patients speaking from experience, highlighted that it was important to agree a plan "*best for you and your lifestyle*" (P17). This sometimes involved fluctuating their doses depending on life events and responsibility "*I was busy for a weekend with the kids and I had to increase it just a touch*" (P21).

Post weaning

Three of the thirteen patients interviewed successfully discontinued their opioid medication. It is worth nothing that these patients had only discontinued recently (at time of interview) and so, their immediate experience of this might differ to someone who has discontinued for longer. Of these three patients, two weaned off their medication following a reduction plan, one opted to go cold turkey due to the buprenorphine making him sick. A fourth patient at the time of interviewing just started a buprenorphine weaning plan however reported having previous experience of coming off her opioids. Patient's experience post weaning resonated their love-hate relationship with opioids. For example, these patients commonly reported how they felt better coming off their opioids; explaining they had improved cognitive functioning, being more alert and feeling back to their old self. At the same time, they also discussed experiencing increasing levels of pain which affected their ability to function 'normally'.

*"I'm finding that a lot better, not being on the opioids for my general quality of life, but as for the pain aspect, it's hard because it is a constant daily battle with pain" (P9)*

*"I get a little bit more clear headed but coming off them means I have the pain and so I have to make the choice of which is more important to me at that time" (P2)*

As a result, these patients described how it left them feeling confused and anxious with regard to what pain relief they could now take. Patients were concerned of becoming dependent on another medication and anticipated having to wean off it again.

*"I could definitely do with some sort of pain relief, what is available to me, I don't know. Dr X didn't seem to be keen to give me anything at the moment" (P17)*

*"I don't know what's available to me now. I obviously don't want to go down that same track [opioid dependence], erm but I don't know what I can, what's there now you know that's going to give some relief" (P17)*

<u>Support</u>

All patients faced with or having gone through weaning discussed needing or that they would have liked more support. It was often the case, that once established on a weaning plan that patients reported feeling left on their own to complete it and deal with the anticipated withdrawal. This appeared to accumulate an increased level of distress among patients which they felt a check-up or review with a HCP could have helped.

*"I think you need somebody, because we had nobody… it was basically right get on with it and see us in three months, but there was nobody" (P12)*

*"The tapentadol itself needs monitoring over the period of time that you're on it…You're supposed to have a dose check and see how you're getting on is it working" (P15)*

In response to the lack of support, patients talked about how they would benefit from having a support group of people going through similar experiences. They also mentioned that it would be useful to have an intermediate HCP with sufficient knowledge that meant they didn't need to go to their GP all the time.

*"I think it'd be more support… talking to other people that are you know suffering the same as me" (P14)*

*"If there was something in between, not necessarily the GP but someone you could go to who is knowledgeable and who can advise" (P3)*

Support groups however may not suit everyone. Some patients discussed how their own anxieties such as sharing personal details, previous bad experience and generally undervaluing group support were factors which discouraged them from attending facilitated support groups.

*"No that's not erm that's not for me that [support groups], I got enough of my own problems I don't want to be listening to anybody else's" (P23)*

Patients were more likely to be happy with their treatment when they received regular contact or MDT support.

*"Dr x came to see me every single morning to check on my progress" (P17)*

*"It's been a bit more MDT like from the GP, community and pharmacist" (P21)*

There is still a clear gap in terms of support for these patients during a time at which they are vulnerable. Barriers such as these in addition to patient's preparedness and level of knowledge should be considered when developing strategies to support weaning regimes.

## 4.7 Summary

The experiences of living with chronic pain and receiving opioid treatment from a patient's perspective have been captured and depicted across three main themes: the treatment journey, living with opioids and weaning experience. The connection between these themes begins with patient's description of their treatment journey and the inevitable interaction they have with the HCPs. As opioids play a key role in patient's treatment, living with opioids and whether they are worth it were themes that were indicative of their experience. An accumulation of their experience ultimately led to considering or engaging in an opioid weaning plan. A summary of patient's experiences is presented here.

**The treatment journey**

Patient's treatment journey typically involved transitioning through different HCPs where they tried various opioids for long periods of time (between 2-40 years). During this time, some patients commented on the ease of obtaining stronger opioids from their GP, yet also reported little support for effective pain management or medication reviews. Non-adherence to dose instructions among patients was common, particularly among patients established on higher doses. Barriers to treatment included long referral times, limited access to treatment, funding cuts to treatment and communication breakdown. Patients were more likely to report positive treatment experiences when a HCP listened, supported, were genuinely interested and more knowledgeable about managing their pain. Operationally, tertiary care was perceived to be better equipped to deliver the level of care needed and thus deemed more trustworthy. The lack of dialogue with their GP meant that patients did not fully comprehend some treatment decisions. The involvement of multiple HCPs further attributed to their confusion and conflicting advice. As a result, patients suggested that having a single point of contact who they can seek support from (someone other than their GP) would help bridge these barriers.

**Living with opioids**

Patients are in constant pain and use opioids to help manage it, at the same time opioids also controlled patients' ability to live a 'normal' life. As a result, patients commonly perceived opioids to be both a saviour and an enemy. Patients discussed how the combination of pain and opioids changed their identity and general well-being through their inability to work, socialise or look after family. A combination of these experiences contributed to developing poorer mental health. This in addition to the various unwanted side effects, desire to regain mental clarity and little pain relief were reasons given to discontinue opioids. Ultimately, patients did not like taking opioids but the fear of making the pain worse justified their continuance. In hindsight, patients described how they would have benefited from being better informed of the risk and benefits of prior to initiating opioid treatment. Those who were more informed had better expectation of treatment outcomes.

**Weaning experience**

Of the patients interviewed n=8 were currently weaning, n=3 had successfully discontinued treatment and n=2 were initiating a weaning plan. It was often the patient's decision to initiate a weaning plan. They often underestimated the difficulty of weaning and despite having a slow reduction plan frequently relapsed back to higher doses due to withdrawal and increased pain. It was at this point that patients particularly struggled and expressed the need for more support. Post weaning patients reported having more mental clarity but were anxious about starting any new treatment and did not understand how their pain would be managed in future. Patients consistently requested more support, before, during and after receiving opioid treatment.

**Integrating HCP and CNCP patient themes**

There was noticeable consistencies across the themes developed from HCP and CNCP patient analysis. These consistencies led to identifying three overarching themes that integrate HCP and CNCP patient experiences. These include: **Treatment** - which highlights HCPs and patients perspectives on methods to manage CNCP, access to and preference for particular treatment; **Communication and education** – captures issues that link the breakdown of communication between HCPs and patients and inconsistent treatment advice and how limited knowledge and understanding may exacerbate these issue.; **Weaning** - draws together the difficulties HCPs and CNCP patients describe with weaning, including having capacity and adequate support. The integration of these themes are depicted in table 16 below along with suggestions of implications for practice and research to address them.

| Theme | HCP | Patient | Implication for practice and research |
|---|---|---|---|
| **Treatment** | **Multi-modal therapy**<br>HCPs agreed that non-pharmacological treatments should be trialled first but ultimately CNCP treatment should be multi-model (comprising both pharmacological and non-pharmacological). Access to supplementary treatment in primary care is limited. | **Treatment preference**<br>Patients were often more reliant on pharmacological treatment and more likely to be sceptical of non-pharmacological therapy. They also discussed the ease with which opioid prescriptions escalate and lack of medication review. | In practice it is difficult for primary care to prioritise non-pharmacological treatment when provision is limited, and GPs feel they need to "do something" now. This may lead to an over reliance on opioids that is equally driven by patient's being content to receiving a prescription. Additionally, lack of medication reviews risk prolonging inappropriate prescribing. There is need for research to investigate how non-pharmacological methods can be better implemented in primary care and how GPs can better manage consultation pressures and long-term opioid prescriptions. |
| **Communication and education** | **Breakdown**<br>Communication is more likely to breakdown when HCPs are not co-located. There was a disconnect between primary and tertiary care due to restrictive or limited methods used to update patients care (e.g. different systems or relying on letters). There was also a sense of conflict between HCPs where treatment plans may not always be followed accordingly.<br><br>**Education**<br>HCPs highlight that patients are not given enough information prior to starting opioid treatment. It is often not until tertiary care that patients are offered education sessions on opioids. The barrier to educating patients once they are established on opioid is the (albeit temporary) cognitive dysfunction and their ability to adequately comprehend information.<br>**HCP knowledge**<br>HCPs (in primary care) called for more guidance indicating the use of opioids and | **Inconsistency**<br>Consulting with multiple HCPs often resulted in inconsistent or contrary advice. Patients were perceptive of the lack of communication between HCPs involved in their care. As a result, it was common for patients to suggest having a consistent point of contact e.g key worker, to bridge these disparities.<br><br>**Comprehension**<br>Patients indicated general awareness about the risks of opioids but often underestimate the actual severity. In hindsight patients expressed that they wish they had known more before initiating opioids. However, their pain and the effects of opioids made recalling information and communicating difficult.<br><br>**Perceptions of HCPs**<br>Patients often perceived their GP to be less knowledgeable of CNCP, thus | Poor communication had an obvious impact on practice as a delay in sharing patient information had a subsequent delay on initiating treatment "they can't do anything without a letter". Additionally, this disconnect risked fracturing patient care, leaving patients confused and lacking confidence in their HCP. Research should investigate ways to improve dialogue between HCPs, particularly in updating treatment progress. This may include creating shared platforms or incorporating pharmacists or key workers to facilitate in patient care.<br><br>There is a clear lack of information provision and education around the risks associated with using opioids for CNCP. In practice, this may contribute toward the misaligned expectations HCPs and patients have of opioid treatment. Research should investigate how best to deliver and ensure patients comprehend information. Education packages may need to be modified to reflect different stages in patient's opioid treatment journey (e.g. initiating, during and after).<br><br>The combination of these experiences feed into a cycle that results in care not being optimised, particularly in primary care. This may be exacerbated by the limited capacity, |

| | | | |
|---|---|---|---|
| | for specific pain modules to be implemented into the medical curriculum. | somewhat sceptical of their ability to deliver care compared to tertiary care HCPs. Often, patients saw their GP as a source of prescription and justified treatment safety because it was provided by a HCP. This rationale may have a role to play in patients recognising their need to understand opioids better. | consultation times and non-pharmacological treatment available in primary care. Research should investigate how improving HCPs knowledge and key skills (e.g. negotiating and managing patient pressures) can improve the patient experience and treatment outcomes within a primary care setting. This may incorporate having to also address some of the operational barriers to treatment. |
| **Weaning** | **Capacity**<br>Opioid weaning in primary care is challenging. GPs often don't have time or capacity that is needed to best support patients due to the other co-morbidities they present to clinic with. HCPs recognise that opioid weaning needs an MDT approach. Furthermore, the displacement of patient responsibility was an issue for HCPs who perhaps are not adequately trained to deliver specific elements of care e.g. nurses who are expected to counsel patients during weaning. | **Support**<br>Patients discussed lack of support or review from HCPs once initiated on a weaning plan. The absence of this was particularly challenging when patients struggled to reduce their dose any further. Patients had additional anxiety of what to expect and how their pain will be managed in the future. Patients with a positive mind-set and supportive network were more motivated to engage in treatment. | HCP capacity is a recurring issue for delivering optimal health care. In practice, this issue subsequently evokes increased distress among patients at a vulnerable time in their treatment journey. As well as placing undue responsibility onto HCPs who are not trained to deliver aspects of care. A limited supportive network risks prolonging patient's hardship and seems illogical when patients also explain feeling ill-equipped or uninformed of the adversity they face. It is clear that an MDT approach is the gold standard of care for CNCP patients, however this this not widely available in primary care. There is need for research to explore how to better integrate levels of care and clearly define the roles of HCPs so patients can be adequately supported at the right time. |

**Table 16. Integrating HCP and Patient experiences**

## 4.8 Discussion

Overall, each of the themes that developed throughout the analysis of HCP and patient interviews address different points of the objectives set out at the beginning of this study: 1) what does treatment decision making entail, 2) how are reduction plans negotiated and managed, 3) what concerns and barriers commonly occur and 4) what support mechanisms are considered helpful or needed to facilitate opioid weaning.

The combined lived experiences reported by HCPs and patients who treat and receive treatment for CNCP explored in this study uncovered the complex nature of the multi-faceted need to optimise patients care. The majority of patients are managed in primary care however the data reported here supports literature showing that patients often transition through a "*medical roundabout*" (HCP10, consultant psychologist) throughout the course of their treatment (BPS, 2013b; McCrorie et al., 2015). In light of this, amidst the increase of opioid prescribing, Stannard (2018) highlights the importance of frequently reviewing and monitoring patients opioid treatment particularly if they have been established on it for a long time and are experiencing no beneficial value from it (Stannard, 2018). Although this appears a logical approach to better managing opioid prescribing, GPs in this study described how their already limited capacity makes this difficult to achieve "*to be honest there just isn't the time to do that at the moment, I don't think there is ever going to be*" (HCP25, GP). Perhaps nominating an opioid prescribing lead to manage patient cases would help distribute this workload. The ultimate goal of treating CNCP involves orchestrating a treatment plan that avoids inappropriate opioid prescribing yet strives to improve patients' well-being and functionality, and reduces pain where possible (NICE, 2019; Toye et al., 2013). The problem of much treatment offered to CNCP patients, is the trial and error of different medications and consultations with different HCPs that can elicit unintentional consequences. For example, patents in this study describe being frustrated and disappointed when treatment expectations are not met, or treatment fails. This may contribute to further negative outcomes when patients end up over relaying on opioids to manage pain due to limited other treatment options. The evidence synthesis review of CNCP patient experiences by Toye and colleagues (2013) describes this experience as part of the wider adversarial struggle that patients commonly go through (Toye et al., 2013). The composition of adversarial experiences

is believed to contribute to patients' mistrust or misunderstanding particularly in regard to HCP's treatment decisions and ongoing treatment adherence and engagement (objective 1, 3).

In order to mitigate the impact of negative treatment outcomes, HCPs and patients simultaneously discussed the need for more education (namely around opioids as this was the focus of the interviews) prior to initiating any new course of treatment (objective 4). HCPs recognised that patients "*are not given enough information*" (HCP24, GP) and retrospectively patients emphasised the need to be better informed about their treatment before deciding to engage in it (objective 1). The need for better delivery of education for patients was highlighted in the 2013 UK national pain audit (BPS, 2013b). Yet 7 years on it is still common to hear that patient have not been adequately educated about their pain and potential treatment (de Sola et al., 2018). Patients must be made aware of and fully comprehend the risks involved with opioid treatment and the challenges of eventually discontinuing it. As such, information and education should inherently be part of a patients' treatment package; the extent to which it is being currently delivered in primary care however, often relies on patients reading information provided inside boxes of medication. Considering how frequently HCPs in this study recalled that patients did not fully comprehend their own treatment plans and patients who requested more information, it is doubtful this method is effective in adequately educating patients. The alternative, for example HCPs delivering information, places increased responsibility and additional burden on HCPs who already have limited capacity "*nobody has the time* [to *fully educate patients*]" (HCP24, GP), particularly in primary care. This raises the issue of how and when patients are informed about their treatment and the need to develop educational methods that will ensure patients have a better comprehension of what their treatment entails (objective 4).

The delivery of such approaches should also consider that the long-term use of opioids has been linked to deficits in patient's attention (often amplified in conjunction with other antidepressant or anticonvulsant medication) which may affect how well they retain and understand information (Allegri et al., 2019). It is common that individuals have different learning styles, and so it may be beneficial to incorporate different methods of delivering learning might help overcome this barrier. For example, Whiteley (2003) recommends inter-

changeable use of visual, audio, verbal, physical, logical, solitary and social learning methods (cited in (Webb et al., 2016)) to promote learning. A combination of these methods is commonly used in interventions designed to targeting substance misuse (Elison et al., 2015) and opioid weaning (Garland et al., 2019; Naylor et al., 2010; Sandhu et al., 2019). For example, the Breaking Free Online (BFO) intervention recognises the inter-individual variability of service user needs and designed their intervention to tailor content based on prior user assessments (Elison et al., 2015). One of the strengths of the tool is its flexibility in allowing users to opt for self-directed, guided 1-1 or group assisted therapy thus considering users individual learning style and preference. Furthermore, BFO has been shown to be effective for reducing substance use among individuals and is suitable for individuals with mental health difficulties such as anxiety and depression (Dugdale et al., 2016). Additionally, previous individual and group therapy sessions (primarily CBT) in interventions targeting opioid weaning among chronic pain patients have incorporated methods of learning using audio Compact Discs (CDs) (Garland et al., 2019; Sandhu et al., 2019; Zgierska et al., 2016), , tailored hand outs (Jamison et al., 2010; Sandhu et al., 2019), video recordings (Sandhu et al., 2019; Sullivan et al., 2017) and automated telephone services (Naylor et al., 2010) to deliver learning and training. These studies target a similar behaviour (i.e., substance reduction) that is of interest to this research, thus such methods may also be useful when considering how to best deliver learning and information to CNCP patients.

The impact of patients' medication on their cognition was a common barrier that HCPs recognised and would often have to delay delivering educational sessions until patients reduced their medication (objective 3). It may be worth considering delivering different pockets of information tailored to patients prior to starting opioids and those already established on long-term treatment. The caveat would mean that HCPs (predominantly in primary care) will also need to maintain up-to-date knowledge on the latest chronic pain evidence and guidance in order to best advice and educate patients. A nominated prescriber would perhaps also benefit from this. The need for enhanced focus on chronic pain management during early medical training was recommended in an evidence review on ways to better support GPs in managing opioid prescribing as part of CNCP treatment (Currow et al., 2016). HCPs acknowledge the need for more professional training around chronic pain, this need was also evident to patients who recognised that tertiary HCPs were more

knowledgeable thus perceived more trustworthy than their primary care HCP (objective 4). Research exploring patient satisfaction in the long-term use of opioid for CNCP highlight that that trust is an integral part of the relationship patients develop with their HCP (Ljungvall et al., 2020). Trust can be difficult to establish and maintain, particularly when there is a shift in the health care approach, from biomedical to biopsychosocial discredits patients trust in their HCP (Toye et al., 2017). Patients in this study described being a lot more positive about the treatment they received from tertiary care "*they've* [pain clinic] *been brilliant so far*" (P17). Part of this positive experience involved the opportunity for patients to see a specialised expert. Perceiving that their HCP was confident and knowledgeable in chronic pain was important to patients and likely to positively influence their treatment experience (e.g., feeling better prepared to engage in treatment recommendations). This perhaps explain why patients preferred to be referred or seek a second opinion as they begin to lose trust in their GP knowing how to best managing their pain "*My GP's they're maybe not specialist in pain management issues*" (P17).

These issues around establishing and maintaining trust and portraying knowledge, in addition to the healthcare approached taken (e.g., biomedical) may there contribute to HCP decisions to prescribe. The mismanagement of these factors risk HCPs engaging in a continuous wheel of inappropriate opioid prescribing (objective 2 and 3). In practice getting this balance of trust and knowing how to manage patients' pain without giving into pressure to 'do something' is difficult for HCPs. Getting this balance was more of a challenge for primary care practitioners and led to a juxtaposition whereby opioids eventually did not effectively relieve patients' symptoms of pain and ultimately led to decisions to wean or discontinue treatment (objective 1). At this point of a patient's treatment, GPs were skilled to implement a weaning plan but because of the multi-faceted health problems that patients present to clinic with it made it difficult to manage. As a result, GPs recognised the need to refer patients onto specialist services as they felt primary care was not adequately resourced to deal with them.

The findings indicate a sometimes fractured network that exists between primary and tertiary care services delivering treatment to CNCP patients. This ranged from limited access to different treatment provisions including medical (e.g., medication or medical procedures) and non-medical (e.g. physiotherapy, psychologists) therapy to the inefficient communication

between HCPs and patients. For example, inconsistent advice and appointments with different HCPs (namely in primary care) were additional barriers that attributed to patient's dissatisfaction and uncertainty toward treatment outcomes (objective 3). Conflicting advice from HCPs made it difficult for patients to fully engage and again raised issues of trust, particularly when managing opioid reductions. Inherently this disconnect between HCPs also affected how well HCPs work together on best managing ongoing treatment plans. *Gjesdal et al.,* (2017) found that breakdown in communication results in inappropriate referrals that increased waiting times and cause difficulty delivering optimal care when HCPs have different views of how to approach treatment. As a result, Gjesdal (2017) advocates the delivery of interdisciplinary care (e.g., better coordination among HCPs and patients sharing a common treatment goal) opposed to multidisciplinary care (e.g., HCPs integration and communication) is limited (Gjesdal et al., 2019). Improved communication between tertiary and primary care would help facilitate the transference of skills and knowledge and tie together the multifaceted branches of the biopsychosocial model considered fundamental to the optimal delivery of healthcare to patients with CNCP (objective 4).

The biopsychosocial model focuses on embodying patients experiences of their chronic pain (Toye et al., 2018) and incorporates supportive therapies which aim to improve their coping strategies and functioning (Gjesdal et al., 2019). This model can be difficult to deliver for some HCPs. For example, GPs report increased treatment difficulty among patients (albeit a small proportion of less than 10%) frequently consuming clinic appointments due to unsatisfactory pain relief (Henry et al., 2018). Henry et al., (2018) found that GPs are 14 times more likely to offer pain related recommendations than provide any supportive or empathic nurturing. Similar experiences were also reported in this study where HCPs inherit responsibilities that perhaps sit outside of their remit, or that they may not be fully trained in (e.g., counselling patients) were also found. Such occurrences were reported among specialist pain nurses who frequently discussed having to counsel patients (mostly via telephone helplines) on a spectrum of mental health issues ranging from mild (e.g., anxiety) to severe (e.g., mention of suicide). It may be worth considering implementing HCPs training around psychological first aid to help overcome these issues, doing so may provide HCPs with the knowledge on how to deescalate emotionally drive consultations and identity when to refer on in a crisis.

This study found that clinical psychologists don't often see patients until they are entrenched in long established unhelpful behaviours "*we see them much further down the line and I think that causes us some problems*" (HCP10, consultant psychologist). As a result, the combination of HCPs lack of capacity, training and optimal allocation of trained recourses may put patients in a position whereby they are not receiving the optimal care needed to support them at the right time (objective 3). The patients interviewed in this study discussed the need for more support before, during and after an opioid weaning plan "*I think you need somebody, because we had nobody*" (P12). This suggests that during this time the psychosocial element of the biopsychosocial model is not currently well managed or delivered. It may also be indicative of patients being stuck in the perseverance loop featured as part of the misdirected problem solving model (Eccleston & Crombez, 2007). When this happens Eccleston proposes to help patients reframe their problem though methods of CBT or ACT to identify new ways of solving it. It is concerning, that HCPs this study highlighted that if patients don't have the right support in place, then they are more likely to experience treatment failure. Ensuring patients have the right support emphasises the need to invest in improving the psychosocial element of care (objective 4). The value of operating a biopsychosocial approach to treat chronic pain has recently been acknowledged by the UKs health and clinical excellence body, NICE. NICE have announced that we may expect their forthcoming clinical guidance to include information around biopsychosocial approaches to chronic pain treatment (NICE, 2019). It therefore justifies the need to explore methods of best practice that will effectively employ this interconnected approach to chronic pain treatment.

**How this applies to opioid weaning**

This study found that patients were more likely to initiate the decision to discontinue their opioid treatment themselves and often seek guidance from their GP on how to do this. Patient's motivations for this decision revolved around the unwanted side effects of opioids, namely impaired cognitive and physical functioning. Meta-analysis and systematic reviews of RCTs and open label trials of opioids have also found that high dropout rates are usually due to intolerable side-effects or insufficient pain relief (Bialas et al., 2020; Häuser et al., 2016; Noble et al., 2008). It is difficult to assert what dose reductions minimise side-effects as most interventions that target opioid weaning do not measure specific side-effects but rather

improvements in function, disability, pain interference, mental health or coping to name a few (Garland et al., 2014; Naylor et al., 2010; Sullivan et al., 2017). However, reducing doses has been recommended as one strategy to help manage common side-effects in patients who are prescribed opioids (Harris, 2008).

It is important to understand that by the time patients are faced with weaning or discontinuing their opioid treatment they will have frequently already experienced years of various treatments for their pain, most of which involved increased doses or stronger variations of opioids. As a result, whether it is a patient's decision or HCPs recommendation to wean off opioids, by default it is likely to occur when patients have been exposed to high dose or high strength opioids and yielding no benefit (objective 1). This experience inherently carries with it all of patient's previous experiences of chronic pain treatment and thus preconceived judgement and expectation that has developed along the way. These preconceived perceptions may be difficult to manage when new treatment such as opioid weaning is recommended (objective 3). Preceding all other tried and tested treatment, opioid weaning means engaging with something else patients have no established reason or evidence to trust and giving up a method of treatment they thought reliable. There is a need for HCPs to manage patients concerns about weaning in order to get them onboard with it (objective 2). Some interventions designed to target opioid weaning have used motivational interviewing as a method to address patients concerns and establish goals specific to them to encourage their engagement (Sandhu et al., 2019; Sullivan et al., 2017). Conversely, the provision of MDT support available in tertiary care might mean they are better placed to address these issues, there would still be need to review HCP responsibility and job role remit particularly when they are not trained to deliver optimal care (i.e. counselling).

Apart from patients treated as inpatients, the most difficult experience for patients reducing opioid doses was the onset of withdrawal effects and increased pain. All patients with experience of weaning discussed a point where the withdrawal effects intensified and felt unable to reduce their dose any further. Patients described how the combination of different emotions (including frustration, anger, and hopelessness) and effects of withdrawal left them in a limbo, unsure whether they could continue yet afraid to go back. Reflecting upon patients experiences it appeared they often underestimated the intensity of weaning. It would be

useful therefore to ensure patients are given more information, their expectations are managed, and continued support and guidance is given before and during weaning (objective 2 and 4). Opioid weaning is a long and discomforting experience for CNCP patients, and they often feel alone in this process. Reassuring patients with empathy and understanding is believed to help HCPs maintain their therapeutic relationship and navigate in a supportive manner though a weaning plan (Tobin et al., 2016; Toye et al., 2018). Overall, patients reported having a good relationship with their HCP however they did not want to feel like a nuisance when they need support. Having a HCP they can contact in between their clinical appointments would help fulfil the void of feeling alone and the uncertainty of who to turn to (objective 4).

This study depicted experiences from patients who have successfully discontinued their opioid treatment, those currently undergoing weaning or those about to begin a weaning plan. Patients described how they could not live with, nor live without opioids due to the level of pain they experienced. Ultimately patients did not like how opioids changed them as a person and hindered their functionality and cognition. Collectively these experiences describe the adversity and successes that come with initiating and maintaining opioid treatment and weaning regimes. Combined with the lived experiences of HCPs it is recommended that the following factors of care should be considered when implementing opioid weaning plans:

- Improved information and education on opioids and opioid weaning plans for patients.
- Improved information and guidance for HCPs on how to effectively manage patients.
- Maintain a sense of trust, focus on empathic treatment and consistency among HCPs involved in patients care.
- Better communication among the HCPs involved in patients care.
- Promote interdisciplinary care in the community by utilising resources such as clinical pharmacists.
- Involve a key worker who could connect the links from all the HCPs involved, monitor the progress of patients weaning and give them the time needed to feel listened to and invested in their care.
- Consider earlier referral for psychological support.

With regard to initiating and managing an opioid reduction plan HCPs identified that it is best delivered by an MDT where there is a specific focus on supporting and guiding patients with the treatment plan. GPs are generally encouraging and supportive of their patients who wish to wean off their opioid medication, however they acknowledge that they are not fully equipped to deliver the optimal level of care needed. As a result, constructing an intervention comprising both patient and HCP experiences may help address some of the issues that commonly arise and develop methods of best practice to optimise opioid weaning.

**Reflective learnings**

CNCP has a domino like effect that impacts on life across the spectrum of society, whether it is living every day in pain and its subsequent consequences (e.g., inability to work, financial worries, trialling ineffective treatment), caring for someone in pain or managing patient healthcare. Prior to starting this research and as someone who has never experienced prolonged periods of pain, I never really understood what it meant to live a life in pain nor feel unable to adequately treat patients for a condition that isn't terminal, but causes great distress, yet is unlikely to ever go away. As a person, I have a great sense of empathy and therefore felt connected to the experiences shared by both HCPs and CNCP patients. As a researcher, I had the opportunity to critically analyse these experiences in attempt to better understand how it impacts those directly affected. Approaching the research with these two lenses made it difficult to write an objective concise observation whilst not losing sense of the participants' experience. Using participant quotes helped overcome this issue, but there were many to choose from. The quotes depicted therefore come from my own subjective judgement to best describe the themes discussed. I followed a framework (Braun and Clarke, 2006) to help limit personal bias, conversely, I understand that my lack of lived experience in the pain field may influence my interpretation of the data collected. I have learned that the lenses researchers wear to analysis qualitative data vary and therefore such data may benefit from a second set of lenses to review individual interpretations that will ultimately influence research outputs. From a personal perspective I was interested in learning how CNCP patients coped with their pain so I could better empathise and support my own mother who at the time of researching this topic developed chronic lower back pain. Similarly, I wanted to understand the health care system so I could help adjust my mother's expectations of

treatment and treatment outcomes. Ultimately, what I learned was that although patients may go through similar medical roundabouts and HCPs may share similar challenges in treating patients, there is an element of early prevention needed to avoid unhelpful coping behaviours and over reliance on opioid medication during the initial onset of chronic pain. Currently a challenge remains on how best to support patients who are long established on opioid medication to reduce or discontinue their use and replace it with self-management strategies. There is a sense of ambiguity among HCPs and patients on what may replace opioids and how pain management can be sustained. This research identified the need to change how CNCP patients are managed in primary care, improve the network of support, as well as better managing patient fears, anxiety and expectations of treatment outcomes.

**Study strengths**

The strengths of this study lay in capturing valuable first-person accounts of both HCPs and patients regarding their experience of opioid treatment. Interviews were carried out with participants until no new information emerged (Baker & Edwards, 2012), offering contextual in-depth descriptions among cohorts with recent opioid treatment experience. Goldstein (2012) emphasises the importance of obtaining insights from different vantages points an important aspect of conducting qualitative research (Goldstein, 2002). Therefore, an advantage of this study is that it offers insight from various HCPs with different job roles and patient experiences at different stages of opioid weaning depicting a fuller insight to the phenomenon in question. Furthermore, the flexibility of offering participants an option of interview style (e.g., telephone or face-to-face) increased their opportunity to take part. This was particularly noticeable among patients who could not easily leave their home due to their CNCP and for HCPs with busy schedules but wanted to take part in the research.

**Limitations**

Conducting this study was not without some limitations and in order to provide complete transparency they will be discussed here. The range of interviews held with patients captured insights from those with very recent experience of discontinuing or engaging in a weaning plan. Interviews with patients who discontinued their medication for longer may have provided some additional insights not captured here. Similarly, all patients were recruited

from a tertiary care pain clinic which may only represent one sub-group of the population and is not representative of the wider chronic pain population, particularly those in a primary care setting. Patients receiving high dose opioids who have only received treatment in primary care may have provided a different insight in terms of their expectations of weaning and experience of being treated by only their GP. These experiences would have been insightful due to the difference of HCP expertise and therefore management of CNCP patients in primary care compared with tertiary care. Tertiary care provided an opportunistic setting to recruit patients who match the inclusion criteria for this study, as patients here will have been taking opioids above 120mg MED and being targeted for opioid weaning. There was a missed opportunity in not exploring the MSc student's interpretation of their own analysis and the analysis conducted in this study. Cross-referencing their findings may have highlighted interpretations from a differing lens that could have been overlooked here. Additionally, as the majority of interviews were conducted via telephone, there was a lack of visual communication which is considered by some an important element of interview research (Creswell, 1998). Finally, conducting interviews that focus on individual experiences requires an element of memory recall, a caveat of which questions the measure of reliability and validity (Henry et al., 2018). For example, when conducting interviews professionals may speak subjectively from their position of employment to justify their role and therefore may not always reflect an honest objective (Berry, 2002).

# Chapter 5: Identifying intervention recommendations

## 5.1 Overview

There is limited evidence on which psychological interventions are most effective at safely reducing or discontinuing opioid use among CNCP patients (Eccleston et al., 2017; Frank et al., 2017; Mathieson et al., 2020). The MRC guidance which sets the precedent for developing and implementing complex interventions in the UK, recommends that the early stages of intervention design should be: informed by existing literature, theoretically developed and adequately reported in order to increase the likelihood of effectiveness and replicability (Craig et al., 2008). Using theory to understand the nature of a behaviour may help identify potential approaches likely to be effective or ineffective in changing a behaviour. This chapter sets the scene by providing context to targeting behaviour change, whilst also referring to the existing evidence on opioid weaning interventions specific to CNCP patients. Subsequently, a description of the Behaviour Change Wheel (BCW) (Michie et al., 2011) and its use in the context of the current thesis to develop recommendations for an opioid weaning intervention is provided.

## 5.2 Introduction

Interventions are a coordinated set of activities usually designed to influence change. Often used in public health, interventions that are designed effectively have the potential to improve clinical practice and encourage healthy lifestyles (Glanz & Bishop, 2010). Changing behaviour is fundamental in health interventions and often requires implementing several interacting components using various BCTs to bring about the desired change. BCTs such as self-monitoring, feedback or behavioural practice are considered the active ingredients of an intervention and are used to alter or redirect causal processes that underlie behaviour (Michie et al., 2013). There are many BCTs that may influence behaviour, a taxonomy structuring a comprehensive list of 93 BCTs was developed to help categorise techniques that are likely to change specific behaviours (Michie et al., 2013). However, identifying which BCT is most relevant in predicting or influencing behaviour change can be difficult, and it is recommended that we need to first understand the nature and context within which a behaviour occurs

(Michie, West, et al., 2014). Understanding behaviour can be complex as various factors such as social, cultural and economic factors may be influenced simultaneously at individual, organisational and community levels (Glanz & Bishop, 2010). Inter-relating factors like this can make the design, delivery and evaluation of an intervention 'complex' (Craig et al., 2008). The application of theory can help establish constructs that determine behaviour (i.e., the how, when and why) and targeting relevant constructs may have greater potential to elicit behaviour change (Michie & Prestwich, 2010). Furthermore, there is increasing evidence that interventions informed by theory are more effective than those that lack theoretical input (Davies et al., 2010), which is why the use of theory in intervention design is strongly recommended (Craig et al., 2008). The issue with employing theory, however, is that there is a vast range to choose from and arguably before 2011 no comprehensive framework to systematically guide developers on how to apply theory, or chose the most relevant theory to inform an intervention (Michie et al., 2011).

Identifying this gap, Michie and colleagues developed the Behaviour Change Wheel to inform intervention design, implementation and evaluation (Michie et al., 2011). The wheel consists of three layers that synthesize features of 19 existing behaviour change frameworks overcoming common limitations to theoretical input, clarity and coherence (Michie, Atkins, et al., 2014). Featured at the centre of the wheel (depicted on Figure 5.1), the COM-B model postulates that all behaviours are the result of having capability (C), opportunity (O) and motivation (M) to undertake behaviour (B) and changing behaviour requires change in one or more of these components. This model guides users through in-depth behavioural analysis of the target behaviour, identifying sources of influence and indicating potential ways to structure an intervention. An additional feature of the COM-B model is that it succinctly links with the Theoretical Domains

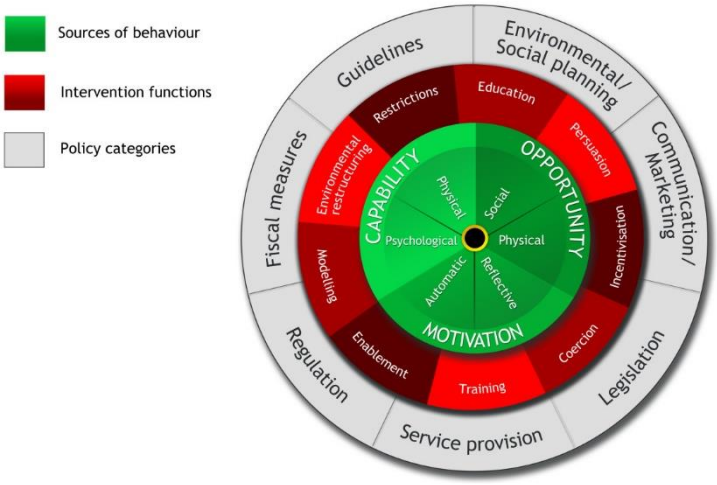


**Figure 5:1: The Behaviour Change Wheel**
(Reproduced with permission from the author; sourced from Michie et al, 2011)

Framework (TDF) (Cane et al., 2012). The TDF is limited in its theoretical construct, but it attempts to understand behaviour further by characterising it into 14 potential domains, these can then be mapped back to the 3 components of the COM-B model succinctly offering a further detailed analysis of a behaviour. The BCW links the COM-B analysis to a second layer of nine intervention functions (education, persuasion, incentivisation, coercion, training, restriction, environmental restricting, modelling and enablement) which are further linked to specific BCTs likely to be effective in eliciting change of a targeted behaviour. Finally, the outer layer links onto seven policy categories (communication/marketing, guidelines, fiscal, regulation, legislation, environmental/social planning, and service provision) that contribute to successfully delivering intervention functions. Further details on the content and links between the behavioural components and intervention functions can be found in Michie et al (2011) and Michie et al (2014). Since its development, the BCW has been widely used to design, implement, and evaluate many successful interventions across various healthcare systems. For example, improving adherence to evidence-based guidelines in hospital (English, 2013) and primary care settings (Hanbury et al., 2013), medication management (Sinnott et al., 2015), smoking cessation (Gould et al., 2017; Tombor et al., 2016) and improving the uptake of hearing aid use (Barker et al., 2016) and physical activity (Webb et al., 2016). The BCW encourages developers through a systematic and rigorous design process, harnessing what is already understood about a behaviour combined with theory and principles of behaviour change to inform a more effective intervention design.

Using COM-B and what is already understood about pain behaviour and prescription opioid weaning among CNCP patients will therefore theoretically help inform what may be needed to support CNCP patients to reduce or discontinue their opioids in primary care. Theoretically, the experience of pain is understood not just as a physiological response to noxious stimuli, but a result of ascending and descending signals from the brain analysing an individual's response to sensory-discriminative, affective-motivation and cognitive-evaluative cues (Melzack & Casey, 1968). This understanding revealed the interconnectedness between pain and emotion (e.g. anxiety, depression and anger) and pain and cognitive factors (e.g. appraisal, catastrophising and beliefs) explained succinctly by the fear avoidance model of pain (Vlaeyen & Linton, 2000). These correlations led to recognising that negative mood states, determined by ruminating cognitive appraisals and maladaptive beliefs, significantly

impact on individuals' affective and behavioural response to pain including their motivation and compliance toward treatment (Gatchel et al., 2007). This may also explain why increased fear of pain worsening and scepticism of psychological treatments are recurring concerns that CNCP patients express when confronted with opioid weaning (Nichols et al., 2020; Sullivan et al., 2017). The application of psychological therapies designed to target and change the negative appraisals of sensory-discriminative, affective-motivation and cognitive-evaluative cues may therefore improve how CNCP patients experience pain. For example, in an early review of the evidence on psychological therapies to help manage chronic pain, Keefe *et al*., (2004) highlight how improving coping strategies, increasing levels of self-efficacy, patients readiness to change and acceptance, decrease reported pain and improve adjustment to pain (Keefe et al., 2004). This is still evident over a decade later in a study of 91 fibromyalgia patients compared with 51 healthy controls revealing that patients with higher levels of pain acceptance and behavioural coping had lower levels of depression, anxiety and impairment (Lami et al., 2018).

Coping strategies for pain can vary, however they can largely be identified in psychological therapies such as CBT and ACT. The principles of these therapies are explained in more detail in Chapter 2, briefly CBT uses methods of self-instruction (e.g. distraction or motivation self-talk), relaxation, redefining maladaptive beliefs and goal setting to help change unhelpful thoughts and beliefs, improve problem solving and to establish habitual practice of helpful behaviours (Gatchel, 1999). Whereas ACT embraces a sense of psychological flexibility via techniques such as mindfulness and focuses on accepting events as they are, detaching values held toward unhelpful thoughts and behaviours and developing new goal orientated values (Hayes et al., 2006). The essence of these psychological approaches does not aim to reduce the sensation of pain per se, rather they target cognitive processes linked to behaviours exacerbating the pain experience e.g., psychological distress, quality of life and physical functioning; a reduction in pain may be a secondary outcome (Gatchel, 1999; Penlington et al., 2019). Driven by the increasing evidence on the limited effectiveness and risk of harm of long-term opioid treatment, there has been growing interest to identify psychological therapies that are most effective in managing CNCP. For example, a sequence of reviews investigating the treatment and management of CNCP has recently been published by the UK's NICE (NICE, 2020b, 2020c, 2020d). NICE reviewed evidence on 47 RCTs applying

psychological therapies for CNCP including: CBT, ACT, mindfulness and relaxation and hypnosis, pain education and sleep hygiene (NICE, 2020c). Overall, the review reported mixed results indicating inconsistent benefits of different therapies on improving quality of life, psychological distress, physical dysfunction, sleep, and pain interference. Furthermore, studies were considered low quality due to their risk of bias, small sample sizes and intervention indirectness (i.e., mixing multiple therapies). This made it difficult for NICE to draw on any direct conclusions, however there was consensus that CBT and ACT may be beneficial and in addition to their cost-effectiveness should be considered in the treatment of CNCP (NICE, 2020c). Despite the uncertainty of treatment effect reported by NICE, an esteemed Cochrane review found moderate evidence that CBT can have improved outcomes for pain, disability and distress, and also agrees that there is low quality evidence indicating ACT is any better than active control (de C Williams et al., 2020).

In theory, principles of CBT or ACT may therefore be useful to include in an intervention that targets opioid weaning, as they encourage patients to learn self-management approaches and recalibrate maladaptive or negative thoughts about their pain. The evidence indicating which psychological therapies are most effective in supporting opioid weaning, however, is limited (Eccleston et al., 2017; Frank et al., 2017). Eccleston *et al*., (2017) reviewe

d the literature for RCTs using psychological therapy to reduce opioids among CNCP patients, whilst Frank *et al*., (2017) included RCTs and observational studies. Both reviews agree that the evidence is insufficient and of low quality which prevents any meaningful conclusions being drawn, warranting further research (Eccleston et al., 2017; Frank et al., 2017). More recently, Mathieson *et al.,* (2020b) conducted a systematic review of RCTs targeting the deprescribing of opioids among CNCP patients (Mathieson *et al*., 2020b). The findings concur with those of Eccleston *et al.,* (2017) and Frank *et al.,* (2017) in that there was no conclusive evidence of trials effectively reducing opioids in the intermediate term, largely due to small study sizes and great heterogeneity. Mathieson *et al*., (2020) state that evidence from one HCP intervention study using educational and decision making tool techniques may be effective in reducing the number of opioid prescriptions issued (Mathieson *et al*., 2020b). Given these recent reviews, it was not necessary to conduct another one to inform the current intervention design. Rather, what can be learnt from these reviews is that although the

available evidence is limited and no direct conclusions can be drawn, there are some potential methods to support opioid weaning. For example, Eccleston et al (2017) found 2 of the 5 RCTs included in their review reported significant opioid reductions post treatment and at follow-up following a course of CBT (Naylor et al., 2010; Sullivan et al., 2017). In addition to delivering CBT both these studies incorporated additional methods of support, reviewing patients progress, and amending their actions plans where necessary. For example, preceding an 11-week course of CBT Naylor et al (2010) delivered Telephone Interactive Voice Responses (TIVR) to an intervention group (n=26) for 4 months. This automated mechanism of support aimed to improve relapse prevention (of both opioid dosing and pain behaviour) through improving self-monitoring, encouraging habitual practice of taught skills and self-efficacy. Compared to controls (n=25) the intervention group significantly maintained opioid reductions at 4 and 8 months and n=3 patients completely discontinued their opioid medication (Naylor et al., 2010). Similarly, Sullivan et al. (2017) conducted booster phone calls among the intervention group after they received CBT tapering support. However, they also recognised patients' uncertainty and hesitancy around initially engaging in opioid weaning. Sullivan therefore used methods of motivational interviewing to encourage discussion around patient concerns, collaboratively identifying solutions to barriers prior to weaning. Opioid reductions were found for both intervention (n=18) and control group (n=17) however the intervention group also reported improvements in pain severity, pain interference and pain self-efficacy. Both these studies indicate some promise around potential BCTs which may be useful to improve coping skills, adherence to weaning plans and prevent relapse behaviours. Two of the other five studies included in Eccleston's review did not measure objective opioid use but did report changes in desire and compliance of prescribe opioid treatment (Garland et al., 2014; Jamison et al., 2010). For example, using evolved methods of CBT (e.g. a combination of mindfulness and positive psychology) Garland *et al*., (2014) reported decreased desire for opioids and reduced risk of misuse among 57 CNCP intervention patients compared to 58 CNCP control group patients (Garland et al., 2014). Garland found that patients reduced desire to use opioids was not maintained at three-month follow up in the intervention group, indicating the need for booster intervention sessions. The study also did not report on opioid dosing; however the authors are conducting a new RCT that will consider these measures. These limitations are worth considering in the design of the opioid weaning intervention being proposed in this thesis. In addition, using cognitive behavioural substance

misuse counselling, Jamison *et al*., (2010) also reported improved likelihood of opioid compliance among the intervention group (Jamison et al., 2010). The remaining study in Eccleston's review compared real electroacupuncture with a sham version and although they found a reduction in opioid use, results were not maintained after 8 weeks and there was no between group difference (Zheng et al., 2008).

Alongside this, Frank *et al*., (2017) expanded their search criteria to include studies using any method to reduce or discontinue long-term opioid therapy and identified one other behavioural RCT and three observational studies (Frank et al., 2017). The RCT used a mindfulness and meditation based approached to unpick unhealthy patterns, reinterpret triggers of pain and understand acceptance (Zgierska et al., 2016). Zgierska et al., (2016) did not find a reduction in opioid use, conversely their intervention was well accepted and improvements in reported pain severity and sensitivity were found. Two of the three observational studies included in Franks review delivered CBT in primary care and reported significant codeine reductions (n=5) and discontinued use (n=6) among chronic lower back patients (N=11) (Nilsen et al., 2010); in addition to unintentional discontinued use in four of the 22 patients receiving high dose opioids for non-specific chronic pain (Whitten & Stanik-Hutt, 2013). The remaining observational study delivered a six month-pain management programme in primary care, incorporating psychoeducation and physical activity and found that of the 42 patients who completed the intervention, 18 reduced their opioid dose and eight discontinued completely (Mehl-Madrona et al., 2016). These studies indicate the potential transferability of CBT skills to primary care practitioners which could improve the opioid weaning support for CNCP patients in the community.

The majority of these studies commonly report difficulty engaging patients into an intervention as well as having high dropout and relapse rates post-treatment. Recognising that these issues are common among behavioural interventions, Kerns and colleagues developed the Pain Stages Of Change Questionnaire (PSOCQ) to help predict patients' readiness to change and identifying the likelihood of engagement and adherence to treatment (Kerns et al., 1997). Informed by the four stages of change (1st - precontemplation, 2nd - contemplation, 3rd - action and 4th - maintenance) from the transtheoretical model (Prochaska et al., 1983) and using principles of CBT, Kerns demonstrated the validity and utility of this tool, testing it among 109 chronic pain patients (Kerns & Rosenberg, 2000). Using

the PSOCQ to measure patients' readiness to adopt self-management approaches, Kerns found that patients' beliefs can determine which stage of change they may be at and thus determine their willingness to engage and predict potential treatment outcome (Kerns & Rosenberg, 2000). For example, individuals characterised at the 1st stage of change held strong beliefs opposing self-management strategies and were less likely to complete a programme of psychological treatment compared to those in stages 2-4, whose beliefs were more consistent with self-management. However, those who completed their treatment programme (n=59), indicated that psychological therapy may be useful in developing beliefs toward a commitment to self-management subsequently mediating engagement and active participation of self-management. It was concluded that the PSOCQ may help determine the most effective clinical approach through tailoring patients' treatment to their readiness to change and thereby increasing the likelihood of engagement and active participation (Kerns & Rosenberg, 2000; Kerns et al., 1997; Mun et al., 2019).

NICE recommend that in order to make medium and long-term health improvements, behaviour change must be sustained and to do this effectively involves ensuring new behaviours become habitual and equipping individuals to deal with relapses (NICE, 2014a). In the absence of conclusive evidence informing effective approaches to help CNCP patients reduce or discontinue opioid treatment, approaches to reduce study limitations should be considered alongside theory and practice to improve intervention design. This chapter aims to address objective 5 (outlined in section 1.2) in this programme of research, by using evidence from study 2 (chapter 4) and from the literature to theoretically identify intervention content designed to reduce or discontinue opioid treatment for CNCP in primary care.

## 5.3 Methods

### Design

An exploratory research design was used to identify intervention recommendations to support CNCP patients wean or discontinue their opioid treatment in a primary care setting. This involved incorporating findings from HCP and CNCP patient interviews in study 2 and existing evidence from the literature to inform the early stages of the BCW framework and intervention design.

**Procedure and settings**

The BCW framework was used to systematically guide the researcher (EB) through an 8-step process of understanding behaviours related to opioid weaning and identify relevant intervention functions and BCTs likely to influence behaviour change that would facilitate opioid weaning. This chapter describes steps 1-5 & 7 involved in completing the BCW (steps 6 and 8 are discussed in chapter 6). Here, steps 1-4 of the BCW were followed to better understand the behaviour in question, i.e., opioid weaning; step 5 explored potential intervention functions most likely to influence behaviour change; and step 7 explored potential intervention content i.e., the active components or BCTs likely to trigger the changed needed.

**Materials**

*Intervention design*

Michie et al.'s (2011) 8-step framework for the BCW was used to help guide development of the intervention recommendations. Simultaneously, the evidence generated in study 2 (Chapter 4) and from the literature (Chapter 2 and introduction to this chapter) also informed the behavioural analysis of opioid weaning.

**Analysis**

The analysis section of this study reports on 6 of the 8-steps in the BCW framework used to conduct a behavioural analysis of opioid weaning and identify the most relevant intervention functions and BCTs for an intervention design suitable for primary care. Each step is outlined below.

*Step one: Define the problem*

To begin understanding what needs to change, the problem (opioid weaning) was defined in behavioural terms. This involved being specific about the behaviours surrounding opioid weaning that need to change in order to acquire the desired outcome, where these behaviours occur and by whom they are performed.

*Step two: Select the target behaviour*

Behaviours operate within an interactive system, often influenced by other behaviours. There was need therefore to identify and prioritise all the behaviours relevant to opioid weaning. A conceptual map of all the behaviours associated with opioid weaning was developed and then prioritised according to Michie et al.'s (2014) four criteria on impact and outcome that considered: the impact a behaviour change will have on opioid weaning, the likelihood of a target behaviour changing, potential overspill onto other related behaviours and the ease the behaviour change can be measured. The purpose of prioritising behaviours like this was to narrow the intervention design targeting specific incremental changes more likely to be effective at facilitating change. The targeted behaviours (N=3) were then selected for further in-depth behavioural analysis.

*Step three: Specify the target behaviour*

In preparation for step four, it was first important to describe and understand the targeted behaviours selected from step two. Each selected behaviour was described in detail regarding the *who, what, when, where, how often* and *whom* the behaviour affects.

*Step four: Identify what needs to change*

A behavioural analysis of the targeted behaviours (N=3) using the COM-B model was conducted to determine what exactly needs to change in order to facilitate opioid weaning. This is considered a vital part to the intervention design as a unidirectional change in one or more of the COM-B components is predicted to influence change and determine the most relevant intervention functions and BCTs (see figure 5.2). Each targeted behaviour was therefore analysed for its physical and psychological capability (C), its physical and social opportunity (O) and its automatic and reflective motivation (M). Findings from the interviews conducted with HCPs and patients (reported in Chapter 4) alongside evidence from the literature (in Chapter 2 and introduction to this Chapter) surrounding barriers to and facilitators of opioid weaning informed this stage of the behavioural analysis.

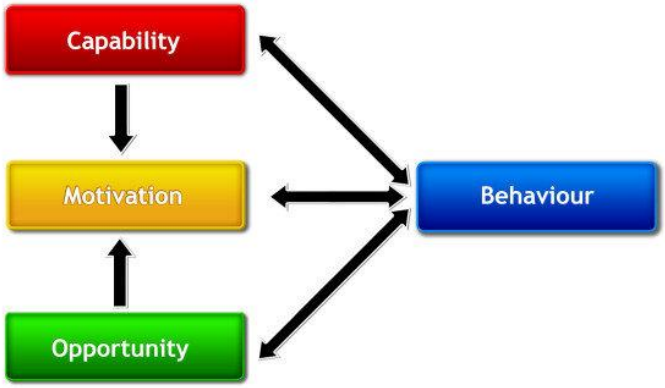


**Figure 5:2. COM-B model**

(Reproduced with permission from the author;
sourced from Michie et al, 2011)

*Step five: Identify intervention functions*

The behavioural analysis of step 4, led to identifying constructs of the COM-B components considered relevant to influencing the target behaviours. This information was used to identify potential levers of change specific to each construct. Nine intervention functions represent potential levers and link into the constructs that influence capability, opportunity and motivation. This provided the means to identify the most appropriate intervention function that, in theory, would target the constructs linked to the COM-B components that ultimately determine behaviour. In practice, not all intervention functions are viable so to establish their suitability the APEASE criteria were consulted. This considers the Affordability, Practicability, Effectiveness and Cost-Effectiveness, Acceptability, Side-effects/safety and Equity of designing and evaluating an intervention (see appendix 19). The most applicable intervention functions considered important to support opioid weaning were selected.

*Step six: Identify policy categories*

This step of intervention design sits outside the aims of this study and was subsequently followed only to inform discussion and recommendations for future research. The output of this step is reported in Chapter 6 'Stakeholder feedback and supporting intervention delivery'.

*Step seven: Identify BCTs*

The BCW reviewed and synthesised 93 BCTs into 16 categories that are evidentially linked to facilitating the delivery of the 9 intervention functions. Using this framework, a list of BCTs both frequently and less frequently used to elicit change were identified for each intervention function, relevant to each targeted behaviour. The identified BCT were subsequently assessed using the APEASE criteria and selected to inform the intervention recommendations.

*Step eight: Identify mode of delivery*

Similar to step 6, this step is reported in chapter 6, stakeholder feedback and supporting intervention delivery.

**Quality and rigour**

To ensure a measure of quality and rigour in this research, steps of the BCW were systematically followed and described in detail. Applying the APEASE criteria also provided a consistent method of making informed decisions regarding intervention content. Additionally, each output of every BCW stage was consulted with a member of the supervisory team (HP) in order to reduce risk of bias.

## 5.4 Results – Stage 1, 2 and 3 of the BCW

Following the design process of the BCW framework, results are presented according to their defined stage, 1) understanding the behaviour, 2) identify intervention opioids and 3) identify content and implementation options.

**Stage 1: Understanding the behaviour**

Stage 1 laid the groundwork for understanding the interrelated behaviours associated with opioid weaning. It involved completing steps 1-4 as described in the method above.

Step 1 *Defining the behaviour*

Opioids have long been used to ease the symptoms of pain (Portenoy, 1986), an exponential increase in their use has led to concerns over their long-term efficacy and safety for treating

CNCP (Zin et al., 2014). Evidence has indicated that risk of harm such as falls, cognitive dysfunction, dependency, overdose or death increase when long-term doses above 120mg MED are taken (Bedson et al., 2019). There has been a year on year trend of increased opioid prescribing in the UK (BMA, 2017) with an estimated 5.6 million adults being prescribed at least one opioid during 2017/18 (Taylor et al., 2019). The problem behaviour of interest in this study therefore is reducing or discontinuing opioids, specifically those prescribed above 120mg MED/day to CNCP patients. Informed by the interviews with HCPs and CNCP patients reported in Chapter 4 and evidence from the literature, potential behaviours identified as needing to change in order to address this problem include:

- Engaging patients into an opioid weaning plan
- Improving patients' adherence to an opioid weaning plan
- Reducing patients' fear and anxiety of weaning
- Improving provision of support
- Improving the training and knowledge of HCPs delivering care

This intervention is intended for delivery in primary care therefore it was apparent all these behaviours occur in primary care, with an overspill of patients' fear and anxiety occurring at home in addition to support also taking place in the wider community. HCPs including GPs, pharmacists or community nurses are considered to be involved in performing all these behaviours in primary care, with additional experts from tertiary care disseminating training and knowledge. Patient involvement includes committing to engage with a weaning plan and adhering to it, as well as addressing personal fears and anxieties though seeking support and practicing methods of self-management.

Step 2 *Selecting a target behaviour*

All behaviours including opioid weaning occur within an interactive system with other competing or influencing behaviours. For example, studies exploring patient and healthcare experiences of treating and living with CNCP (Nichols et al., 2020; Toye et al., 2018; Toye et al., 2013) alongside the research interviews conducted in Chapter 4 reveal that opioid weaning may be dependent on behaviours from 1) the patient weaning, 2) the HCP delivering care, 3) the health care system and 4) family and friends. To identify which behaviour/s may be best to address opioid weaning an initial list of 34 behaviours was created from these

groups. These are embedded into a conceptual map (figure 5.3) depicting the system of interacting behaviours that might be relevant to supporting opioid weaning.

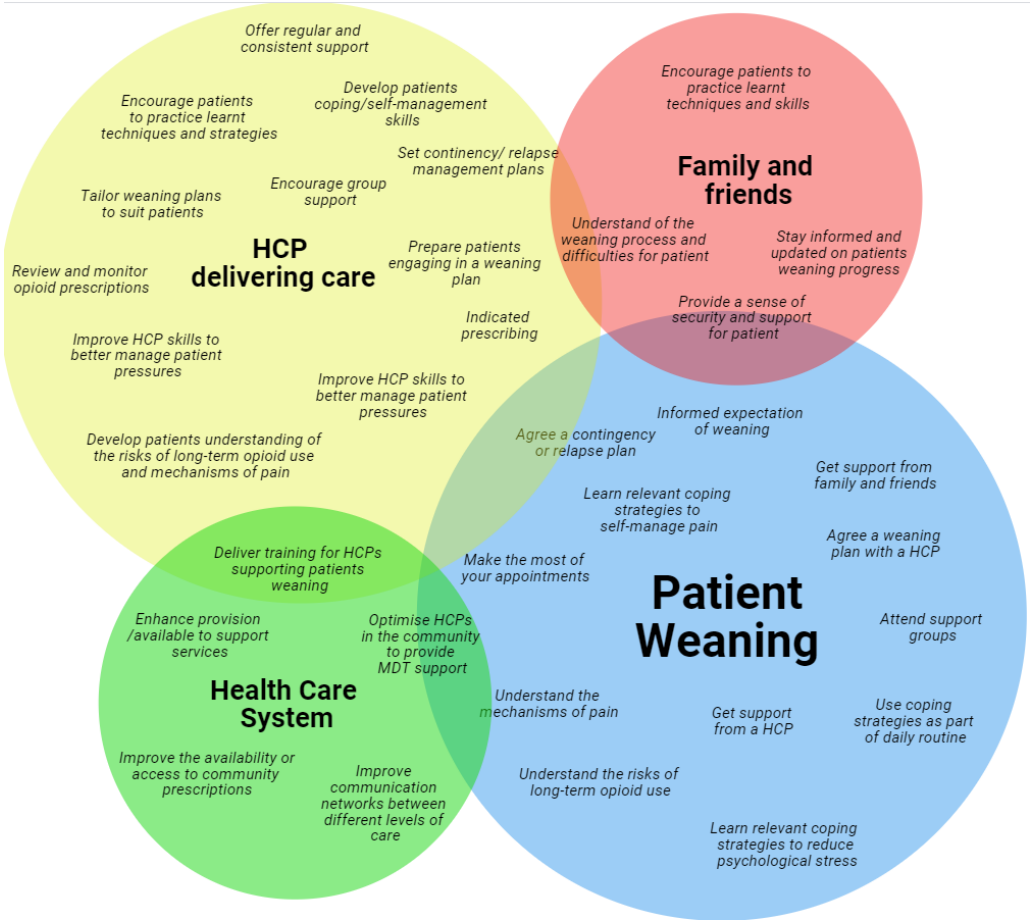


**Figure 5:3. Conceptual map of target behaviours**

There is clearly a complex overlap of many interacting behaviours influencing opioid weaning and an effective intervention cannot target them all. It would neither be feasible nor perhaps necessary, as such Michie *et al*. (2014) advise to review and prioritise the list using four criteria measuring impact and outcome (likelihood of impact, likelihood of preforming the behaviour, the potential impact on other behaviours and ease of measurement of behaviour). A table depicting this prioritisation is available in appendix 20. This process resulted in identifying three behaviours considered most relevant to focus the design of an opioid weaning intervention, these include:

- Improve adherence to a tailored weaning plan.
- Reduce patients' fears and anxiety in relation to weaning.
- Improve the provision of relevant information and support.

Step 3 *Specify the target behaviour*

Consideration of the *who, what, where, when* and *how often* and *with whom* the targeted behaviours feature revealed that a certain level of preparedness needs to happen prior to initiating a weaning plan. Changes are needed to prepare both HCPs and patients involved in weaning, this may include education and skills training on opioid weaning and teaching of self-management strategies. These changes should be implemented collaboratively (between HCPs and patients) and need only occur once per course of treatment. Trained experts in chronic pain may contribute to training primary care HCPs who can continue to deliver the relevant education and skills training to patients in a community setting. The target behaviours are specified in detail in table 17 below.

| **Target behaviour** | **Who** | **What needs to be done differently** | **When** | **Where** | **How often** | **With whom do they need to do it** |
|---|---|---|---|---|---|---|
| Adhering to a weaning plan | HCP/patients | Work collaboratively to develop a plan; provide information on the risks of opioids and benefits of weaning; consider contingency/relapse management and progress reviews, allowing flexibility where needed. | Prior to initiating weaning | Primary care | Once | HCP and patients together |
| Reduce patient fears and anxiety | Trained therapists | Provide skills training and knowledge on recommended psychological techniques to reduce fear and anxiety.<br><br>Encourage patients to routinely practice learnt skills. | Simultaneously alongside plan development | Primary care | An 8-12-week course delivered once | HCPs and patients |
| Improve the provision of information and support | HCPs | Support patients to identify and interpret reliable sources of information.<br><br>Confront perceived barriers to patients attending support services and identify a consistent point of contact to liaise between the treatment team and patient. | Any time a patient visits a healthcare setting making enquires. | Primary care | Pathways of support and information should be offered consistently. | HCPs |

**Table 17. Specifying the target behaviour**

Step 4 *Identify what needs to change*

In order to elicit the change needed to support opioid weaning there is need to investigate if HCPs and patients have the capability, opportunity, and motivation to carry out the target behaviours identified. A behaviour analysis using the BCW COM-B model for each target behaviour revealed consistent results:

*Improving adherence to a weaning plan* – there is need to change HCPs psychological capability, physical and social opportunity, and reflective motivation. This involves, improving HCP knowledge of weaning, understanding the risk and benefits and how to manage patient pressures (psychological capability); having the time and capacity to implement and monitor plans effectively and having the provision of relevant prescription medication to support the plan (physical opportunity); maintaining consistent communication and treatment decisions among the HCP team and patient (social opportunity); and regularly reviewing patient progress (reflective motivation). Similarly, there is need to change patient's psychological capability, physical opportunity, and reflective and automatic motivation. This includes, improving patient's knowledge of weaning and understanding of the risks and benefits (psychological capability); improving the provision and access to discuss plans and concerns with HCPs (physical opportunity); establishing helpful beliefs around the benefits of weaning (reflective motivation) and reducing the impulse and desire to relay on opioids to manage pain (automatic motivation).

*Reducing fear and anxiety* – there is need to change HCPs psychological capability, physical opportunity, and reflective and automatic motivation. This includes, improving HCPs knowledge and training on how to use relevant strategies to target patient concerns (psychological capability); the time and resources to implement recommended strategies (physical opportunity); believe that their role can facilitate coping plans and encourage patients to routinely practice coping strategies and convey the benefits of doing so (reflective motivation), establish routine progress reviews with patients and avoid relenting into patient demands and pressure to automatically prescribe (automatic motivation). Similarly, there is need to make changes to patient's psychological capability, physical and social opportunity, and reflective and automatic motivation in order to reduce their own fear and anxiety. For example, there is need to improve patient's knowledge and skills on how to self-manage

distress linked to weaning and subsequently their experience of pain (psychological capability); improve access to healthcare offering education and skills training and the availability of local support services (physical opportunity), reduce hesitancy toward engaging in local support services (social opportunity); change maladaptive beliefs held toward recommended coping strategies and instead recognise their value (reflective motivation), and placed importance on routinely practicing coping skills so they become habitual thus reducing desire to relay on opioids (automatic motivation).

*Improving information and support* – there is need to change HCPs psychological capability and physical opportunity. This includes the need to improve HCPs knowledge on using opioids to manage chronic pain, approaches to weaning, self-management of chronic pain and of resources to support patients (psychological capability); HCPs need the time and capacity to attend educational or training sessions as well as time and capacity to deliver information to patients (physical opportunity). Patients' psychological capability, physical and social opportunity and reflective and automatic motivation need to change. This involves, targeting patients ability to interpret and comprehend reliable sources of information (psychological capability); the availability and access to local support services (physical opportunity) and accept support from friends, family and people with similar experiences (social opportunity); using reliable information as a reminder of the negative consequence of not weaning and building beliefs that in doing has long-term benefit (reflective motivation) and establishing regular plans to attend local support groups (automatic motivation).

**Stage 2: Identifying intervention options**

Using what is understood about the targeted behaviours paved the way to identifying the most relevant intervention options to help deliver the change needed to support opioid weaning. This required completing steps 5 of the BCW framework.

Step 5 *Identifying intervention options*

The behavioural analysis revealed which constructs of the COM-B components need to be targeted to bring about change. These components link to nine intervention functions likely to be effective in delivering the change needed to support opioid weaning. Not all

intervention functions will be feasible therefore subjective judgments were made informed by findings from HCP and patient interviews in study 2 (chapter 4) and existing evidence from the literature and guided by the APEASE criteria. Overall, six intervention functions were identified as being potentially promising to deliver change in HCP and patient behaviour. This included three functions specific to HCP behaviour (education, training and environmental restructuring) and six functions specific to patient behaviours (education, training, enablement, environmental restructuring, persuasion and modelling). The COM-B components and the constructs that link to intervention functions applicable to APEASE are presented in tables 18-20 for each target behaviour for HCPs and patients.

| **COM-B component** | **Constructs of the COM-B components** | **Intervention function** | **Applicability of the APEASE criteria for HCP?** | **Applicability of the APEASE criteria for patient?** |
|---|---|---|---|---|
| Psychological capability | Knowledge | Education | Yes | Yes |
| | Skill | Cognitive training | Yes | No |
| | Stamina/endurance | Train, enablement | No | Yes |
| Physical opportunity | Time | Train, restructure the environment | Yes | Yes |
| | Resources | Restructure the environment | No | No |
| Social opportunity | Resources | Restructure the environment | No | Yes |
| Reflective motivation | Plan | Education, training | Yes | Yes |
| | Evaluation | Education, persuade | No | Yes |
| | Motives | Persuade, incentivise, coerce, model or enable | No | Persuade or model only |
| Automatic motivation | Impulses/inhibition | Train, enable | No | Yes |

**Table 18. Intervention functions to target HCP or patient's adherence to weaning plans.**

| COM-B component | Constructs of the COM-B components | Intervention function | Applicability APEASE criteria for HCP? | Applicability of the APEASE criteria for patient? |
|---|---|---|---|---|
| Psychological capability | Knowledge | Education | Yes | Yes |
| | Skill | Cognitive training | Yes | Yes |
| | Stamina/endurance | Training or enablement | No | Yes |
| Physical opportunity | Resources, location/physical barriers | Training, environmental restructuring | No | Yes |
| Social opportunity | Interpersonal influences/ cultural expectations | Restructuring environment, modelling. | No | Yes |
| Reflective motivation | Motives | Persuasion, incentivise, coerce, modelling, enable | No | Persuasion, modelling, enablement only. |
| | Evaluations | Education, persuasion | No | Yes |
| | Plans | Education or training | Yes | Yes |
| Automatic motivation | Impulse/inhibition | Training or enable | No | Yes |

**Table 19. Intervention functions HCPs or patients may use to reduce patients' fear and anxiety during opioid weaning.**

| COM-B component | Constructs of the COM-B components | Intervention function | Applicability of the APEASE criteria for HCP? | Applicability of the APEASE criteria for patient? |
|---|---|---|---|---|
| Psychological capability | Knowledge | Educate | Yes | Yes |
| | Skill | Cognitive training | Yes | Yes |
| Physical opportunity | Time | Train, restructure the environment | Yes | No |
| | Location/physical barriers | Train, restructure the environment | No | Yes |
| Social opportunity | Resources | Restructure the environment | Yes | Yes |
| | Interpersonal influences/ cultural expectations | Restructure the environment, modelling | No | Yes |
| Reflective motivation | Evaluations | Educate, persuade | No | Yes |
| | Motives | Persuade, incentivise, coerce, model or enable | No | Persuade, model or enable only. |
| Automatic motivation | Impulses/inhibition | Train, enable | No | Yes |

**Table 20. Intervention functions HCPs or patients may use to improve the availability and uptake of information and support.**

The 3 targeted behaviours (adherence to weaning, reducing fear and anxiety and improving information and support) led to identifying 6 relevant intervention functions likely to deliver the change needed to support opioid weaning. These include education, persuasion, training, environmental restructuring, modelling and enablement.

Step 6 *Identifying policy categories*

Results from step 6 are reported in Chapter 6.

**Stage 3: Identifying content and implementation options**

Step 7 *Identifying BCTs*

Judgements were conducted on the 93 BCTs linked to the six intervention functions for each of the three targeted behaviours identified as needing to change in order to better support opioid weaning. Using the APEASE criteria this was refined to 24 unique BCTs that promised content options to achieve the desired change targeted. Theoretically, an intervention that harnesses the following intervention functions and BCTs should help facilitate the change needed to 1) improve adherence to weaning, 2) reduce patients' fear and anxiety and 3) improve information and support, that will accumulatively support opioid weaning:

- Education - should be used to influence change in both psychological capability and reflective motivation of all three target behaviours. Applicable BCTs include providing information about the health and emotional consequences of opioid weaning, information about others' approval of weaning, introducing prompts or cues to the environment and self-monitoring of the weaning progress and outcomes of weaning.
- Persuasion – should be used to influence change in the reflective motivation for target behaviours 1 and 2. Applicable BCTs include providing information from a credible source, information on the health and emotional consequences of weaning and providing feedback on weaning and weaning outcomes. Only one BCT (creditable source) was considered potentially relevant to target behaviour 3.
- Training – should be used to influence change in the psychological capability, social opportunity, reflective and automatic motivation in target behaviours 1 and 2. BCTs specific to help reduce fear and anxiety include, demonstrating techniques,

behavioural practice of techniques and habit reversal. In addition, the following BCTs are also judged useful to improve adherence to opioid weaning: instruction on how to perform the behaviour, providing feedback on the behaviour and outcomes of the behaviour and self-monitoring the behaviour.

- Environmental restructuring – should be used to influence change in the social and physical opportunity for improving target behaviours 1 and 3. Applicable BCTs include providing prompt/cues and restructuring the social environment e.g., providing space to host community support groups.
- Modelling – should be used to influence change in the social opportunity and reflective motivation of target behaviour 2 and 3. The BCT considered suitable to change these behaviours is demonstration of the behaviour.
- Enablement – should be used to influence change in the psychological capability, social opportunity, and reflective and automatic motivation of all three target behaviours. Applicable BCTs include setting goals for the behaviour and desired outcome, action planning such as relapse management and coping planning, problem solving, providing social support, and helping to reduce negative emotions, adding objects to the environment such as the provision of appropriate pharmacological medication and reviewing the behaviour and outcome goals.

Step 8 *Identifying modes of delivery*

Results from step 8 are reported in chapter 6.

## 5.5 Discussion

This chapter described the systematic and theoretically based process used to inform development of an intervention to reduce or discontinue prescription opioids among CNCP patients in primary care. The recommendations developed here aim to address ways in which HCPs can better support patients who are weaning and ways in which patients can learn to live without opioids, encouraging a self-management approach to CNCP. Currently there is little guidance informing opioid weaning for chronic pain (Sandhu et al., 2018) and a lack of research evidence indicating which methods are safe or effective (Eccleston et al., 2017; Frank et al., 2017; Mathieson et al., 2020b). Using the BCW framework, this chapter addressed

objective 5 of this research by synthesising the knowledge learned from Chapters 2 and 4, and succinctly linked perceived behaviours to opioid weaning and theoretical determinates of behaviour change. This triggered a sequence of steps that identified possible intervention functions, policy categories and BCTs likely to bring about the change needed to support opioid weaning.

*Using the BCW*

The BCW does not claim to be a "magic bullet" for eliciting behaviour change (Michie, Atkins, et al., 2014) (p.27), however it does incorporate recommendations for developing complex interventions considered to increase the likelihood of effectiveness (Craig et al., 2008; Glanz & Bishop, 2010) . Using the BCW was time consuming and labour-intensive, taking almost two years to establish the groundwork needed to identify the recommendations presented here. Previous research addresses the same criticisms, as well as concerns around lack of guidance (Connell et al., 2015) and subjective judgement that is needed to select intervention functions and BCTs (Webb et al., 2016). The BCW offers bi-directional flexibility between each stage, which is pragmatically useful when making decisions about intervention content; conversely this can also make it challenging to document. It is reassuring therefore that the detail involved at each stage ensures every step is thoroughly developed before moving onto the next.

*Identifying the target behaviours*

Prioritising HCP and CNCP patient behaviours in terms of their potential to change and impact on opioid weaning, resulted in identifying three target behaviours considered most relevant for change if a reduction or discontinuation in opioids is to be achieved. These include:

- Improving adherence to a weaning plan
- Reducing patients fear and anxiety
- Improving information and support

These behaviours are considered relevant for both HCPs and patients due to the interlinking synergy between them. For example, maintaining adherence to a plan was particularly difficult when a patient's reluctance to engage was driven by their fear and anxiety, which was often a result of a lack of information, inconsistent advice, and support (see figure 5.4).

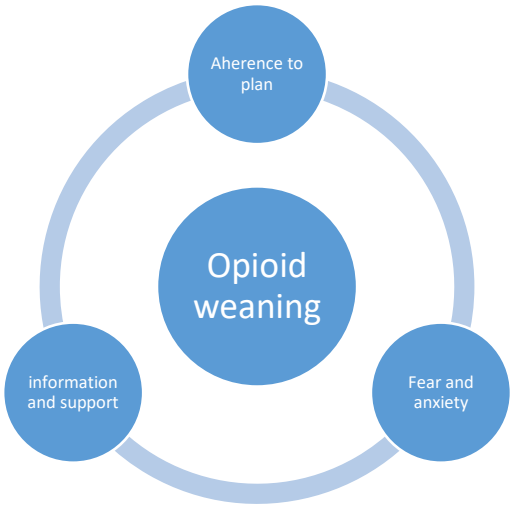


**Figure 5:4. Target behaviours associated with opioid weaning**

Similar behaviours have been targeted in the limited number of interventions designed specifically to reduce opioids for CNCP. For example, decreasing catastrophising and maladaptive behaviours (that contribute to fear and anxiety) feature frequently and often involve targeting the cognitive processing and automatic responses (e.g., reliance on opioids or unhelpful behaviours) to pain (Garland et al., 2014; Naylor et al., 2010; Sandhu et al., 2019; Sullivan et al., 2017). There is a need therefore to understand and target these behaviours in a way that will trigger change to ultimately achieve opioid weaning.

*Identifying Intervention functions and BCTs*

Ability to perform each of the target behaviours were mapped to the constructs of the COM-B model to determine the capability, opportunity and motivation to undertake each behaviour (Michie et al., 2011). Conducting a behavioural analysis in this way was useful because it specified what constructs of each behaviour needed to be addressed in order to bring about the desired change. Mapping behavioural analysis to intervention functions and BCTs was complex as there was often an overlap between them. For example, to address the behaviours mapped to a patient's ability to adhere to a weaning plan, five intervention

functions were selected which involved making judgements on 26 frequently used BCTs and 71 less frequently used BCTs. The BCT taxonomy maps 93 unique BCTs to 16 groups, but the same BCT can be linked to different intervention functions and feature as either a frequently or less frequently used technique (Michie et al., 2013). Without duplicates, 20 unique frequently used BCTs and 52 unique less frequently used BCTs were considered potentially appropriate for addressing patients' adherence to weaning. On review of the APEASE criteria, a total of the 12 most frequently and four less frequently used unique BCTs were selected and recommended to trigger change in patients' adherence to change. This process was repeated to identify BCTs linked to the three intervention functions (education, training and environmental restructuring) relevant for HCPs and the six intervention functions relevant for patients (education, training, enablement, environmental restructuring, persuasion and modelling), for each of the target behaviours.

*Targeting adherence to a weaning plan*

Nineteen BCTs[8] linked to six intervention functions were selected to target change in HCP and patient behaviour to improve adherence to weaning (see appendix 21). The BCTs that satisfied the APEASE criteria indicate that delivering educational sessions which are persuasive in context may increase HCPs' and patients' psychological capability and reflective motivation. For example, information that relates to the *health and emotional consequences* of opioids and perceived as a *credible source* (including *others' approval*) are considered particularly relevant to answer questions on why weaning is recommended. Educational components feature quite frequently in interventions targeting pain or opioid weaning (Mehl-Madrona et al., 2016; Sandhu et al., 2019; Sullivan et al., 2017; Zgierska et al., 2016) although on their own they may not be enough to change behaviour (Keefe et al., 2004; NICE, 2020c). To overcome this, it is recommended that training is provided on *how to perform the behaviour* and implement features such as *feedback* and methods of *self-monitoring* to reaffirm new beliefs (reflective motivation) about weaning. Similar techniques were used in an intervention to reinforce consistent coping and improve self-efficacy of patients' weaning (Naylor et al., 2010). Having the actual opportunity to perform the behaviours recommended

[8]Reference to BCTs are depicted in italics.

may also be a particular barrier for HCPs where capacity is limited. It is important that they have the *social support* of other HCPs particularly when they are new to weaning. Introducing *prompt/cues* may improve HCPs' motivation to establish new routines that encourage periodic review or monitoring of weaning plans. Interventions designed to improve medication management in primary care have incorporated similar techniques (Sinnott et al., 2015; Timmerman et al., 2017). Motivating patients to engage and adhere to weaning is a particular challenge, techniques such as *setting and reviewing goals*, *problem solving,* and *action planning* are recommended to help with this. Motivational interviewing has been used successfully to encourage change talk, address perceived barriers and problem solve prior to initiating a weaning plan with the aim of improving patient engagement and adherence to weaning (Sandhu et al., 2019; Sullivan et al., 2017).

*Targeting patients' fear and anxiety*

Twenty-one BCTs linked to six intervention functions were selected to target change in reducing patients' fear and anxiety (see appendix 21). Many of the BCTs (n=18) recommended to improve adherence to weaning are also recommended here. Delivering education and training on the association between opioids, pain, *health, and emotional consequences* is recommended to improve HCPs' and patients' psychological capability and reflective motivation. Understanding the links between these issues and subsequent ways to mitigate them are considered helpful to trigger changes in patients' evaluations in what they believe to work and subsequently modulate how they respond to pain (reflective and automatic motivation). CBT has been shown to be particularly promising at targeting unhelpful thoughts and maladaptive behaviours that exacerbate fear and anxiety and is commonly utilised in opioid weaning interventions (Jamison et al., 2010; Naylor et al., 2010; Nilsen et al., 2010; Sullivan et al., 2017; Whitten & Stanik-Hutt, 2013). BCTs recommended for this intervention include some CBT methods such as *setting and reviewing goals*, identifying *problems and solutions* to barriers with the aim of improving self-efficacy and *reducing negative emotions*. However, both HCPs and patients need to acquire the skills to be able to perform these behaviours, it is recommended that *demonstration and instruction of how to perform the behaviour* is needed. Lastly, *action planning* and using reminders (*prompt/cues*) to routinely practice taught skills has been shown to be effective in increasing adherence to medication

(Sinnott et al., 2015) and prevent relapse in CNCP weaning from opioids (Naylor et al., 2010). Strategies such *feedback*, *self-monitoring* or establishing social or subjective norms (information about *others approval*) may help reaffirm evaluations and reflex responses to pain.

*Targeting the improvement of information and support*

Eleven BCTs linked to six intervention functions were selected to target change in the improvement of information and support provided for opioid weaning (appendix 21). The strategies proposed to improve information and support is what sets this intervention aside from other opioid weaning interventions. As discussed, most interventions incorporate a component of education, delivering information to recipients. Interventions providing information usually pre-package it as handouts and deliver it alongside the face to face intervention (Sandhu et al., 2019; Sullivan et al., 2017). It is suggested here that HCPs and patients are educated about where to access, identify, and interpret reliable sources of information independently. Combining techniques (e.g., *credible information*) that target education and persuasion is recommended to improve recipient's psychological capability and reflective motivation. Furthermore, a weaning ambassador is recommended to act as a credible source of *social support* and *demonstrate* recommended behaviours that may increase patients' social and physical opportunity to perform the behaviours. Sullivan and colleagues have used a similar approach but used video recordings to depict experiences of patients weaning (Sullivan et al., 2017). Similarly the IWOTCH study included lay facilitators with experience of weaning to co-deliver the 8-10 week intervention to patients who were weaning (Sandhu et al., 2019). It is proposed this intervention develops *social support* groups championed by weaning ambassadors to establish social norms around accessing social support outside of regular HCP care. Being reassured that there is a network of support even via automated messages has been shown to increase adherence, practice of coping skills and reduce relapse in CNCP patients weaning (Naylor et al., 2010).

*Intervention summary*

Collectively, the BCTs and intervention functions recommended here represent potential 'TIPS' for opioid weaning. This encompasses *Training* for HCPs and patients on how to

implement and routinely practice self-management strategies for pain during weaning; *Inform* HCPs and patients about opioid weaning by means of educational sessions and brief interventions to entice engagement; *Prepare* patients about what to expect and how difficulties of weaning will be managed; *Support* both patients and HCPs who are new to weaning by establishing support groups and incorporating lived experiences to encourage engagement. Figure 5.5 below depicts what an intervention targeting opioid weaning based on TIPS might look like.


**Figure 5:5. TIPS for opioid weaning an intervention summary.**

*Strengths*

The recommendations presented in this chapter have followed the MRC guidance on early intervention development (Craig et al., 2008). They have been generated from empirically collated data and evidence-based research that is grounded in behaviour change theory (Michie, Atkins, et al., 2014). Using the BCW framework helped standardise and depict the transparency of developing intervention recommendations. This is important to improve the ease of replication, evaluation and identification of active intervention components (Glanz & Bishop, 2010). The recommendations presented here add to the limited evidence base on interventions targeting opioid weaning in CNCP and focus specifically on delivering strategies in primary care. The level of input from HCPs and patients was integral to identifying intervention content. It provided multiple perspectives from varying HCPs backgrounds and expertise as well as patient experiences of weaning, ultimately shaping the intervention design.

*Limitations*

Aligned with MRC guidance (Craig et al., 2008) an in-depth literature search was carried out prior to initiating intervention development. This identified three recent systematic reviews on opioid weaning interventions (Eccleston et al., 2017; Frank et al., 2017; Mathieson et al., 2020b). Thus, although other studies which have employed the BCW incorporated a systematic review (Sinnott et al., 2015; Timmerman et al., 2017), it was not deemed necessary in this instance. Furthermore, mapping the BCTs to intervention functions required a measurement of subjective judgement which may increase bias. This was reduced by consulting the literature, using the APEASE criteria and presenting the recommendations to supervisors and end-users. However other BCW intervention development studies have consulted larger teams to make these decisions (Griffiths, 2019; Webb et al., 2016).

*Conclusion*

This study presented a systematic method, grounded in behaviour change theory that identified a series of recommendations to bring about the changes needed to facilitate opioid weaning. The recommendations propose that changes to HCP and patient behaviour associated with adhering to a weaning plan, reducing patients fear and anxiety and improving

information and support are needed. The overlapping constructs of these targeted behaviours indicate that HCPs and patients need to be adequately Trained, Informed, Prepared and Supported (TIPS) in order to increase the likelihood of reducing or discontinuing opioids prescribed for CNCP. The strategies and BCTs presented here therefore offer 'TIPS' on ways that may support HCPs and patients to reduce opioids in primary care.

# Chapter 6: Stakeholder feedback and supporting intervention delivery

## 6.1 Overview

Involving end-users in any intervention design is thought to increase adherence and effectiveness of those who the intervention is aimed at (Leask et al., 2019). Using feedback consultations with HCPs and CNCP patients, this chapter consolidates the acceptability and feasibility of implementing the recommendations proposed in chapter 5. It also explores the outer aspects of the BCW, following the process for steps 6 and 8 to identify potential policy levers and modes of delivery (respectively) that may support the implementation of the intervention. This chapter is a continuation of chapter 5 therefore a brief introduction outlining step 6 and 8 of the BCW and intervention feedback is provided, followed by the methods, results, and discussion.

## 6.2 Introduction

As highlighted in the introduction to chapter 5 (section 5.2), the outer layer of the BCW consists of seven policy leavers that might help deliver an intervention on a larger scale. This includes considering functions such as communication/marketing, guidelines, fiscal, regulation, legislation, environmental/social planning, and service provision. The use of such functions has already been successful in helping to deliver UK health strategies on smoking and obesity (Michie et al., 2011). In addition, the final step of the BCW encourages users to consider a range of modes of delivery that might be best suited to the behaviour, the population and the setting being targeted. For example, evidence from published literature indicates that group sessions of CBT or ACT may be both effective and cost-effective in managing CNCP (NICE, 2020c) whereas approaches incorporating methods of motivational interviewing may be more effective on a one-to-one basis (Sullivan et al., 2017). Furthermore, it is well understood that individuals have different learning styles and so it is important to consider various methods of delivering different aspects of intervention content (Webb et al., 2016). This may include using visual, audio, verbal, physical, logical, individual or group learning (Whiteley, 2003 cited in (Webb et al., 2016)). It is common therefore that

interventions targeting opioid weaning might use a combination of these approaches aligned with what is most cost-effective and acceptable to the target audience (Garland et al., 2019; Naylor et al., 2010; Sandhu et al., 2019; Sullivan et al., 2017). In this chapter, steps 6 and 8 of the BCW were followed, firstly to systematically complete the process encouraged by the BCW and secondly to inform what modes of delivery future research considering implementing an intervention of this kind should consider.

The 8-step process of the BCW does not include guidance on conducting feedback evaluation of the intervention content that emerges from the completed steps; however, Michie *et al*., (2011) and the MRC guidance recommend this as an additional measure (Craig et al., 2008; Michie et al., 2011). Involving end-users in this way is thought to improve the likelihood of engagement and help revise the feasibility and acceptability of the intervention design before implementing it into practice (Leask et al., 2019). For example, Sandhu *et al*., (2019) included lay person advisors in the development and delivery of their opioid weaning RCT which helped refine the structure (e.g., length of intervention, content) and design (e.g., randomisation, recruitment and outcome measures) of their study (Sandhu et al., 2019). Given the insight that end-users may provide, this study carried out feedback consultations with HCPs and CNCP patients to consolidate and refine the recommendations proposed to support opioid weaning.

## 6.3 Methods

### Design

A mixed method qualitative research design was developed to establish the feasibility and acceptability of the intervention recommendations proposed in chapter 5. This involved conducting online focus groups and interviews with end-users (HCPs and CNCP patients) to establish feedback and refinement. Additionally, to support the delivery of the intervention, outer aspects of the BCW exploring the policy and modes of delivery were also investigated.

**Setting**

Interviews and focus groups were conducted online using Microsoft teams. Participants were sent individual meeting requests and were able to take part from a space that best suited them.

**Participants**

This study was granted approval by LJMU Research Ethics Committee (REC) 20/NSP/041 (appendix 22). Participants who expressed interest following their involvement in study 2 (Chapter 4) were initially contacted via email and invited to participate (appendix 23). Following this, snowball and opportunistic sampling methods were then used to encourage participants to pass on the study details to other potential participants. Recruitment posters (appendix 24 and 25) were designed and emailed to interested participants alongside a participant information sheet (appendix 26 and 27) and consent form (appendix 11). Recruitment for focus groups was prioritised, however due to participant availability and project time constraints individual interviews were also arranged. Participant recruitment took place between November 2020 – December 2020. A mixture of three focus groups (2 with HCPs and 1 with CNCP participants) and two individual interviews (1 with a HCP and 1 with a chronic pain participant) were conducted. See table 21 below for further breakdown of participant characteristics.

| Participant Group | No. of male/female | Employment status | Interview style |
|---|---|---|---|
| HCP | Female, n=7<br>Male, n=1 | Pharmacist, n=5<br>Psychologist, n=2<br>Physiotherapist, n=1 | Online individual interviews, n=1<br>Online focus groups, n= 2 (n=5 and n=2 participants in each group) |
| Patients | Female, n=2<br>Male, n = 1 | In employment (not specified), n=3 | Online individual interviews, n= 1<br>Online focus group, n= 1 (n=2 participants attended) |

**Table 21. Participant characteristics and interview style from feedback consultations**

All participants were required to be over the age of 18 and able to converse in English. Participants were excluded if they had a record of major medical or psychiatric conditions or a history of substance misuse.

HCPs invited to take part included those involved in the care of, or prescribing for, CNCP patients (e.g., GPs, psychologists, pharmacists, nurses, consultants). Of the 12 HCPs invited to take part, all expressed keen interested in attending the arranged focus groups or interviews, however due to increased work commitments arising from the impact of COVID-19 only 8 HCPs participated.

Similarly, CNCP participants invited to take part included those who were currently or recently (within 2 years) treated with opioids for their CNCP. Of the 8 CNCP participants who were invited to take part, 3 participated. Reasons for opting out were primarily due to health complaints associated with their pain.

**Procedure**

Similar to the procedure explained in chapter 5, step 6 (policy categories) and step 8 (modes of delivery) of the BCW were followed to explore potential mechanisms that would support the delivery of the proposed intervention content.

Once consent was obtained for the focus group and participant interviews, a date and time was arranged and individual links to meeting requests were emailed out. Participants were informed that the study would take up to one hour and reminded that they could stop or opt out of the interview at any time.

During the first half hour of the meeting, participants were presented with the results from studies 1 and 2, and the development of intervention recommendations. In the last half hour, each intervention recommendation (N=3) was reviewed individually and both groups of participants were asked similar questions regarding the feasibility and acceptability and to discuss any perceived barriers to implementation. No set interview guide was developed, however discussions were informed by the APEASE criteria (appendix 19). The meeting concluded with a summary of participant feedback and overview of what an opioid weaning intervention might look like.

**Materials**

Miche *et al.'s* (2011) BCW framework was used to inform potential policy and modes of delivery that may support the delivery of the recommendations proposed for this intervention (Michie et al., 2011).

Two separate PowerPoint presentations were developed; specifically, to amend the language used to suit the intended audience i.e., HCPs or CNCP participants (see appendix 28). Microsoft Teams was used to conduct and record focus groups and interviews, which lasted for 1 hour on average[9]. Recordings were stored onto a password protected computer until they were transcribed verbatim by the lead researcher (EB) and then securely deleted.

**Analysis**

*Step six of the BCW: Identify policy categories*

Although identifying policy categories sat outside the aims of this study, this step was followed in sequence to simply inform discussion points and recommendations for future research. The intervention functions identified in step 5 (chapter 5, section 5.4) link into policy categories likely to be effective in supporting the delivery of the relevant intervention functions. Using the output of step 5 therefore helped identify the most relevant policy categories. These were then considered using the APEASE criteria to identify the most applicable in practice.

*Step eight of the BCW: Identify mode of delivery*

Michie et al. (2011) developed a taxonomy of modes of delivery; this was used to identify the most appropriate method to deliver the intervention. Selection was informed by those commonly used in studies discussed in the literature (from chapter 2 and the introduction to chapter 5) and assessed for their suitability and feasibility by applying the APEASE criteria.

[9] 30 minutes consisted of a presentation of the research findings from study 1 and study 2 leading onto the development of the intervention recommendations.

*Stakeholder feedback*

Transcripts from HCPs and CNCP participant feedback were read and re-read to establish familiarity. Using a deductive approach, feedback was coded separately for HCP and CNCP participants according to the COM-B model framework. This involved linking any perceived barriers to performing the recommended behaviours to recipients' Capability, Opportunity and Motivation. General feedback and refinements to these behavioural components are discussed for each of the three recommended target behaviours.

**Quality and rigour**

To ensure the quality and rigour of this study, the principles developed by Yardley that were discussed in section 4.3 of Chapter 4 were also applied here.

## 6.4 Results

Step 5 *Identifying policy categories*

The six intervention functions identified in step five were mapped across the seven policy categories of the BCW. After applying the APEASE criteria, four levers were identified as being potentially relevant to support the delivery of the intervention functions (see table 22). Service provision was deemed appropriate for five of the six selected intervention functions (education, persuasion, training, modelling and enablement) in all three target behaviours. In addition, regulation was also considered appropriate to support the delivery of one intervention function (enablement) for one target behaviour (adherence to weaning). The need for regulation stems from interviews with HCPs and patients who commonly discussed difficulty in accessing prescription drugs recommended to support opioid weaning e.g., Tapentadol. Similarly, environmental/social planning policy was judged appropriate to support the delivery of one intervention function (environmental restructuring), however this lever may be relevant for two target behaviours (reducing fear and anxiety and improving information and support). This emerged due to the need to provide space to deliver education and training on coping skills and facilitating community support groups. Lastly, communication and marketing levers were considered relevant to support the delivery of two intervention functions (education and persuasion) for one target behaviour (improve

information and support). This stems from the need to produce convincing, reliable, and accessible information that can reach out to CNCP patient considering weaning.

| **Intervention function** | **Policy categories** | **Policy categories that meet the APEASE criteria for each target behaviour?** | | |
|---|---|---|---|---|
| | | ***Adherence to weaning*** | ***Reduce fear and anxiety*** | ***Information and support*** |
| Education | Communication/ marketing, Guidelines, Regulation, Legislation, Service provision. | Service provision | Service provision | Service provision/ Communication /marketing |
| Persuasion | Communication/marketing, guidelines, regulation, legislation, service provision | Service provision | Service provision | Service provision, Communication /marketing |
| Training | Guidelines, Fiscal measures, Regulation, Legislation, Service provision | Service provision | Service provision | Service provision |
| Environmental restructuring | Guidelines, Fiscal measures, Regulation, Legislation, Environmental/social planning | Non-applicable | Environmental/ social planning | Environmental/ social planning |
| Modelling | Communication/ marketing, Service provision | Non-applicable | Service provision | Service provision |
| Enablement | Guidelines, Fiscal measures, Regulation, Legislation, Environmental/social planning, Service provision | Regulation | Service provision | Service provision |
| Applicable policy functions for each target behaviour | | Service provision, regulation | Service provision, Environment/ social planning | Service provision, communication/ marketing, Environment/ social planning |

**Table 22. Policy categories relevant for delivering intervention functions according to APEASE.**

Step 8 *Identifying modes of delivery*

The mode of delivery will vary depending on the target behaviour, the target audience, and the context to which they apply. Michie et al (2011) developed a taxonomy of modes of delivery to guide selection and recommend that the APEASE criteria also be used to identify the most applicable method/s (see table 23 below). Consideration of patients' individual experiences of living with and being treated for CNCP and the aim of this intervention to be

delivered by HCPs in primary care informed the decision making for modes of intervention delivery. The variation of patient experiences reflected the need to consider that they are a heterogeneous population. Perceptions of what might be acceptable and work for one person therefore might differ to someone else. As a result, both face-to-face and distant individual and group approaches were considered applicable but dependent on the stage of intervention. For example, some patients may not feel ready or want to wean from their opioids and may prefer to seek support or guidance in different forms (e.g., one-to-one compared to group support). It was not considered appropriate to deliver this intervention on a population level, however methods using print and digital media were considered useful to trigger local awareness of opioid weaning.

<table>
<tr><th colspan="4">Mode of delivery</th><th>Does the mode of delivery meet the APEASE criteria to support adherence to weaning, reducing psychological distress and improving information and support?</th></tr>
<tr><td rowspan="2">Face-to-face</td><td colspan="3">Individual</td><td>Yes</td></tr>
<tr><td colspan="3">Group</td><td>Yes</td></tr>
<tr><td rowspan="5">Distance</td><td rowspan="4">Population level</td><td>Broadcast media</td><td>TV<br>Radio</td><td rowspan="4">These modes of delivery were not considered relevant for target behaviours 1 and 2. Print media or digital media may be useful for establishing awareness of information and support (target behaviour 3).</td></tr>
<tr><td>Outdoor media</td><td>Billboard<br>Poster</td></tr>
<tr><td>Print media</td><td>Newspaper<br>Leaflet</td></tr>
<tr><td>Digital media</td><td>Internet<br>Phone app</td></tr>
<tr><td rowspan="2">Individual level</td><td>Phone</td><td>Telephone helpline or Mobile text</td><td rowspan="2">Delivery via telephone or mobile might be considered useful as a follow-up measure for all three target behaviours once individual or group approaches have been delivered first.</td></tr>
<tr><td colspan="2">Individually accessed computer programme</td></tr>
</table>

**Table 23. Modes of delivery**

Guided by the BCW framework, recommendations on which target behaviours and strategies considered relevant to trigger the change needed in these behaviours have been identified. These suggestions were presented to stakeholders (HCPs and CNCP participants) for feedback and refinement, findings are presented below.

## Stakeholder feedback and refinement

A review of stakeholder feedback and points for further consideration are presented below for each key recommendation (1. Adherence to weaning, 2. Reducing fear and anxiety and 3.

Improving information and support). The framework of the COM-B model was used to group feedback discussions into capability, opportunity, and motivation to perform the recommended strategies and identify refinements where necessary.

**Recommendation 1: Improve adherence to a weaning plan**

| | |
|---|---|
| **1.a** | Provide regular feedback reviewing patient progress, goals and amending the plan where and if necessary. |
| **1.b** | Explore patient concerns and barriers of weaning with the aim of reducing negative thinking, help resolve problems and establish patient orientated goals. |
| **1.c** | Discuss and agree with patients a plan of action including plans to cope better and relapse management. Provide instruction on how to wean and self-monitor progress/response. |
| **1.d** | Improve the provision of medicine available on practice formularies that are often used to help patients who are weaning. |
| **1.e** | Incorporate a CNCP 'ambassador' who has experience weaning in the delivery of information, training, and wider support network. |

**Table 24. Recommendations to improve adherence to weaning.**

*Capability*

Discussion was particularly drawn to the recommendation for education and training around opioid weaning in primary care as neither HCPs in primary care nor CNCP participants felt comprehensively informed (1.a and 1.c).

"*If you are better informed you can make a better judgement if that is the right way forward for you or should you try something else"* (CNCP P1)

*"I think you need to education the prescribers as much as the patients. So, educations sessions for prescribers would be a great help to begin with, because this is new to a lot of us"* (HCP1, Pharmacist)

For CNCP participants, being adequately educated meant acquiring knowledge and skills that made them feel prepared to initiate a weaning plan. This included understanding the process, establishing realistic expectations, and knowing what actions to take that can make the weaning experience more bearable.

*"If I have a flare up or if the pain gets worse, what can I do… it is knowing that I have got something else I can try that makes these things a little bit better"* (CNCP P1)

Pharmacists in primary care discussed the need to be educated on methods to reduce different opioids, standardising how risks of opioids are communicated and being informed of coping strategies they can recommend to patients (1.a and 1.c).

*"Some medications you know to do a 10% reduction… but ive had some patients on fentanyl patches or buprenorphine patches where it's not easy to do a little reduction"* (HCP7, Pharmacist)

*"I try and communicate those risks but if you have anything that would standardise that, that would be useful"* (HCP6, Pharmacist)

Some barriers to implementing these strategies were discussed. For example, CNCP participants recognised that primary care HCPs lack knowledge and skills for weaning patients meaning that initiation of plans was usually dependent on tertiary care feedback. (1.c) This delayed patients' progress, keeping them at a standstill with no immediate support to turn to.

*"To enable plan A and back-up plan B… putting that into action without having constant communication with tertiary centre is difficult"* (CNCP P1)

HCPs highlighted getting patients on board with a weaning plan to be a particularly challenging barrier. There were concerns over patients' reluctance to engage unless their opioids were going to be replaced with another treatment (1.b and 1.d).

*"People are very reluctant to engage in this and unless you can say this is the support we are going to give you and this is the help you will receive and these are the ways you can manage it they aren't going to engage"* (HCP1, Pharmacist)

<u>Opportunity</u>

Given current provision and the need to implement the strategies recommended, both HCPs and CNCP participants discussed physical and social barriers to opportunity. This included having the means to travel to sessions or attending to patients who struggle with social anxiety in group settings (1.b). Having flexibility and options to receive the intervention one-to-one or in group sessions and online or face-to-face were therefore preferred (1.c).

*"I could travel somewhere but there may be days where I can't"* (CNCP P2)

*"Some people prefer the comfort that there is other people there… whereas there are others who are perhaps a little bit more shy who would prefer a less personal and more online course"* (CNCP P3)

Conversely, HCPs recognised that although GPs may be better placed in terms of using their relationship with patients to get them on board, they do not have the capacity to maintain these strategies. Whereas pharmacists may have more flexibility and time they do not have the same rapport with patients. This instigated discussion around which HCPs could be educated and trained to deliver intervention components (1.a).

*"I try to engage with patients… that is really time consuming, I think GPs are better placed to it in a way"* (HCP8, Pharmacist)

*"We could train one or two people* [HCPs] *thoroughly but ideally it needs to be across everyone which is really difficult"* (HCP1, Pharmacist)

<u>Motivation</u>

Accruing new knowledge (Capability) was considered to help shape patients' judgements and having options of how to deliver that information was felt to provide a sense of flexibility (Opportunity), that would subsequently help influence patients' evaluations of self-motivation (1.a). In addition, feeling a sense of achievement (e.g., meeting a personal goal) and being able to share experiences with someone in a similar position were also considered motivational factors (1.b and 1.e).

*"I have learnt new skills in all sorts of different things by doing that same kind of thing. I have a life now that I lost for years"* (CNCP P3)

*"If patients are able to exchange how they feel and their experience with someone else they learn they are not alone"* (CNCP P3)

A key challenge for HCPs revolved mostly around finding ways to initially get patients on board and adhere to a plan (1.b and 1.c). The resilience that HCPs discussed needing therefore stemmed from having methods that they could offer patients, instead of reverting back onto opioids (1.a, 1.c and 1.e).

*"I feel where it all fails is…. when the patient calls and says they aren't coping they want to 'go back up' the GP is just going to* [prescribe opioids]*, well not now because they are bit more conscious about it but that's where we struggle"* (HCP1, Pharmacist)

Table 25 below highlights potential barriers and facilitating factors of implementing the strategies recommended to improve adherence to weaning, for both CNCP patients and HCPs.

| **COM-B Component** | **Factors for patients** | **Factors for HCPs** | **Intervention function** |
|---|---|---|---|
| **Capability**<br>*Psychological* | • Lack of knowledge about weaning<br>• Poor collaboration activating plans<br>• Feeling better prepared (e.g., expectations) | • Lack of skills and knowledge to implement strategies recommended<br>• Identifying who needs training/upskilling<br>• Delays initiating continency plans | Education, Training |
| **Opportunity**<br>*Physical*<br><br>*Social* | • Means to travel to appointments<br>• Flexibility of intervention delivery<br>• Improved social support<br>• Stigma of opioids | • Funding<br>• Capacity<br>• HCP-HCP support | Environmental restructuring, Enablement, Persuasion |
| **Motivation**<br>*Reflective* | • Social anxiety<br>• Worry replacing opioids | • Getting patients onboard | Education, Persuasion, Modelling |

**Table 25. Factors attributing to implementing strategies to improve adherence to weaning.**

**Recommendation 2: Reducing fear and anxiety**

| | |
|---|---|
| **2.a** | Provide educational sessions on the link between pain, weaning and cognitions to improve patient's knowledge and to persuade change in existing misconceptions and unhelpful beliefs. |
| **2.b** | Use methods of CBT to facilitate problem solving and restructure unhelpful cognitions such as setting desirable goals, understanding the benefits of using relaxation and breathing techniques. |
| **2.c** | Demonstrate and provide patients with instruction on how to use CBT, encourage routine practice and use feedback and self-monitoring to amend action plans/goals where and if needed and to enhance self-efficacy and resilience. |
| **2.d** | Incorporate a CNCP 'ambassador' who has experience weaning in the delivery of information, training, and wider support network. |

**Table 26. Recommendations to reduce fear and anxiety.**

Capability

Discussions with CNCP participants indicated that they often did not know how to cope with their pain without opioids and that their anxiety around this was exacerbated when their significant carer also did not know how to best support them (2.a and 2c).

*"That has been the worst part for me, I felt totally isolated as much as my family wanted to support me they haven't got a clue"* (CNCP P2)

This difficulty was shared among primary care HCPs who discussed not knowing where to signpost or how to teach strategies to patients who want something to replace their opioids (2.a, 2.b and 2.c). The recommendation to train and educate HCPs and patients in relevant coping strategies therefore "*made sense"* (CNCP P1, P2 and P3 and HCP6 Pharmacist).

*"I have heard that mindfulness does work but I don't know how to teach it I haven't got a resource to send to people"* (HCP6 Pharmacist)

HCPs from tertiary care, discussed being better equipped to support patients and understood the input of skills and knowledge required. Reflecting on this they expressed some concern around what is safe to practice in primary care and the need to clarify when referrals to specialist care are needed (2.a).

*"I think there is need to careful about what can be expected and what can be safe to practice in the remits of primary care and then when do we triage up to specialist pain service"* (HCP2 Psychologist)

Opportunity

The suggestion of using daily prompts or cues to establish a habit of practicing recommended coping strategies was considered physically possible among CNCP participants (2.c). This was because they were methods already incorporated into CNCP participants daily routine ("*I do that anyway*" (CNCP P2) e.g., practicing mindfulness whilst brushing your teeth or stretching in the shower). However, having a social contact who could share experiences of using different coping strategies or elevate feelings of loneliness was not something readily available, yet it was commonly sought out (2.d).

*"Still have a point of contact who could be a real-life example even through text messages that gives you this idea that you are not alone"* (CNCP P1)

*"Having someone who has gone through that experience, and can say yes that worked and this happened to me, I think that would be amazing"* (CNCP P2)

HCPs discussed how they thought it was important for CNCP patients who are weaning to have a good support network, "*right from the beginning*" (HCP, Pharmacist 2). The recommendation of identifying a weaning ambassador who could share personal experiences was viewed particularly valuable (2.d).

*"I love the idea of an ambassador… I think patients would find that really helpful"* (HCP8 Pharmacist)

*"The ambassador thing would be really good, I am not sure where we would get one"* (HCP6 Pharmacist)

<u>Motivation</u>

CNCP participants explained how hearing from someone with experience of weaning and using coping strategies may help change negative misconceptions or beliefs and encourage engagement (2.c and 2.d).

*"They* [CNCP ambassadors] *have been through it and can say well this has worked quite well, and this hasn't, I think that might work well"* (CNCP P1)

*"I would happily talk to them* [patients] *about my experiences of weaning and life on the meds and life afterward and hopefully help them see that it is not all bad"* (CNCP P3)

Establishing and maintaining a sense of motivation among patients who are weaning was a recurring challenge for HCPs. Steering patients away from a "*sense of failure*" (HCP5, Pharmacist) was important, therefore HCPs agreed with the recommendation of setting achievable goals other than simply focusing on dose reductions (2.b and 2.c).

*"An achievement… helps them kind of little by little achieve the goals rather thinking oh I may as well not bother because I haven't got to that 10mg reduction"* (HCP3 Physio)

Additionally, sharing short brief messages was considered a good method to instigate and attract patients to think about weaning and an attempt increase their awareness and change negative thinking (2.a).

*"I think just to get people engaged with something, short messages or one side of A4 to read you have more likely of hooking them in than you do a 45min session or 20 pages of leaflets"*

(HCP6 Pharmacist)

Table 27 below highlights potential barriers and facilitating factors that might occur for patients and HCPs trying to reduce associated fear and anxiety associated with weaning.

| COM-B Component | Factor for patients | Factors for HCPs | Intervention function |
|---|---|---|---|
| **Capability**<br>*Psychological* | • Lack of information on how to use self-management strategies<br>• Information for local HCPs or significant carers on how to support someone weaning | • Lack of skills and knowledge on delivering coping strategies<br>• Standardising safe self-management practice and identifying need for referral | Education<br>Training |
| **Opportunity**<br>*Social* | • Awareness of support networks<br>• Opioid weaning ambassador | • Identifying/ engaging weaning ambassadors | Environmental restructuring<br>Enablement<br>Persuasion |
| **Motivation**<br>*Reflective* | • Believe how setting goals can help the weaning experience | • Developing clear, persuasive and relevant messages to patients<br>• Focus on patient's achievements not failures | Education<br>Persuasion<br>Modelling |

**Table 27. Factors attributing to implementing strategies to reduce fear and anxiety of weaning.**

**Recommendation 3: Improve information and support**

| | |
|---|---|
| **3.a** | Improve access to sources of reliable information and information on sources of community support. |
| **3.b** | Use prompts or cues to remind patients of the information and community support available to them. |
| **3.c** | Incorporate the use of case study examples or approval from others who have lived through similar experiences and have accessed the same information or support services. |
| **3.4** | Explore patients' expectations of community sources of support to understand any barriers preventing engagement and identify realistic outcomes or goals using such services. |

**Table 28. Recommendations to improve information and support.**

Capability

In the absence or lack of advice and guidance from primary care HCPs, CNCP participants expressed concern about knowing if what they were reading online about opioids was correct or even safe (3.a). HCPs also recalled how patients often recited out of date information and agreed the need for better signposting to reliable information.

*"From the support side for an individual when they* [patients] *are in a period of crisis to know they can find the right information they can ensure the information is correct and follow it knowing it is safe and approved"* (CNCP P1)

*"I agree about the reliable information, I think I had a patient quote saying you should be given a much more effective dose of opioids than a small dose and when I looked it up it was a quote from 1986"* (HCP6, Pharmacist)

The provision of better or easily accessible information was considered useful to encourage patient engagement and help manage their expectation of the weaning process (3.a and 3.b).

*"More people have been better engaged starting weaning and sticking to it once they have some information about what to expect"* (HCP5, Pharmacist)

However, HCPs were concerned about the potential effect high opioid doses have on CNCP patients' cognitive ability to comprehend information and their own ability to clearly explain some of the more complicated effects of opioids.

"I*t's difficult to try not to bombard them* [patients]*"* (HCP4, Psychologist).

*"As we know high doses of opioids can cause hyperalgesia… if anyone can help me get that message across that would be useful or indeed how to identify when it is happing"* (HCP7, Pharmacist)

Opportunity

The strategies recommended to improve the provision of information and support were considered practical and necessary. Although HCPs discussed that the provisions to implement and provide these strategies (e.g., community support groups or communication platforms) needed to be in place first (3.a).

*"Yeah, all these things could be provided in primary care as long as the community support is out there, at the moment I struggle to find community support to signpost patients to"* (HCP8, Pharmacist)

To overcome the issue around disseminating information among patients who are weaning, both HCPs and CNCP participants mentioned how using platforms patients can relate to or easily access e.g., short videos via What's App messages may be useful (3.c).

*"It might be a bit more acceptable [to use WhatsApp], if its short under 5min videos might be the limit patients can manage"* (HCP4, Psychologist)

*"Having a group WhatsApp where you can feel you can ask those questions easily would be handy and avoid you looking up the internet where you might find something dodgy"* (CNCP P1)

Furthermore, as the role of managing opioid weaning is new to many primary care HCPs, they discussed the need for specialist support who they can contact themselves, as well as better provisions to inform and support both patients and their significant carers (3.a).

*"I think offering families support or information they can watch, or access would be really, really helpful"* (CNCP P2)

*"It would be really important that the prescriber has a specialist they can perhaps go to… if patients did hit a wall and they didn't quite know where to go and you didn't know where to go"* (HCP8, Pharmacist)

<u>Motivation</u>

CNCP participants recognised that some patients might have preconceived beliefs that negatively influence their intentions to attend support services. Some of these beliefs were discussed in regard to the stigma attached to opioids, indicating the need to encourage change around these thoughts. There was consensus among HCPs and CNCP participants that incorporating a weaning 'ambassador' who had successfully stopped opioids could help reform patients' misconceptions or negative beliefs (3.c and 3.d).

*"You are more likely to believe that it is possible if you speak to someone who has actually gone through the whole process and come out the other side so to speak"* (CNCP P3)

*"A key benefit and positive thing that patients do take from it* [support networks] *is the interaction with other people in the same position"* (HCP4, Psychologist)

An additional barrier to engaging patients with weaning was perceived to be the breakdown of trust between patient and GP once patients are confronted about weaning. HCPs recalled how patients might become somewhat reluctant given the GP was likely to have initiated opioids in the first place. As a result, HCPs believed that patients who instigate wanting to wean to be the best motivator.

*"I think it is a hard thing if the GP tells you that you need to reduce… the patient is quite naturally why did you give it to me to start with if it is harmful"* (HCP1, Pharmacist)

*"Generally, it tends to be more successful if they have volunteered to do this themselves they their own reasons or motivations for wanting to do this"* (HCP4, Psychologist)

Table 29 below highlights potential barriers and facilitating factors for patients and HCPs when considering implementing the recommendations to improving information and support.

| COM-B Component | Factors for patients | Factors for HCPs | Intervention function |
|---|---|---|---|
| **Capability**<br>*Psychological* | • The ability to interpret reliable sources of information<br>• Knowledge on where to seek support and information | • The impact of opioids on patient's cognitive abilities<br>• Easy to read information<br>• Better signposting for support and information | Education<br>Training |
| **Opportunity**<br>*Physical* | • Access to devises that facilitate virtual support<br>• Improved community support | • Provisions to implement support platforms for patients and significant carers | Environmental restructuring<br>Enablement |
| **Motivation**<br>*Reflective* | • Reducing negative thoughts and stigma with opioid weaning<br>• Shared experiences | • Changing patients' perception that quality of care in primary care is any less than in specialist services<br>• Maintaining trust among primary care HCPs and patients | Education<br>Persuasion<br>Modelling |

**Table 29. Barriers for patients and HCPs to improve information and support**

Overall, the feedback from HCPs and CNCP participants on the recommended approaches to support opioid weaning were generally positive and encouraging. Conducting the feedback consultations was useful as it highlighted potential barriers as well as facilitators to implementing the recommended strategies; these are outlined in the discussion below.

## 6.5 Discussion

*Identifying policy categories*

This intervention was designed to target local primary care health services, it was not the current intention to identify policy categories that could support the role out of a larger scale intervention. As such, it was not necessary to conduct this step, however for completeness and the potential to inform future testing and roll out of the intervention, this step was carried out. Four policy categories (service provision, regulation, environmental/social planning, and communications/marketing) were identified as being potentially useful to support the delivery of an intervention of this kind. These categories should be considered in future implementation and refinement of the intervention.

*Mode of delivery*

Individual and group face-to-face or distant modes of delivery were considered appropriate for intervention delivery. Evidence from the literature suggests that patients who are recommended to wean from their opioids benefit from an initial one-to-one mode of intervention delivery before going on to receive group delivered therapy (Sullivan et al., 2017). A review of the research evidence on effective psychological therapy for pain management also found that group sessions delivering CBT or ACT are both acceptable and cost-effective (NICE, 2020c). Furthermore, there is additional evidence indicating that follow-up communication via telephone support is beneficial to maintain adherence to weaning, habitual practice of taught coping skills and prevents relapse (Naylor et al., 2010; Sullivan et al., 2017). The heterogeneity that exists among CNCP patients requires consideration that a one size fits all approach would be limited in its effectiveness, therefore providing options or tailoring strategies may be required (Leask et al., 2019). The preference for flexibility in the mode of intervention delivery was evident from the HCP and CNCP participant recommendation feedback. For example, HCPs discussed how having regional training

sessions or a "*local hub*" (HCP1) would be beneficial and CNCP participants discussed how having the option of online or face-to-face would address barriers of opportunity to attend and readiness to engage "*I can see it working well for everyone to have an option to do it as a group or do it as an individual*" (CNCP P1). Face-to-face or online modes of delivery was also considered preferential and to have met the APEASE criteria in an intervention recently designed to deliver training to nurses (Webb et al., 2016). In the feedback consultations of this study, HCPs also reflected that individuals have different learning styles, and implementing different delivery strategies such as visual, audio, or verbal may therefore be more effective (Vinales, 2015).

*Stakeholder feedback*

The general feedback from HCPs and CNCP participants agreed that these behaviours need to be addressed "*they all sound great and good recommendations*" (HCP7, Pharmacist), "*I agree with all the points you have come up with*" (CNCP Participant 3). Participants reiterated the current lack of information provision and support for patients weaning which was consistently identified throughout the literature and interviews analysed in Chapter 4. The need to improve information provisions available for family and carers was also highlighted during feedback consultations. Primary care HCPs discussed how they do not feel adequately trained to effectively communicate information coherently to facilitate patients weaning. The IWOTCH study addresses these issues by incorporating a three day training course for intervention facilitators and providing them with an instruction manual (Sandhu et al., 2019). Identifying the opportunity to implement and deliver such training might be a significant barrier for some HCPs who don't have the capacity to attend. A brief online training course might be an alternative way to deliver this and has been shown to be successful in training nurses to deliver brief intervention advice (Webb et al., 2016). Behavioural outcomes of the IWOTCH study are yet to be published but some of the same BCTs are recommended in this study which perhaps indicates a promising direction in opioid weaning intervention development.

HCPs also discussed that getting patients onboard with weaning is difficult therefore strategies to initiate or steer attention toward weaning should also be considered "*I wonder if there is a step before that point* [maintaining adherence] *to consider how we can support*

*GPs to initiate these type of conversations* [opioid weaning]" (HCP2). Establishing better patient engagement will feature as a refinement to these recommendations. Incorporating end-user feedback in this way provides some indication that the recommendations presented are acceptable and feasible to implement within a primary care setting.

**Strengths**

Inviting CNCP patients and HCPs to provide feedback on the intervention recommendations, the acceptability and feasibility of the content was a strength. Involving end-users and stakeholders is considered to improve buy-in and increase adherence and effectiveness and is considered favourably among funders and governing bodies (Leask et al., 2019). Feedback from HCPs and CNCP patients confirmed that the theoretically informed recommendations are not only needed, but also considered feasible to practice.

**Limitations**

Due to study time constraints brought about by the impact of the COVID-19 pandemic, the opportunity to recruit for the feedback consultation phase was severely curtailed. Due to the extra demand COVID placed onto primary care, no GPs were available to attend the online consultations and patient recruitment was restricted to snowballing. Of the HCPs who did participate, it is believed that data saturation was achieved for this group. Conversely, CNCP patient feedback was limited to 3 participants who had already discontinued their opioids. Feedback from CNCP patients thinking about weaning or those currently weaning may have provided a different perspective. Furthermore, the opportunity to conduct interactive workshops encouraging HCPs and CNCP patients to contribute to content decisions would have been preferred. An interactive participation of this kind may have strengthened likelihood of positive effect (Leask et al., 2019).

*Impact of COVID-19 on research design and recruitment*

The impact of COVID-19 restricted the possibility of conducting any in-person research during the timeframe of this study (December 2020). This subsequently influenced the research design and also impacted on recruitment. It was the intention to approach a local community pain group (SMILE) and advertise via recruitment posters, however the group were not

operating during lockdown. As a result, recruitment posters were distributed to participants who previously expressed interest and were asked to share them. Furthermore, the increased demand that COVID placed on primary care meant that local GPs did not have the capacity to take part even though they had previously expressed interest in doing so.

**Conclusion**

Interventions designed to reduce opioid medication in a primary care setting may be better supported if changes to: service provisions, regulation of high dose prescribing, environmental and social settings or communication and improved marketing on using opioids and opioid weaning are made. Furthermore, it is also recommended that opioid weaning interventions consider implementing a combination of modes of delivery including face-to-face, online, individual and group settings. Future research should explore the effectiveness of these methods.

# Chapter 7: General Discussion

This thesis aimed to identify ways HCPs in primary care can better support CNCP patients prescribed opioids above 120mg MED/day to reduce or discontinue their treatment. To this end, the thesis investigated local level prescribing practices of opioids issued to CNCP patients across Liverpool, a city in the North West of England (study 1), identified HCP and CNCP patient behaviours that might impede or facilitate opioid weaning (study 2a and 2b), and applied knowledge to a theoretical framework to identify intervention content most likely to facilitate changing behaviour with the aim of increasing the likelihood of opioid weaning (study 3). This chapter discusses the findings in regard to the wider chronic pain literature and helps to better understand opioid weaning and ultimately inform intervention recommendations.

First, the main results and conclusions are summarised. The results described in study 1 (Chapter 3) indicate that a small minority of patients (3.5%), more likely to be women, aged 58 or older, receiving 3 opioids and residing in North Liverpool, are often prescribed opioids above 120mg MED, reflecting similar national prescribing trends. Barriers identified in study 2a and 2b preventing opioid weaning arise from poor communication, lack of education and training, patients' attitudes and beliefs, HCP inconsistency and capacity, lack of support, and access to supplementary treatment. Conversely, poor pain relief and intolerable side effects were common reasons for wanting to reduce or discontinue opioids, patients also felt they had a good working relationship with their GP and local pharmacist which might facilitate weaning (Chapter 4). Intervention recommendations were identified in study 3 (Chapter 5), these were established by following the BCW framework and informed by findings from HCP and CNCP patient interviews in Chapter 4, supported by the extant literature. The convergence of this information identified the need to improve patient engagement and adherence to a weaning plan (recommendation 1) and that this was dependent on reducing patients' fear and anxiety (recommendation 2) and improving the provision of reliable and relevant information and support (recommendation 3). Overall, it is recommended that change needs to occur in these three behaviours in order to help CNCP patients reduce or discontinue opioid treatment; this should form the basis of an opioid weaning intervention.

Potential intervention functions, BCTs and modes of delivery to trigger this change are also recommended. The recommendations were subsequently presented to HCPs and CNCP patients through online focus group and interviews to assess their feasibility and acceptability, to which the general response was positive. See table 30 for a summary of each study.

The main themes from the discussion focus on, localising the prescribing problem reflecting on findings from study one; how health inequalities across the UK might impact on opioid prescribing and healthcare; using the role of HCP and CNCP patient experiences from study two to understand individual, organisational and environmental factors that might influence opioid weaning; intervention content established from study three, in response to the problem (i.e., high dose opioid prescribing); and lastly study reflections followed by strengths and limitations of the research are discussed.

| Study 1: Opioid prescribing audit across Liverpool | Study 2: interviews with 16 HCPs and 13 CNCP patients | Study 3: Identifying intervention context and stakeholder feedback |
|---|---|---|
| A total of 93,236 prescriptions were issued to 30,474 CNCP patients in Liverpool during 2016-2018. A small proportion (3.5%) were issued opioids exceeding 120mg MED/day. Of those patients:<br><br>• 66% were female<br>• Aged ≥58<br>• White British<br>• More likely to receive a combination of 3 opioids.<br>• Issued a strong opioid long-term (ranging between minimum of 127 days and a maximum of 287 days of a prescription episode)<br>• Receiving long-term prescription for morphine, oxycodone, buprenorphine or fentanyl.<br>• Located in North Liverpool | Treating CNCP in primary care is difficult, GPs are restricted by limited capacity, access to MDT, resources, patient co-morbidities and pressure to do something. Coupled with HCP and patient lack of knowledge and training on managing CNCP, results in over-reliance on opioids.<br><br>GPs and pharmacists are well placed to instigate conversations about weaning. Opportunities may arise when patients discuss their dislike of opioids, often due to the side-effects and limited pain relief.<br><br>Consulting between levels of care risks fragmenting lines of communication, confusing patients, and inconsistency among HCPs. This triggers a sense of mistrust and disengagement with patients. A better platform and plan agreement between HCPs and patients is recommended.<br><br>Expectations and treatment outcomes are misaligned resulting in disappointment and negative experiences. Clarity is needed from the outset and support provided before, during and after weaning. HCPs and patients identified the need for consistent point of contact.<br><br>Patients are faced with not being able to live with or without opioids in the absence or knowledge of other methods of pain management. Withdrawal effects exacerbate their difficulty weaning and often require more support at this time. For patients it is important they feel listened to, that they are not alone, fully understand the process and trust their HCP. | Behaviours identified as being most relevant in facilitating opioid weaning in primary are:<br>• Improve engagement and adherence to opioid weaning.<br>• Reduce patients fear and anxiety of weaning.<br>• Improve provisions of information and support.<br><br>Six intervention functions (education, training, modelling, enablement, persuasion, environmental restructure) are considered relevant for changing behaviour.<br><br>24 BCTs were identified to trigger change in HCPs and CNCP patient's capability, opportunity and motivation to perform the behaviours.<br><br>Individual, group, face-to-face and online modes of delivery are considered relevant.<br><br>End-users approved of the proposed recommendations and suggested additional recommendations for HCP support and information for families. |

**Table 30. Summary of findings from study 1-3**

## Localising the problem

The second objective of this research was to investigate the nature of high dose opioid prescribing in primary care practices across LCCG. Liverpool is a city located in the North West of England, a region that is consistently identified as having one of the highest increases in opioid prescribing across the UK (Chen et al., 2019; Jani et al., 2020; Mordecai et al., 2018). Conducting an audit on opioid prescribing for CNCP in 62 out of 88 GP practices across Liverpool, therefore, contributes to knowledge by providing insight into local level prescribing practices in a prevalent location. Overall, the findings of the audit (Study 1, Objective 2, Chapter 3) complement the wider national prevalence figures, demonstrating that a small but significant proportion of patients receive opioids exceeding the advised 120mg MED/daily threshold (Jani et al., 2020; Zin et al., 2014). Indeed, 3.5% (n=1,069) of patients receiving an opioid for CNCP in Liverpool were identified to exceed the advised daily MED threshold. Studies suggest this cohort may be at higher risk of harm, especially if they have been receiving high doses for a long time and are not deriving much benefit in terms of pain relief (Chou et al., 2015; Furlan et al., 2006; Vowles et al., 2015). Due to the mounting evidence that opioid related harm is dose dependent (Bedson et al., 2016; Chou et al., 2015; Dunn et al., 2010), it is concerning that of the 3.5% of patients exceeding 120mg MED/day, 34% (n=360) of them received average daily dose above this threshold. Stratifying patients in this way enabled consideration for the complex nature of prescribing e.g., prescriptions issued but perhaps not dispensed or used, whilst also identifying those at increased risk of harm and potentially mismanaged pain. For example, the number of patients who were prescribed high doses in 61 of the 62 GP practices included in this study varied greatly (from 1 – 82 patients), giving some indication of case management load. The reason for this variation is unclear, but it identifies a potential caveat in the management of such patients. The FPM recommend that patients receiving doses above 120mg MED are referred to tertiary care for pain management (FPM, 2020); however, sending 1,069 patients to tertiary care would not be viable. Identifying, reviewing, and referring patients who on average are exceeding 120mg MED/day might offer a way of stratifying these patients between tertiary and primary care management. Furthermore, there are clearly some GPs with higher patient caseloads than others indicating scope to review and share best practice within the prescribing community. It is not possible to make direct comparisons between Liverpool and other cities as most prevalence data make

regional or generalised practice level prescribing comparisons. For example, Chen et al., (2019) mapped high opioid prescribing to specific cities by calculating the defined daily dose, per day, per 1000 patients registered at GP practices and using IMD scores. Although Chen (2019) identified Manchester (a city 34 miles east of Liverpool) as prescribing the highest proportion of opioids, the data used was aggregated for all types of pain, meaning it was not possible to compare patient level data with study 1 conducted here (Chen et al., 2019). Additionally, one further study investigating opioid prescribing in 111 GP practices in Leeds and Bradford (districts located in West Yorkshire in the North of England) used patient and practice characteristics but focused specifically on long-term prescribing trends and the likelihood of transitioning to stronger opioids (Foy et al., 2016). Although these studies indicate increases in opioid prescriptions, number of patients prescribed opioids and the risk of stepping up to higher strength opioids, they don't highlight practice level case management load that primary care HCPs can expect. Recognising prescribing risk factors and patient characteristics may be important to help GPs identify at risk patients, but it is equally important to understand the magnitude of the problem to allow HCPs to prepare for management of patients.

Nonetheless, prevalence data has allowed researchers to indicate the likelihood of long-term prescribing occurring (e.g. its estimated in 14.6% of new users (Jani et al., 2020)), patient and practice characteristics (e.g. gender, age, level of deprivation), comparable regional trends (e.g. North-South divide) and other prescribing risk factors (e.g. type of opioid, initiated dose, duration of opioid episode, polypharmacy) associated with high opioid prescribing (Bedson et al., 2016; Chen et al., 2019; Foy et al., 2016; Jani et al., 2020; Mordecai et al., 2018; Torrance et al., 2018). This provides an opportunity to educate HCPs about these indicators so they can become more vigilant of patients who might be at high risk of long-term high dose opioid prescribing. It is assuring therefore that there was much consistency between the risk factors reported in the literature and those found in the prescribing audit conducted in study 1. For example, HCPs in Liverpool might benefit from the knowledge that in LCCG those prescribed high opioid doses are most likely be female, ≥ 58 years and receive three opioids contributing to their total daily dose. Additionally, given the other attributes consistently highlighted in the literature e.g., lower level of education, higher BMI, co-morbidities (e.g., anxiety and depression) and overall poorer self-rated health (Chen et al., 2019; Sjøgren et al., 2010) it

seems pertinent to highlight the biopsychosocial needs of these patients. Such attributes may be cofounding factors that impede how successful HCPs engage and maintain engagement with high risk patients when it comes to addressing concerns about their current opioid treatment. A further contribution to knowledge that the audit (study 1) provides is recognition of the combination of opioids that attribute to patient's daily dose. It is common for prevalence studies to discuss that CNCP patients are often prescribed a combination of opioids (as well as other non-opioid analgesics e.g., benzodiazepines or gabapentinoids (Furlan et al., 2006; Jani et al., 2020)) but none have reported on what the potential cross-over might be. For example, study 1 found that when prescriptions were controlled for daily doses exceeding 120mg MED, patients were most likely to be prescribed three opioids, including at least one prescription for morphine, buprenorphine, oxycodone, or fentanyl. Analysing this closer, it was highlighted that morphine was 14 times more likely to be prescribed in combination with another opioid and the higher the dose, the longer the prescription episode lasted. In this case morphine is an additional risk factor for long-term high dose prescribing that HCPs should be cautious about. In comparison, oxycodone was three times as likely and buprenorphine twice as likely to be prescribed in combinations equalling doses above 120mg MED. Fentanyl being the most potent analgesic, was least likely to be prescribed in combination with another opioids, but most likely to contribute to daily doses above 120mg MED on its own. It is likely that patients receiving these prescriptions for CNCP are not obtaining optimal pain relief, potentially due to opioid hyperalgesia, and subsequently increasing their risk of adverse harm.

## Health inequality

There are consistent regional differences reported in the volume of opioids prescribed across the UK, with higher increases in the North of England compared to the South and in areas with greater social deprivation (Chen et al., 2019; Mordecai et al., 2018; Todd et al., 2018; Torrance et al., 2018). This is thought to be driven partly by the higher prevalence of chronic pain in individuals with lower SES. For example, the HSE in 2011 found that chronic pain was more prevalent among people with lower socioeconomic income compared to those who are more affluent (Craig, 2012). The association between opioids and deprivation is further supported by Torrance et al., (2018) who found that patients from more deprived areas were

3.5 times more likely to be prescribed a strong opioid (Torrance et al., 2018). Implicitly, this suggests that Liverpool, located in the North of England and ranked the third most deprived local authority (out of 317) in England's 2019 IMD scores, is exposed to a greater challenge in managing CNCP patient's healthcare needs. The present study confirms the relationship between opioid prescribing and deprivation, highlighting that GPs in neighbourhoods in the North of Liverpool were more likely to prescribe high doses of opioids (9%) compared to South (7%) and Central Liverpool (5%), see Table 4 and Figure 3.2 in Chapter 5. Some of the higher prescribing practices in the North (e.g. Anfield and Everton) and South (e.g. Speke and Belle Vale) of Liverpool display the highest levels of deprivation in the City (LiverpoolCityCouncil, 2020). It is not clear whether the differences across these areas are due to prescribing practises or varying patient health needs, nor are these factors mutually exclusive. Todd (2018) argues that a number of compositional (e.g. patient demographic, SES, health behaviours), contextual (e.g. stigma, access to services, employment) and co-morbidity (e.g. anxiety and depression) factors contribute to the differences in pain and prescribing (Todd et al., 2018). Even after controlling for deprivation, Jani *et al* (2020) found disparities in prescribing between the North and the South of England indicating greater health care needs in the North (Jani et al., 2020). Jani *et al* (2020) also found some evidence that a minority of prescribers (3.5%) contribute to the small proportion of high prescribing practices (25.6%) and the likelihood of patients continuing a long-term opioid prescription (Jani et al., 2020). It is likely that the increase in opioid prescribing is driven by a combination of all these factors, indicating the need for changes in policy in regard to the distribution of budgets and resources for healthcare.

For decades there has been a growing disparity in the health equality reported between the North and South of England that has resulted in poorer health outcomes and a 2-3 year shorter life-span in the North (Whitehead, 2014). Health inequality within countries is common, however the divide between the North and South of England is reportedly one of the highest in Europe (Dorling, 2010). Much of this divide stems from the deindustrialisation of the North during the 1960's, subsequently exacerbated by the UK recession in 2008 and driven by austerity, unemployment, distribution of resources and power, polarisation of damaging versus health promoting environments and protective opportunities such as, economic security or control over decision in your life (Dorling, 2010; Whitehead, 2014). The

Due North report published in 2014 addresses these issues and asserts that the North of England has had limited influence on the distribution of resources and budgets hindering their ability to take action on health inequalities (Whitehead, 2014). Whitehead (2014) argues that the health sector is well placed to help narrow the inequality gap, but local health services need to be adequately resourced and has recommended local agencies and central government work together to strengthen the role of the healthcare sector (Whitehead, 2014). Liverpool CCG are currently making progressive developments toward doing this, aiming to maintain and improve access to services in primary care, including access to psychological therapies and careful consideration of budget allocations in light of recent grant reductions (LCCG, 2020). The health inequality issue is complex and very broad, but without efforts to address these issues it only risks widening the gap further.

In addressing objective 2 of the research, factors associated with high dose opioid prescribing affirmed through findings of national and international prescribing trends have been identified. These findings are important because they provide specific context to local level prescribing practices located in some of the most deprived areas of Liverpool and the UK. The results from study 1 indicate where and who might benefit from a targeted intervention to reduce high dose opioids and indicate some of the challenges to addressing this problem. Moving beyond the characteristics of prescribing, study 2 investigated HCP and CNCP patient experiences to elucidate and understand the behaviours that may facilitate or inhibit opioid weaning (objective 3 and 4).

## Looking beyond opioids: the role of HCP and patient behaviours

A change to recent UK healthcare guidance recommends that opioids are no longer used to manage the symptoms of chronic primary pain i.e. pain in one or more anatomical region that is not a secondary symptom to other diseases (NICE, 2020a). This recommendation comes from two systematic reviews assessing evidence for the clinical, cost-effectiveness and long-term safety of using opioids for chronic pain (NICE, 2020b). Due to exclusion criteria for these systematic reviews, no studies were identified to contribute evidence on the clinical and cost-effectiveness of opioids. Furthermore, only three low quality observational studies were included to determine the potential long-term safety of opioids. The NICE committee who issued the guideline that opioids should no longer be used, acknowledged there was a large

body of evidence that didn't meet the inclusion criteria but continued to make their decision based on the limited evidence and their expert opinion. This decision does not acknowledge the potential utility of finding a balance between using and manging opioid therapy that some researchers would argue is needed (Bialas et al., 2020; Häuser et al., 2016; Mouraux et al., 2121) and poses the question, 'if opioids are not to be used then what should replace them?' Furthermore, there appears to be no consideration for any supplementary therapy that is meant to be delivered alongside opioids as part of an MDT approach to managing pain. Instead, healthcare is now focused on ways to reduce or discontinue opioids, disregarding how at potentially lower doses opioids could be better managed and beneficial. Conversely, as supported by study 1, there is still a proportion of patients receiving opioids at harmful doses, identifying the need to wean these patients and establish other ways to optimise their pain management.

The weaning/management experiences of different HCPs and patients revealed the intricacy of inter-related factors that attribute to patients' care and ongoing pain management. Through understanding these behaviours and identifying what triggers or modulates them, this work can help illuminate where change is needed and what techniques can be used to facilitate the desired change (Glanz & Bishop, 2010; Michie et al., 2011). With this in mind a number of barriers and motives that may facilitate opioid weaning were identified from the interviews conducted in Study 2. Three key themes emerged among HCPs: treatment, working with patients and the Health Care System (HCS), and three themes among CNCP patients: the treatment journey, living with opioids and weaning experience. Broadly, the behaviours identified reflect individual, organisational and environmental influences, factors described by the ecological perspective in addressing health interventions and therefore will be discussed here in such terms (Glanz & Bishop, 2010). Interventions that consider an ecological perspective are thought more likely to be effective, this is because it is recognised that behaviours do not occur in isolation but often in the context of other behaviours (Michie, Atkins, et al., 2014).

***Individual factors***

Patients interviewed discussed taking opioids for periods ranging from 2-40 years. This period of time, and the *"medical roundabout"* (HCP10, Consultant Psychologist) patients go through,

shape their experience and subsequent perceptions/expectations of treatment outcomes. At an individual level, patients' fear of withdrawal, anticipated pain and tolerance fed into a perpetuating cycle that influenced when they dosed and how they responded to weaning. For example, in the absence of knowledge on how else to manage their pain, patients described over-reliance on opioids, re-dosing early or avoiding engaging in activities that would separate them from their medication. Patients who managed to reduce or discontinue their opioids also reported having no information on how to manage their ongoing pain and were either afraid to initiate any new analgesic or felt they could not discontinue entirely. The mismanagement of these concerns contribute to increases in patients' psychological distress that resonate with constructs of the Fear Avoidance model (Vlaeyen & Linton, 2000), as well as the obstruction or retention in patients' weaning (Goesling et al., 2019; Sullivan et al., 2017). Attitudes and beliefs play an important role in behaviour as they can shape a person's mood and behavioural response, so are likely to influence the uptake of and compliance with treatment recommendations (Gatchel et al., 2007; Martin & Peerzada, 2005). It is difficult to know if addressing patients negative attitudes will improve engagement with weaning, but if the alternative exacerbates negative experiences, then this is worthy of consideration. Separately, but potentially related, some prescriptions analysed in study 1 had missing or abstract dosing instructions such as "per required need", which may contribute to patients over use. If patients are not given enough information or don't understand the information given to them (issues raised by HCPs in study 2), then it's possible they are going to over rely on opioids. This gap in information provision may explain why patients discussed only seeing their GP for a prescription and subsequent lack of confidence or trust in them to manage their pain. Chronic pain is recognised as one of the most challenging health complaints to treat in primary care and studies have shown that GPs don't often feel adequately trained or knowledgeable enough on how best to support patients (Johnson et al., 2013). This was also from interviews conducted with GPs who discussed preferring to refer patients to another service to manage their opioid reduction. Organisational barriers contributed this response and are discussed in the next section below.

Overall, the information presented here implies that at an individual level attending to the psychosocial factors of the biopsychosocial model are not well implemented in primary care. The importance of the biopsychosocial model is recognised by the UK NICE but, they also

recognise that strategies of self-management (that target psychosocial problems) either happen too late in patients' care pathway or not at all (NICE, 2020a). Equally, it is thought that a sudden shift toward a biopsychosocial approach may risk discrediting patients trust in their HCP (Toye et al., 2017). As UK guidance currently recommends moving away from opioids, establishing mutuality and trust between HCPs and patients may therefore become more pertinent. Consistent with the literature, study 2 highlights that patients often decided to initiate weaning or discontinue their opioids because of ineffective pain relief and intolerable side effects (Bialas et al., 2020; Furlan et al., 2006; Goesling et al., 2019; Noble et al., 2008). Such factors may be useful to encourage patients to reduce their opioids, but there need to also consider that patients are often driven to find pain relief and a sense of improvement in their quality of life they (McCrorie et al., 2015). It is important therefore that patients find this in the self-management strategies recommended to replace opioids in order to better manage their pain post weaning (Goesling et al., 2019). This study indicated a mixed response from patients who used self-management strategies, generally scepticism emerged in relation to their effectiveness. The issue with self-management may be that the some of the strategies recommended e.g., meditation, relaxation, or cognitive restructuring take practice and longer to master, thus longer to see noticeable effects compared with the quicker onset of an opioid (NICE, 2020c). Furthermore, the level of effectiveness of self-management techniques is also thought to be determined by how and who delivers training on these methods to patients (NICE, 2020c). Patients in study 2 described not being able to live with or without opioids, whilst evidence for effective pain management is limited with any noticeable benefits relatively modest (NICE, 2020a). Disrupting the cycle of relying on opioids is going to take considerable input from both the patient and HCP, consideration should be given to the individual level factors highlighted here.

***Organisational factors***

Interview analysis from study 2 revealed a number of organisational factors that may contribute to the behavioural responses influencing opioid weaning found at the individual level. The barriers evident from HCP interviews stemmed largely from within primary care including: the lack of alternative non-pharmacological treatment, access to MDT support, GPs' capacity to manage, review and monitor patient responses to treatment and more

widely poor communication throughout the HCS. Primary care practitioners are well placed to engage with and support patients within the community, but in order to do this effectively they need to be adequately resourced (Ernstzen et al., 2017; Penney et al., 2016). Funding plays a large role in this as service cuts have impacted on the availability and access to non-pharmacological support, perhaps also underpinning the biomedical model focus (Penney et al., 2016; Quinlan et al., 2017). It is widely recognised that best practice of care for the management of chronic pain requires input from an MDT (FPM, 2015a). Experts in the management of chronic pain recommend that at a minimum community MDT care should involve input from a GP, pharmacist, and clinical specialist (Stannard, 2018). The qualitative findings from study 2 suggest that many recommended standards for chronic pain management in primary care are not achieved. For example, GPs often discussed not having access to MDT support and HCPs from tertiary care and patient interviews confirmed that it can be years before patients receive this level of support. Similar findings were reported in a recent review investigating patient experiences of support or lack thereof, from UK services for the dependence and withdrawal from prescription drugs (Taylor et al., 2019). The PHE report identified that patients had difficultly accessing or engaging with services, were often uninformed about withdrawal and generally felt unsupported, and weren't offered alterative treatment (Taylor et al., 2019). There is clearly an element missing from primary care services and although funding may play one part, this research found it may also be driven by GPs lack of capacity and knowledge or skills on how to best support CNCP patients. GPs discussed how they struggled to find the capacity to review and monitor patients prescribed opioids and are often restricted by 15 minute clinical appointments. A combination of these factors could explain why GPs preferred to refer patients who were weaning onto a different service, such as addiction services. The problem with this is that addiction services may not be specialised to manage patients' chronic pain, while reducing their opioids (Quinlan et al., 2017). Previous studies investigating patients' experience of weaning found that having access and flexibility to see a HCP were important facilitators for weaning (Frank et al., 2016) although in practice, time and resource constraints restrict this (Krebs et al., 2014). This research also found a breakdown in communication between different HCPs, and between HCPs and patients when patient cases were shared across different agencies. This represents a further barrier at the operational level as it involves use of and access to different systems required to update patient records, as well as inconsistency in HCPs managing a single case. Gjesdal *et al* (2019)

found that miscommunication exerts additional strain on specialist pain clinics causing them difficulty in prioritising their already limited service between existing and new patients being referred from primary care (Gjesdal et al., 2019). Inconsistencies in HCPs managing patients has been shown to negatively affect patients trust and belief and subsequently the likelihood of uptake and adherence to treatment recommendations (Ljungvall et al., 2020; Toye et al., 2013). HCPs and patients in this research both suggested nominating a HCPs whose designated role would be to manage patient cases and operate as a consistent point of contact between everyone involved in patient care. Overall, the management and effect of CNCP is causing significant direct and indirect economic costs and societal burdens exemplified by patients accessing primary care services 5 times more than those without CNCP (Johnson et al., 2013). As it stands, HCPs from primary care in this study described being under resourced, undertrained, and operating within a fractured network in attempt to best support and manage CNCP patients. Organisational changes and better resourcing are needed to improve the weaning experience of CNCP patients. In line with this, Liverpool CCG have announced allocated funding for better community care for chronic pain incorporating psychological support, HCPs and patient education, improved referral pathways and a consultant led tapering clinic (LCCG, 2020).

**Environmental factors**

Patients environment and their perception of their environment have the potential to influence their individual level behaviour (Glanz & Bishop, 2010). Environmental factors are often driven by family and social relationships that influence beliefs and social norms, as well as physical determinants in the environment providing the opportunity to perform certain behaviours (Glanz & Bishop, 2010). Environmental factors may therefore act as potential barriers or facilitators in supporting opioid weaning. This research found potential environmental barriers resonating with patients' perceived sense of stigma, life circumstances (e.g., work or family commitments) and lack of available support. For example, patients described feeling the need to hide or defend their use of opioids and were worried that if they didn't appear to be in pain, it meant they wouldn't be believed. This is corroborated by other studies describing how being issued with a prescription somehow validated patients pain (Ljungvall et al., 2020); whilst at the same time patients also feel the

need to hide their opioid use due to negative connotations and concern about addiction (Goesling et al., 2019; Ljungvall et al., 2020; Penney et al., 2016). This indicates a need to find a balance between communicating the risks such as addiction or dependence with opioids without stigmatising their use when engaging with and supporting patients to wean. Adjusting dosing regimens due to life events was common among patients interviewed; this was particularly relevant for patients who were weaning, as they recalled the need to adjust reductions around what suited them at the time. This experience reiterates the need for person-centred care and the importance of reviewing patients who are weaning so amendments can be made to suit their individual circumstances. As discussed previously, GPs don't often have the time or capacity to continuously review and provide patients with this level of support on their own and ideally need access to an MDT. Patients with concerns about the benefit of social support were less likely to engage, and those who were interested did not know where to find such services. Some patients in from study 2 had the opportunity to attend PMPs, to which there were mixed (positive and negative) experiences; this appeared to be the only opportunity for social support available to patients. The lack of physical opportunity afforded by the environment patients reside may also be the result of health inequalities evident across more socially deprived areas. As discussed earlier there is disparity in opioid prescribing between the North and South of England, partly attributed to increased patient health needs (Todd et al., 2018). Health inequalities driven by public health budget allocations, increased cuts to services and austerity measures (Whitehead, 2014), may prevent people from having the opportunity to change their behaviour in order to improve their health. Previous research investigating patients experience of weaning has highlighted the importance of establishing a social support network for initiating and sustaining an opioid tapering regime (Frank et al., 2016). Positive weaning experiences have been attributed to, supportive, non-judgemental, flexible and accessible networks (Frank et al., 2016). The need for these attributes to exist in health services are recognised by national health bodies in the UK, for example PHE and BMA have recently recommended developing a national telephone helpline and improving provisions of specialist support for patients who are weaning (Quinlan et al., 2017; Taylor et al., 2019). Such improvements to patients' environments will provide more opportunity to access the support considered necessary to facilitate weaning. In summary, the results of study 2 have identified a range of HCPs and patients' behaviours at the individual, organisational and environmental levels that may act as potential barriers and

facilitators to better supporting opioid weaning. Findings indicate the need to improve patient engagement and adherence to opioid weaning; to achieve that information and support that will address patients fear and anxiety of weaning need to be developed. The influence of these behaviours should be considered when designing an opioid weaning intervention.

## Responding to the problem

The main aim of this thesis was to identify potential ways that HCPs in primary care could support CNCP patients to reduce or discontinue their opioid medication. The BCW framework was used to systematically and theoretically identify methods that would inform an opioid weaning intervention. To the researcher's knowledge this is the first time that the BCW has been used to construct the design of an opioid weaning intervention for CNCP patients in primary care, adding original contribution to research. The design of the BCW offers an opportunity to systematically report on each stage of intervention development and highlight clearly where the 'active' components feature. Reporting in this way is considered important to allow for study replication, comparison and identification of mechanisms of change (Craig et al., 2008; Michie et al., 2013). The BCW framework helped identify and select three key behaviours that could facilitate opioid weaning (see figure 7.1).

1. **Improve patient engagement and adherence to opioid weaning**
    - Improve HCP and patient's knowledge of the risks and benefits of opioids and opioid weaning and what to expect from the process
    - Improve HCPs time and capacity to implement and support patients weaning
    - Improve social connection and support throughout a taper and advocate a weaning ambassador to demonstrate social approval
    - Identify and address patient concerns around weaning
2. **Reduce patients fear and anxiety of weaning**
    - Improve HCP and patient's knowledge around pain and emotion and demonstrate methods of self-management to overcome these
    - Support and encourage patients to practice methods of self-management
3. **Improve the provision of information and support for weaning**
    - Improve the dissemination of creditable information to patients
    - Provide patients with skills to critique information and knowledge on where to access support
    - Improve the availability and flexibility of HCP and social support

**Figure 7:1. Target behaviours informing the intervention design**

These behaviours were identified from HCP and CNCP patient interviews (Chapter 4) and supported with evidence from the existing literature. The findings produced from this

research recommend the need to improve patient engagement and adherence to an opioid weaning plan (recommendation 1), and in order to do this there is need to reduce patients associated fear and anxiety of weaning (recommendation 2) and for this to happen, there is need to improve the information and support available to both HCPs and patients (recommendation 3). The consensus and relevance of these behaviours in facilitating opioid weaning was obtained through feedback consultations with HCPs and CNCP participants.

There is currently little support available for CNCP patient opioid reduction and withdrawal within UK health services in the community. In a review of the evidence, PHE found only two conference posters describing opioid reduction services for CNCP patient in primary care (Taylor et al., 2019). Although both posters indicated promising results for opioid reduction, information on the components used and outcome measures was limited, rendering them a high risk of bias. Conversely, the ongoing UK based IWOTCH study has transparently published their intervention design and simultaneous evaluation process allowing the identification of the components used (Nichols et al., 2019; Sandhu et al., 2019). Results are yet to be published and so indication of its effectiveness is still to be determined.

Limitations of most previous studies targeting opioid weaning are thought to be related to their poor design, follow-up periods are short (≤4 months) and they succumb to high dropout rates due to poorly controlled withdrawal effects (Sandhu et al., 2018). These are barriers that future opioid intervention studies need to consider. For example, patients interviewed in study 2 (Chapter 4) who had discontinued opioids or were currently weaning described the withdrawal effects of opioids as being intolerable, specifically symptoms of nausea. Patients recalled how their nausea caused vomiting that regurgitated their opioid medication and subsequently intensified the withdrawal effects. These patients did not discuss seeking help from their HCP for this, instead they described being left alone to deal with it, indicating the need to better prepare HCPs and patients on what to expect and how to manage adverse difficulties. This is among other factors that have been mapped to theoretical determinants of behaviour change that will likely need to be addressed to target weaning (see table 31). According to the BCW, HCPs and patients will need the capability, opportunity, and motivation to perform the target behaviours recommended as needing to change (Michie et al., 2011). In this regard this research indicates the need to educate and train (capability)

patients and HCPs, equipping them with the knowledge and skills needed to feel informed and prepared on how to cope with the adversity of weaning. Acquiring new knowledge can help HCPs and patients plan better and trigger a change in beliefs toward wanting or recognising the need to wean (motivation). This may be further supported when HCPs and patients have the physical and social means (see table 31 below) available to perform the behaviour (opportunity).

| COM-B component | | Factor influencing opioid weaning |
|---|---|---|
| **Capability** (Psychological and physical capacity) | *Psychological* | • Knowledge about the risks and benefits of weaning, why it is recommended and what the process involves<br>• Knowledge about pain and emotion and techniques of self-management<br>• HCPs skills to engage and negotiate with patients<br>• Patients level of comprehension and critical appraisal skills |
| **Opportunity** (Physical and Social opportunities) | *Physical* | • HCP time/capacity as a barrier<br>• Limited access or available of alternative treatment/ support services |
| | *Social* | • Social acceptance and encouragement of weaning and approved methods of self-management<br>• Communication |
| **Motivation** (Automatic and reflective processes) | *Reflective* | • Beliefs of beneficial outcomes to weaning<br>• Beliefs pain can be self-managed<br>• Collaborative weaning plan including relapse/contingency management |
| | *Automatic* | • Resistance to over-relay on opioids to manage pain<br>• Habitual practice of self-management |

**Table 31. COM-B components linked to factors influencing opioid weaning**

There are clearly a complex number of interactions that need to occur in order to bring about the desired change in the targeted behaviours. To facilitate this, 24 unique BCTs that can be delivered via six potential intervention functions to trigger the change are recommended. The essence of the strategies proposed are captured in the logic model below (figure 7.2). The BCTs have been condensed to fit the logic model but a full list can be found in appendix 21. The logic model depicts a series of BCTs that if applied in the suggested manner (application) have the potential to change beliefs (sub-determinates) to trigger change in the behaviour components (determinates). According to the COM-B model, a change in the behavioural components can trigger a change in the sub-behaviours considered most relevant in facilitating opioid weaning (target behaviour).

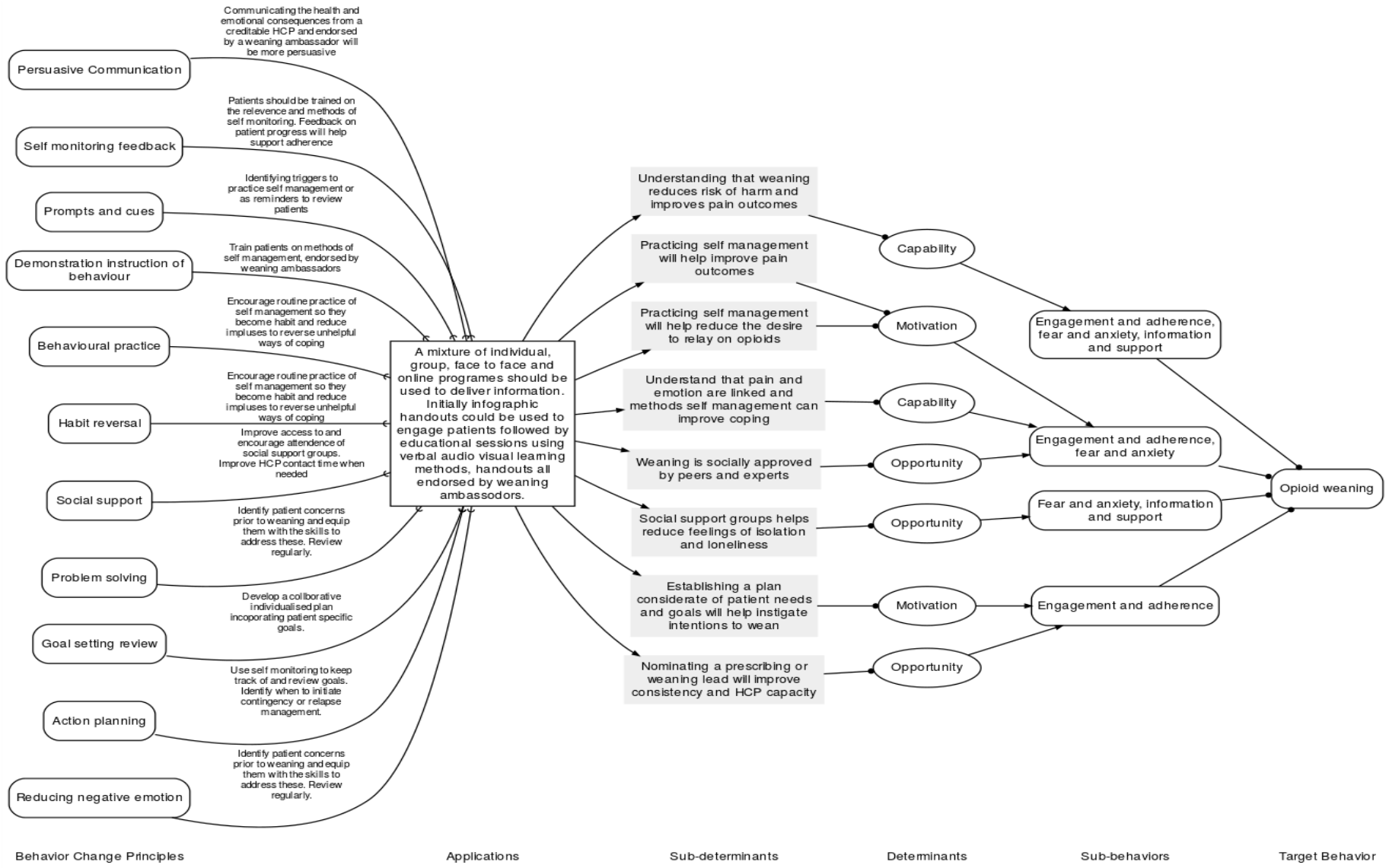


**Figure 7:2. Logic model of strategies proposed to target opioid weaning**

## Study reflections

When I started this research, I was alerted by the urgency and fear of an opioid epidemic depicted by the media emerging across UK healthcare in the management of CNCP. Through the course of the research, three things soon became clear, 1) that CNCP is a complex condition to treat and manage and should not solely rely on an opioid prescription to manage pain, 2) despite healthcare services advocating a biopsychosocial model to treatment, the biomedical model is more relied upon and is at risk of exposing unintended prescribing consequences and, 3) the feared opioid epidemic portrayed from the US does not compare to events across the UK or Europe. Nonetheless, there are clear risks of long-term high dose opioid use in the management of CNCP and subsequent responsibility of HCPs to reduce such risks. The most challenging aspect of addressing this problem was identifying what would replace opioids to manage CNCP if they were to be reduced or discontinued. Upon understanding this further, it became clear that a change of behaviour in both HCPs managing CNCP and in patients seeking treatment was needed. The intricacies of behaviour change are as equally complex as CNCP, but when a behaviour is completely understood, constructs of change can be identified and modified for the better. Further learning developments unfolded, particularly around the methodological aspects of carrying out research, as this project came to completion. These included clarifying and identifying standardised definitions of the phenomenon being studied to allow for data to be compared or pooled in order to enhance collective insight; and recognising how a researcher's worldview can determine the interpretation of data analysis, thus demonstrating how discussion with team members can help reduce research bias.

### Strengths

Specific methodological strengths and limitations for studies 1, 2 and 3 are considered individually at the end of each study chapter in sections 3.6, 4.8 and 5.6, respectively. Similarly, limitations of the intervention feedback study which is an extension of study 3, are considered in section 6.5 of chapter 6. General thesis strengths and limitations will be discussed here. An overall strength of this research is the pragmatic approach used to inform the research design that allowed a level of flexibility in adopting 'what works' when addressing the research aims and objectives (Creswell et al., 2011). This facilitated the mixing

of data sources to uncover in-depth knowledge about managing CNCP and opioid weaning. In doing so, this research identified at a local level who and what opioids are being prescribe at potentially harmful doses, and therefore where to target an intervention designed to reduce these harms. This research theoretically links behaviours associated with opioid weaning to potential intervention content which if implemented has the potential to better support opioid weaning in a primary care setting. In addition, involving end-user feedback also provides some indication of the intervention recommendations being accepted.

**Limitations**

The main limitation of this research is determining the effectiveness of the intervention recommendations in practice. A pilot evaluating the strategies and techniques as a complete intervention package is recommended in order to ascertain effectiveness. This research focused on exploring the health behaviours that surround opioid weaning and health care practice in the UK, consequently the findings are most applicable to this country and its health system and may not be generalisable. Conversely, many of the findings reported in study one (Dunn et al., 2010; Jani et al., 2020; Manchikanti et al., 2012; Mordecai et al., 2018; Von Korff et al., 2008; Zin et al., 2014) and study two (Ljungvall et al., 2020; McCrorie et al., 2015; Toye et al., 2017; Toye et al., 2013) are similar to what has been reported nationally and internationally indicating some consistency among the problems associated with CNCP and opioid weaning. Still, comparing opioid dosing data across studies was difficult, this was often due to the inconsistent measures used to calculate MED and the lack of universal agreement on what constitutes a high daily dose. This research used the UK FPM guideline advising that 120mg MED increases risk of harm with no perceived benefit, consistent with other prevalence reports in the UK (FPM, 2015b).

A further limitation may be considered in the level of subjective judgement needed when using the BCW to identify priority behaviours and aligning behavioural domains. This is usually overcome by consulting with a team involved in the intervention design, potentially including lay participants or end-users. Decisions made in this study were largely led the lead researcher (EB) and reviewed by two supervisors (HP, CM), exposing a potential risk of bias. Participatory research methods actively involving contributions from end-users are considered an

important part of intervention development and can help to increase likelihood of effectiveness (Leask et al., 2019). In an attempt to incorporate Public and Patient Involvement (PPI) and the views of relevant stakeholders (e.g., HCPs), focus groups and interviews were held to establish end-user feedback. However, it is recognised that the recommendations presented may have obstructed any original contributions that a more participatory methodology may have found. Furthermore, although a range of HCP feedback was obtained, CNCP patient feedback was limited to three patients who had already discontinued their opioids. Feedback from patients currently engaged in weaning or considering weaning may have provided further insight. Chronic pain is a complex condition to treat, and the heterogeneity of patients mean that a one size response does not fit all, it is therefore not possible to establish how transferable the recommendations are to all CNCP patients. Lastly, most evidence from RCTs targeting opioid weaning are limited to 3 month follow ups (Garland et al., 2019; Garland et al., 2014; Zgierska et al., 2016; Zheng et al., 2008), only two RCTs have been found to conduct follow-up's longer than 8 months (Naylor et al., 2010; Sullivan et al., 2017) indicating the need for more long-term follow up research.

## Implications for practice and research

The evidence presented throughout this research has led to a number of recommendations for practice and research. The overarching aim of this thesis was to identify recommendations for an opioid weaning intervention for CNCP patients in a primary care setting. The implementation of these recommendations should therefore be piloted in the next stage of intervention development (Craig et al., 2008). To do this effectively it will require further action within practice and research.

### *Practice*

- *Training and education* – the NICE guidance on individual approaches to behaviour change recommend that HCPs are trained to deliver brief advice on behaviour change (NICE, 2014a). This research found that HCPs were not adequately trained or knowledgeable on ways to best support CNCP patients when weaning which was often perceived negatively by patients. This could be due to the lack of chronic pain modules delivered during medical training (Currow et al., 2016). Additionally, the effectiveness

of self-management techniques may be determined by the skills of the person teaching them (NICE, 2020c); it will therefore be important to upskill and educate HCPs on the relevant techniques recommended so that patients are also adequately skilled. It may not be effective or cost-effective to train every HCP, as such identifying HCPs with an interest in chronic pain or who have capacity to case manage patients weaning might be more feasible. It may be beneficial to educate or draw HCPs attention toward key patient demographics indicative of problematic prescribing, so they can prepare and be more vigilant of these patients.

- *Communication* – a breakdown in communication when patient care is shared across levels of healthcare is evident. Inconsistent advice risks leaving patients confused and unsure who to trust or what to do. Furthermore, a delay in sharing patient updates delays subsequent action when patients are seeking immediate help which may be problematic when patients are weaning and reach an impasse on reducing any further. A platform where HCPs can share information on patients weaning is needed and where HCPs in primary care can seek support from other expert consultants when problems arise. Good communication is considered key to help support behaviour change, it is important that HCPs use this to develop a rapport with patients and construct motivating conversations to engage and support them with weaning. NICE recommend that this is best done face-to-face initially, which may be time consuming and costly (NICE, 2014a).

- *Implementation* – NICE have already predicted that efforts to reduce or discontinue opioids are likely to be resource intensive in the short-term (NICE, 2020a). This is therefore likely to occur in any attempt to implement the recommendations for intervention suggested in this study. As a result, it will be important to measure the long-term outputs, potential cost-savings and benefits generated to justify the changes being made.

- *Capacity* – chronicity of chronic pain means that it is unlikely to ever go away and will incur continued demand on primary care services. Currently GPs are restricted in their time, skills and knowledge to best support patients weaning and have limited access

to readily available MDT support. To monitor, review and provide patients with the support indicated here will require longer consultation times and follow ups in primary care. There is need therefore to review how this responsibility can be distributed among HCPs within the community whilst also considering HCPs professional remit to deliver certain elements of care and when they should refer in times of crisis. For example, HCPs roles should not be defaulted or presumed onto other HCP, boundaries and responsibilities should be established.

***Research***

- *Piloting* - *t*he intervention recommendations reported here have been informed by empirical research, literature, and theory. This increases their likelihood of being effective, however they need to be tested in a pilot intervention to determine the direction of effect in practice. It is also recommended that a co-productive workshop involving patients who are weaning or considering weaning is carried out in a further iterative process prior to conducting a full pilot. This seeks to acquire more active input to the intervention design from end-users, encouraging their buy-in and increasing the likelihood of positive outcomes (Cooke et al., 2017; Leask et al., 2019).

- *Prescribing practices* - a difference in high dose opioid prescribing among some of the GP practices across Liverpool is evident. It may be worth investigating why these differences have occurred to identify different methods of prescribing practices, that can be shared among the GP community.

- *Maintaining change* – most interventions designed to target opioid weaning combine multiple BCTs, due to this it often difficult to determine which are more effective at maintaining long-term change. It is also difficult to establish whether an increased number of BCTs or increased number of contact hours during intervention drive effectiveness (Michie et al., 2018; NICE, 2020c). Future research should explore this. Furthermore, methods of self-management are known to take practice and should become habitual to maintain pain management. There is need to investigate common BCTs used among patients with CNCP who have discontinued their opioids to identify their continued use and potential long-term effectiveness. The usefulness of the COM-

B model in clinical practice should also be determined as it might facilitate improved tailored responses to problem solving, goal setting and patient treatment.

- *Continued opioid use* - there remains an argument amongst some researchers that opioids still have a place in CNCP pain management (Häuser et al., 2015; O'Brien et al., 2017), and dismissing them entirely risks increasing pain. There is need to explore the potential benefits of "opioid holidays" (Häuser et al., 2016) and if effective pain management can be obtained at lower doses (lowering risk of adverse harm) combined with adequate measures of psychosocial support. The current focus on reducing opioids is among patients whose daily dose is above 120g MED, however the majority of patients are prescribed doses below this amount. It is therefore necessary to explore how to optimise pain management within this cohort particularly if risk of harm is low, and there is some benefit of pain relief being obtained. A balance needs to be found that prevents new cases of opioid ineffectiveness, reduces adverse risk and manages symptoms of pain (Mercadante et al., 2003).

- *Post discontinuation* – there is limited research exploring the impact of discontinuing opioids long-term; this research found that patients who discontinued their opioid use did not know how they were meant to manage their ongoing pain and were afraid to initiate any new analgesic treatment. Exploring pain management post discontinuation could help identify effective self-management techniques, or a direction for further healthcare requirements.

## Future Research

This research has led to a number of developments to take it forward. Funding has been secured to conduct a small pilot investigating the effectiveness of an intervention developed using the recommendations, delivered alongside a tailored weaning plan in a primary care setting. Patients receiving daily opioids above 120mg MED will be identified and invited to take part in an opioid weaning trial where they will be randomised into one of two groups: a tailored weaning plan with additional support or a tailored weaning plan with care as usual. Additional funding for a follow up PhD to evaluate this pilot has also been secured. It is the

intention of the lead researcher (EB) to support the delivery of these projects and contribute learning outcomes from this research via peer reviewed publications.

## Conclusion

Treating and managing CNCP is considered to be one of the most challenging issues in primary care. Engaging patients and orchestrating a plan to reduce opioid medication adds to the complexity of this problem. There is a well-placed argument that opioids should not be entirely dismissed due to their potential effectiveness, however the evidence on who might benefit from them is unclear. In the absence of this evidence, patients are still exposed to risk of harm and limited pain relief. Health psychology has made significant progress in explaining how our behaviours can influence our health thus advancing the science behind behaviour change. This research used the BCW framework as a lens for identifying and understanding behaviours linked to opioid weaning among CNCP patients in primary care. This helped determine what needed to change and ways to orchestrate that change in order to better support opioid weaning. Feedback consultations show that HCPs and CNCP patients approve of the recommendations to support opioid weaning. In doing this consensus was established that three key behaviours should be targeted in order to better support opioid weaning, these include: improving patient engagement and adherence to a weaning plan, reducing patients' fear and anxieties around weaning, and improving information and support for these patients. To target these behaviours a series of BCTs are also recommended and should be considered in designing an opioid weaning intervention. This research has identified a cohort of patients who are currently receiving daily opioid doses above the recommended 120mg MED and who might be supported in effectively reducing their dose by implementing the recommendations presented here.

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# APPENDIX 1: Audit ethics approval

**From:** Research Ethics Proportionate Review
**To:** Research Ethics Proportionate Review; Begley, Emma
**Cc:** Montgomery, Cathy
**Subject:** Approved - Begley
**Date:** 29 May 2018 14:45:35
**Attachments:** image002.png

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Dear Emma

With reference to your application for Ethical Approval

**UREC decision: Approved**

**18/NSP/050 – Emma Begley, PGR - Investigating the aetiology of opioid prescribing in the North-West of England (Cathy Montgomery)**

The University Research Ethics Committee (UREC) has considered the above and I am pleased to inform you that ethical approval has been granted.

Approval is given on the understanding that:

- Any adverse reactions/events which take place during the course of the project are reported to the Committee immediately by emailing researchethics@ljmu.ac.uk;
- any unforeseen ethical issues arising during the course of the project will be reported to the Committee immediately emailing researchethics@ljmu.ac.uk;
- The LJMU logo is used for all documentation relating to participant recruitment and participation eg poster, information sheets, consent forms, questionnaires. The LJMU logo can be accessed at http://www2.ljmu.ac.uk/corporatecommunications/60486.htm

Where any substantive amendments are proposed to the protocol or study procedures further ethical approval must be sought (https://www2.ljmu.ac.uk/RGSO/93205.htm)

Applicants should note that where relevant appropriate gatekeeper / management permission must be obtained prior to the study commencing at the study site concerned.

Please note that ethical approval is given for a period of five years from the date granted and therefore the expiry date for this project will be **29th May 2023**. An application for extension of approval must be submitted if the project continues after this date.

LIVERPOOL JOHN MOORES UNIVERSITY
**Mandy Williams, Research Support Officer (Research Ethics and Governance)**
**Research and Innovation Services Exchange Station, Tithebarn Street, L2 2QP t: 01519046467 e: a.f.williams@ljmu.ac.uk**
**https://www2.ljmu.ac.uk/RGSO/93042.htm**
**https://twitter.com/LJMUEthics**

# APPENDIX 2: CCG invitation and participant information

Emma Begley
Liverpool John Moores University
Tom Reilly Building
Byrom Street
Liverpool
L3 3AF
T: 07516860587
E: e.k.begley@2017.ljmu.ac.uk

Dear Senior Partner,

**Re: Audit of opioid prescribing in chronic non-cancer pain patients**

I am contacting you to invite your practice to take part in a Liverpool wide audit of opioid medication prescribed to Chronic Non-Cancer Pain (CNCP) patients. The audit is part of a 3-year PhD research project whereby the aim is to understand the aetiology of opioid prescribing amongst different localities across Merseyside and to develop an intervention that will reduce or discontinue inappropriate high dose opioid prescribing within primary care.

The audit is currently underway in collaboration with Liverpool CCG and recently approved by South Sefton head of medical management and the Joint Quality Committee. Liverpool John Moores University ethics board (18/NSP/050) has also approved the study. I will be carrying out the audit (Emma Begley, PhD researcher) alongside experts from LJMU (Dr Cathy Montgomery, Dr Helen Poole, Professor Harry Sumnall) and the Walton Centre (Dr Bernhard Frank, Pain Consultant).

The purpose of the audit is to understand the frequency and variation of opioid medication prescribed to CNCP across your locality, so that a tailored intervention can be delivered to help reduce or discontinue inappropriate prescribing. Therefore, to conduct this piece of research we request your participation to share anonymised individual level prescribing data for all your patients prescribed an opioid for their CNCP in the past two years.

We appreciate the stringent levels of anonymization and data protection involved in this process and would like to reiterate that we request anonymised patient data only and that data will be securely transferred from and to an NHS.net account.

I have attached an opt-in/opt-out return slip, if you are interested in being included in the audit please complete the form and return in the stamped addressed envelope. If you would like some further information before making your decision, please feel free to contact me on the telephone number or email address above.

Kind regards,

Emma Begley
PhD Researcher
Liverpool John Moores University

# Investigating the aetiology of opioid prescribing in the North-West of England

**What**

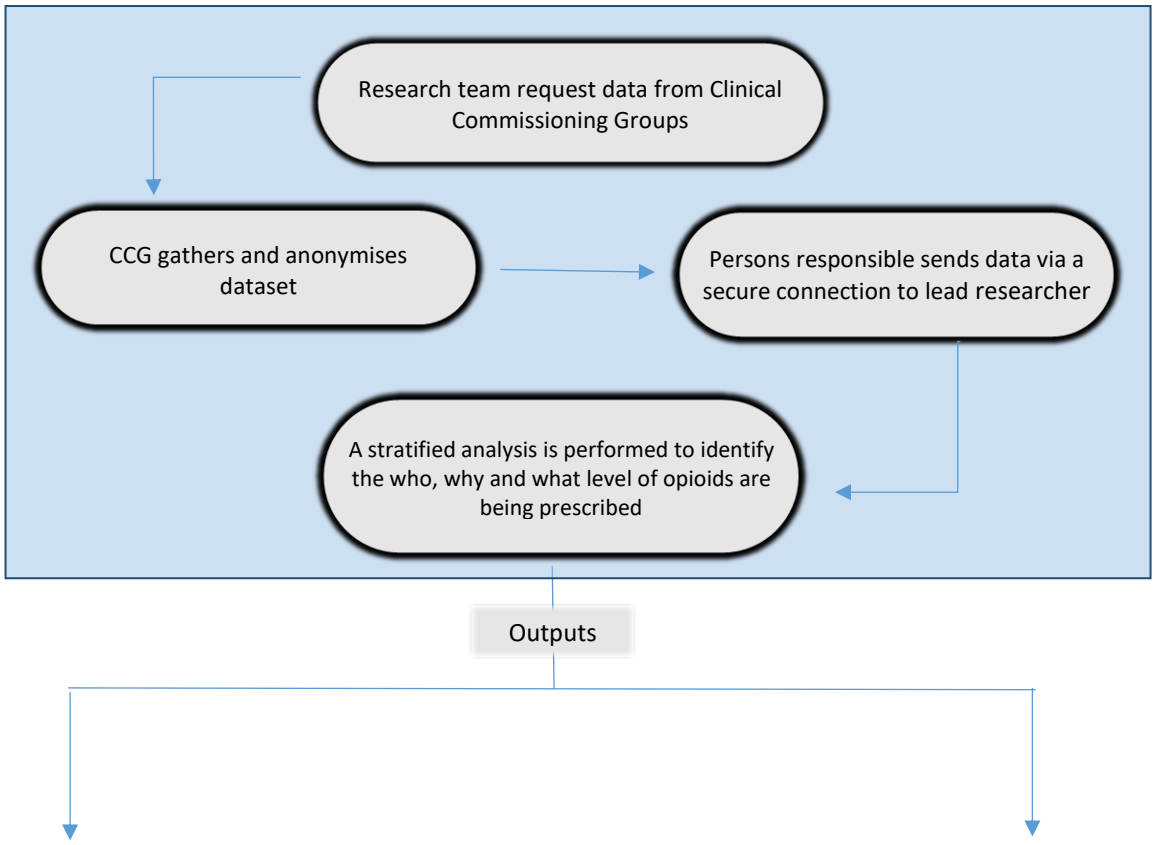
- An audit of opioid prescribing in non-malignant chronic pain patients in various localities in the North-West

**Why**

- To identify:
  - Levels of prescribing and higher prescribing practices;
  - Medicines prescribed;
  - Cost to practices and localities of current regime;
  - Savings to be made if prescribing was reduced

**How**

- Analysing GP and pharmacy prescribing data at practice and individual level.




Persons responsible will receive a report from the research team detailing the prescribing practices of opioid medicine within GP surgeries in sub-group populations of chronic pain patients in the North West.

An algorithm will be developed by the research team to allow other areas to identify their needs in relation to opioid prescribing.

**FAQ's**

**Why is the North West being targeted?**

Prescribing is higher in areas of higher social deprivation. A number of areas in the North-West have been identified as some of most deprived in England, in particular Liverpool, which falls among the top 30% most deprived areas in the UK. In order to create a fuller picture of prescribing practices in the North West it would be useful to compare other localities across the Liverpool City Region. The North West is also home to The Walton Centre, the only leading specialist hospital in the UK who are dedicated to neurology, neurosurgery, spinal and pain management services. This project will be conducted in collaboration with leading experts in pain management at the Walton Centre.

**How will confidentiality be protected?**

Individual patient level data is requested; the data controller will anonymise any patient identifiable information before sharing with auditors. Individual surgeries and prescribers will also be anonymised, however postcodes will be used to identify areas of high prescribing and for the selection process for the intervention. Datasets will be stored on a secured network and password protected; only the lead researcher will have access to the data. There is an alternative option of analysing data on an NHS network (at the Walton Centre), should the data holder prefer this.

**How will the data be stratified and why?**

Data will be stratified on a number of variables, such as, non-malignant chronic pain diagnoses, duration of prescription, frequency and dose of medicine, type of medicine prescribed and locality of GP. Specifically, chronic non-malignant pain patients receiving opioid therapy of morphine equivalent dose (MED) between 25 and 300mg a day for at least three months and/or major physical or psychiatric co-morbidity will be identified. This data will be stratified by Index of Multiple Deprivation (IMD) using postcodes as it will allow for comparisons in levels of prescribing across different localities in the North West. It will also help triangulate which areas might respond better to a theoretically informed intervention developed in stage three of the PhD project.

**How will the algorithm be used?**

Researchers will develop an algorithm that has potential to be utilised on other prescribing databases and will help identify and measure primary care services who are prescribing high dose opioids.

**What happens next?**

If you are interested in collaborating with the project or would like to discuss it further in the first instance, please let me (Emma Begley) know via email (E.K.Begley@2017.ljmu.ac.uk).

Following ethical approval from LJMU ethics board, we will agree on a data sharing and gatekeeper protocol. Once data is extracted we request that you transfer the dataset to a secure LJMU network where it will be stored on a password protected computer. We will also agree on an expected delivery date for the audit report tailored to your CCG.

**APPENDIX 3: Data sharing agreement**

Liverpool Clinical Commissioning Group

Opioid Prescribing Project Dataflow

Agreement Commenced: Date of signature
Agreement expires: 01/07/2019
Unique Reference: 0026

## Change History

| Version | Date | Author | Details |
|---|---|---|---|
| 1.0 | 23.05.18 | LB | Document created |

**Summary and Benefits of the Extract**

This document outlines the specification and information governance arrangements relating to an **anonymised** patient-level data extract which your GP practice would extract and transfer to Liverpool John Moores University (LJMU).

The extract will allow researchers to conduct an audit of opioid prescribing across different localities in the North West of England. The opioid audit is phase 1 of 3 projects that form a PhD programme at Liverpool John Moores University and is funded for 3 years between November 2017 – November 2020 (please see Appendix 1 for an overview of the full PhD project). The audit phase is expected to commence in August 2018 and be completed by August 2019. The purpose of the audit is to uncover the aetiology of high dose opioid prescribing at practice and patient level in chronic non-cancer pain (CNCP) patients. The audit will inform phase 2 (interviews with health professionals and patients) and phase 3 (development and pilot of a brief intervention) of the PhD and provide an indication of the different clusters of patients who may benefit from an alternative treatment. Ultimately, the aim of the overall project will be to wean CNCP patients off inappropriately high dose opioid prescriptions or significantly reduce high dose prescriptions thereby reducing risk of harm linked to high dose opioid medication and overall costs to the CCG.

**Extract Frequency**

This will be a one-off extract to be extracted by the end of February 19.

**Extract Parameters and uses of the data**

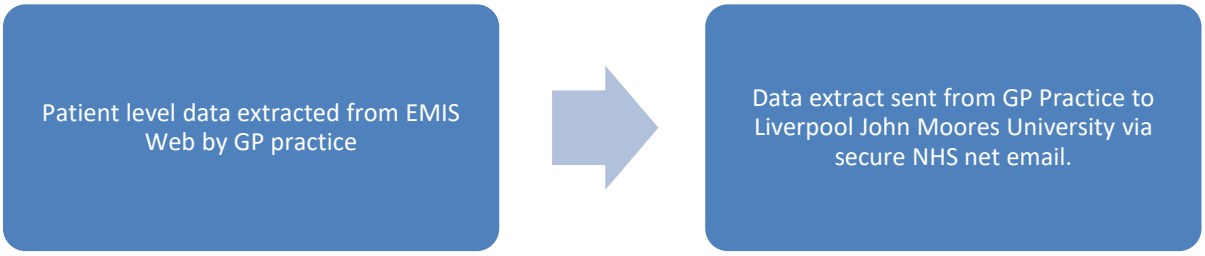
The sole use of the data contained within this extract is for the audit outlined above. This sharing agreement does not permit any other use of the data.

The extract parameters are below.

Search population: Any patient currently prescribed a high-dose opioid, **excluding** Cancer and palliative patients.

| | Field | Codes | Date Range |
|---|---|---|---|
| All Opioid Drugs | Anonymised Identifier | n/a | |
| | Age | n/a | |
| | Ethnic Origin | n/a | |
| | Gender | n/a | |
| | Partial Postcode (e.g. L17) | | |
| | Lower Super Output Area 2011 | | |
| | Practice Code | | |
| | Ethnicity | | |
| | Employment Status Code & Date | 13J% | Latest |
| | Name, dosage & quantity | | For all opioid drugs where most recent issue date is in last 2 years |
| | Quantity | | |
| | Quantity Unit | | |
| | Dose | | |
| | Prescription type | | |
| | Linked Problem's Code Term | | |
| | Date Drug Added | | |
| | Most Recent Issue Date In Course | | |
| | Course Status | | |
| | Count of consultations | | In Last 2 Years |

## Extract Process and Data Management




The data extraction file from EMIS web will be stored temporarily on the GP secure network for the purposes of transmission to Liverpool John Moores University. The data will be transmitted to LJMU via NHS net account. This is an acceptable form of data transmission. The information file extracted will then be immediately deleted from the GP network.

### Governance and Security

**Data Governance**

It is essential that all processing and use of personal data is in line with the Data Protection Act. In order to protect the rights of individuals there is a statutory duty placed on those who decide 'how' and 'why' such data is processed – the 'data controller'. The data controller for this General Practice extraction is the GP Practice as they are the statutory body. Therefore all proposed use of the data must be in agreement with GP practices. Liverpool John Moores University will be acting as a 'data processor' for this data ensuring that it is processed for the purposes it is collected and in accordance with the Data Protection Act and other best practice guidance e.g. National Information Governance policy.

This essentially means that **ALL** decisions regarding the use of the data rest with the GP Practice. The data processors cannot utilise or disclose this information to a third party e.g., Department of Health, without your express permission, unless covered by the terms of this agreement.

The information will only be used in accordance with the specific purpose that it is provided for and will be at all times treated as confidential and handled in a secure manner.

The shared information will not be used for any of the following:

- Advertising, Marketing & Public Relations
- Trading/sharing in personal information
- Research

**Security of the servers/data warehouse**

Data will be warehoused on a secure server hosted by Liverpool John Moores University.

- Servers have routine, auditable back up procedure to prevent data loss
- Secure anti-virus software
- Servers in secure room with key access and log book for access
- Computers have time out screens and screen lock functions for users.
- Users have secure password to network.
- This process is regularly audited by external auditors to ensure it is fit for purpose

**Legal basis for Information Sharing**

The Data Protection Act allows the sharing of person identifiable information where:-

- The processing is necessary for medical purposes and is undertaken by a health professional. Where 'medical purposes' is defined as preventative medicines, medical diagnosis, medical research, the provision of care and treatment or the management of health care services.
- The organisation has taken reasonable steps to inform the patient that information is being shared e.g. via patient engagement events where opinions of patients and carers; Patient information leaflets; Posters in practice of those organisations partaking in the data sharing

The Health and Social Care Act 2012 also allows sharing of information for the purposes of direct patient care, advancing the health and wellbeing of the people in the area, or to encourage persons who arrange for the provision of any health or social care services in that area to work in an integrated manner.

**The information to be shared does not contain any patient identifiable data items.**

**Subject Access**

Subject access requests will be dealt with by the data controller in accordance with the provisions of the Data Protection Act 1998.

**Complaints**

Complaints will be dealt with in accordance with Liverpool John Moores Complaints Policy.

**Transmission**

In line with Department of Health recommendations, the use of laptops or other portable media for storing/transferring person identifiable or other sensitive information is not allowed under this agreement unless it is encrypted to standards approved by the DoH. Data will be transmitted via approved secure routes, in this case NHS net to NHS net email.

**Information breaches**

Partners will take steps to avoid any breach (intentional or otherwise) or disclosure to third parties outside the remit of this Agreement. Breaches must be reported through Liverpool CCG Incident reporting procedures, fully investigated and a report provided to Liverpool CCG.

Any Serious Untoward Incidents occurring within the scope of the information shared under this agreement must be reported to the participating organisations within 1 day of the incident occurring. The SUI must be fully investigated. The GP practices reserves the right to be informed at every stage of the investigation. Disciplinary action will be the responsibility of the organisation where the incident has occurred. This agreement will be reviewed in light of any lessons learnt from such incidents.

Information will only be accessible to those authorised by this agreement or for whom it is essential to access the information to complete the purpose of the sharing.

**Confidentiality**

Partner organisations must have confidentiality clause within staff contracts of employment and or require staff participating in this agreement to sign confidentiality agreements. Staff must have current CRB checks where agreements require the sharing of sensitive data in particular children's data.

Where training needs to meet the requirements of this agreement are assessed and identified, each organisation will ensure that the resource is made available to staff.

**Patient Confidentiality**

Some patients may wish to opt out of sharing data in the same way as they may have done for the national spine. Patients' data will not be shared if any of the read codes listed below are included on their record. Patients will also be hidden from the extract if a practice marks their records as 'private' from within the clinical system. Both methods are acceptable.

| | |
|---|---|
| 93C1 | Refused consent for upload to local shared electronic record |
| 93C3 | Refused consent for upload to national shared electronic record |
| 9M1.. | Informed dissent for national audit |
| 9R1.. | Confidential patient data |
| 9R11 | Conf data- patient not to see |
| 9R12 | Conf data- not to be reported |
| 9R13 | Conf data- staff not to see |
| 9R14 | Conf data- paramedics not to see |
| 9R15 | Conf data- other Dr not to see |
| 9R1Z | Confidential data NOS |
| 9Nd1 | No consent for electronic record sharing |
| 9Nd9 | Declined consent for Primary Care Trust to review patient record |
| 9NdH | Declined consent to share patient data with specified third party |
| 9NdJ | Consent withdrawn to share patient data with specified third party |
| 9Oh8 | Personal risk assessment declined |
| 9Oh5 | Multi-professional risk assessment declined |
| 9Nu4 | Dissent from disclosure of personal confidential data by HSCIC |
| 9Nu5 | Dissent withdrawn from disclosure of personal confidential data by HSCIC |

**Data Protection Impact Assessment**

This dataflow has been the subject of a Privacy Impact Assessment.

**Dissemination**

Copies of this agreement will be provided to each of the signatory organisations. A master copy will be held by Liverpool John Moores University. Liverpool John Moores University will support any changes or amendments to this agreement.

This information sharing agreement will be adopted by the signatory organisations. Key staff will be identified in each organisation to ensure that the protocols in this agreement are adhered to.

**Information Governance**

All signatories to this agreement are required to have approved Information Governance Policies in place that state the legal, ethical and professional obligations to protect service user information.

Signatories to this agreement must ensure that all staff, contractors or other third parties who are involved in the processing of information covered by this agreement have received appropriate Information Governance training.

**Monitoring & Review**

Review of this agreement will be overseen by Liverpool John Moores University, with reference to the signatory organisations, and in particular if there are changes to the agreed purpose or processes. This document will also be reviewed whenever there are changes to legislation or guidelines that may affect the sharing of the information covered by the agreement.

Staff are required to report any adverse incidents to the Business Intelligence Team that may affect the validity of the statements in this agreement and any breaches of security or confidentiality.

Any queries relating to this agreement should be addressed to Liverpool John Moores University.

**Effective Date**

This ISA is considered to be effective following signature of all parties and from the date on the signature page of the agreement unless prior authorisation to share has been approved by the Caldicott Guardian.

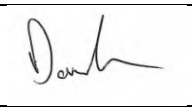
**Information Sharing Agreement**

You agree to share the specified extract against the parameters specified within this document.

**GP Practice**

| | |
|---|---|
| GP Practice | |
| Address | |
| Contact Details | |
| Signature | |
| Name | |
| Designation | |
| Information processing lead for Practice including contact details | |
| Deputy Information Processing lead for Practice | |

**Liverpool John Moores University**

| | |
|---|---|
| Signature |  |
| Name | Dave Harriss |
| Designation | LJMU research Governance Manager |
| Contact Details | Dr Dave Harriss<br>**Research Governance Manager & Chair of the University Research Ethics Committee**,<br>Exchange Station, Tithebarn St, L2 2QP.<br>researchethics@ljmu.ac.uk; 07929999021 (work mobile number) |

**Date of expiry:** 01.07.2019

## APPENDIX 4: Categories of reported CNCP and frequency of prescriptions

| CNCP | No. of prescriptions |
|---|---|
| Musculoskeletal pain | 16,137 |
| Back Pain | 10974 |
| Arthritis | 7154 |
| Mental Health | 2169 |
| skin complaints | 1488 |
| Respiratory problems | 1248 |
| General aches and pains | 1122 |
| Abdominal pain | 1060 |
| Urinary system complaints | 1039 |
| Infection | 1014 |
| Medication Review | 1006 |
| Headache | 924 |
| Gastroenterology Problems | 899 |
| Medication requested | 885 |
| Accident or Fall | 863 |
| Surgery/treatment | 840 |
| ENT Complaint | 762 |
| Gynecological or reproductive issues | 692 |
| Cough | 671 |
| Hypertension | 622 |
| Blood Definency | 507 |
| Bowel Dysfunction | 466 |
| Neuropathy | 414 |
| Diabetes | 346 |
| Osteoporosis | 328 |
| Prosthetic replacement | 310 |
| Tiredness or sleep | 299 |
| Swelling/inflammation | 246 |
| Blood Vessal Conditions | 244 |
| Consultation | 244 |
| Heart Condition | 229 |
| Testing | 205 |
| Lump on body | 189 |
| Spinal stenosis | 181 |
| Brain dysfunction | 180 |
| Sinustis | 176 |
| Chronic Intractable pain | 171 |
| Endometriosis | 153 |
| Shingles | 146 |
| Weight issue | 145 |
| Vertigo | 144 |
| Not medically related | 138 |

| | |
|---|---|
| Repeat Prescription | 137 |
| Eye Complaint | 117 |
| Dental Complaints | 114 |
| Groin discomfort | 111 |
| Assault | 91 |
| Adverse reaction/allergic reaction | 77 |
| Cramping | 74 |
| Wound care | 73 |
| Chronic Regional Pain Syndrome | 72 |
| Other | 72 |
| Viral illness | 71 |
| Facial Pain | 69 |
| Chest Discomfort | 65 |
| Thyroid Issues | 63 |
| Hormone replacement | 61 |
| Fever | 58 |
| Multiple symptoms | 57 |
| Flu | 52 |
| Malaise | 52 |
| Pins and Needles | 51 |
| Therapeutic Prescription | 49 |
| Tumour | 47 |
| Referral | 44 |
| Male Genitourinary Tract | 42 |
| Whiplash injury | 36 |
| Memory | 31 |
| Smoking | 26 |
| Lymphadenopathy | 22 |
| Lupus | 21 |
| Numbness | 18 |
| Supportive care | 18 |
| Burning sensation | 15 |
| Seizure | 15 |
| Spina Bifida | 15 |
| Ingrowing toe nail | 13 |
| Suspected condition | 12 |

# APPENDIX 5: Grouped reasons for health care visit and prescription

- **Abdominal Pain**

Abdominal lump, Abdominal mass, Abdominal pain, Abdominal swelling, Epigastric pain, Hypochondrial pain, Nonspecific abdominal pain, Pain in left iliac fossa, Recurrent acute abdominal pain, Right lower quadrant pain, Upper abdominal pain, Sphincter of Oddi, Spinal nerve root, AAA - Abdominal aortic aneurysm without mention of rupture, Abdomen feels bloated, Abdomen feels distended, Abdominal discomfort, Abdominal distension symptom, Abdominal pain, Abdominal pain type, Abdominal wall pain, Colicky abdominal pain, Dysmenorrhoea, Epigastric hernia, Epigastric pain, Examination of abdomen, Flatulence/wind, Flatulent dyspepsia, Hiatus hernia, Hiatus hernia NOS, Lower abdominal pain, Neoplasm of uncertain behaviour of retroperitoneum, abdomen pain hypochondrium, Paraumbilical hernia, Peritoneal adhesions, Primary dysmenorrhoea, Primary repair of incisional hernia, Primary repair of inguinal hernia, Right iliac fossa pain, Right inguinal hernia, Sliding hiatus hernia, Spasm of sphincter of Oddi, Spigelian hernia, Suprapubic pain, Umbilical hernia, Upper abdominal pain, Ventral hernia, Wind symptom

- **Accident or fall**

Accidental injury, Motorcycle rider injury in collision with car, pick-up truck or van, RTA - Road traffic accident, RTA - Road traffic and other transport accidents, Unspecified fall, Abrasion, lower leg, Accidental fall, Accidental falls, Accidental injury NOS, Closed crush injury, hip, Closed crush injury, shoulder area, Closed injury, suprascapular nerve, Crush injury, Crush injury of arm, Crush injury, elbow, Crush injury, finger(s), Crush injury, foot, Crush injury, lower limb, Crush injury, trunk, Fall – accidental, Fall - accidental tripped over paving stone (GMS), Fall on or from stairs or steps, Fall on same level from slipping, tripping or stumbling, Fall on same level from tripping, Falls, head injury, Had a collapse, Head injury, History of road traffic accident, Injury arm, Injury NOS, Injury of lower leg, Injury toe, Minor head injury, Motor vehicle accident, Motor vehicle traffic accidents (MVTA), MVTA-unspecified - pedestrian injured, Other falls, Other motor vehicle traffic accident with collision on road, Other road vehicle accidents, Post-concussion syndrome, Recurrent falls, RTA - motor vehicle, RTA - motor vehicle-4 days ago side impact-car (GMS), RTA injury examination, Unspecified injury of hand, Unspecified injury of wrist.

- **Adverse medical reaction/allergic reaction**

Accident poison/exposure to narcotic drug at home, Accidental drug overdose / other poisoning, Adverse drug reaction NOS, Adverse reaction to Butrans, Adverse reaction to Matrifen, Adverse reaction to Pregabalin, Adverse reaction to Tramadol Hydrochloride, Adverse reaction to vaccine or biological substance NOS, Allergic reaction, Anaphylactic shock, Dr stopped drugs - side effect, Drug declined by patient - side effects, Drug not taken - side-effects, Drug withdrawal syndrome, FH: Hay fever, drug allergy, hay fever, Has shown side effects from medication, Hay fever, Hay fever - other allergen, Hay fever – pollens, Hay fever - unspecified allergen, Irradiation hypothyroidism, Medication stopped - side effect.

- **Alcohol issue**

Problems related to lifestyle alcohol use, Alcohol abuse – nondependent, Alcohol dependence syndrome, Alcohol detoxification, Alcohol problem drinking, Alcohol-induced chronic pancreatitis, Alcoholic cirrhosis of liver, Alcoholic fibrosis and sclerosis of liver, Alcoholic hepatitis, Alcoholic liver damage unspecified, Alcoholism, Binge drinker, Chronic alcoholism, Excessive use of alcohol, Nondependent alcohol abuse unspecified, Referral to specialist alcohol treatment service.

- **Arthritis**

Inflammatory polyarthropathies, Other specified arthritis, Seropositive rheumatoid arthritis unspecified, Acute polyarticular juvenile rheumatoid arthritis, Ankle arthritis NOS, Ankle osteoarthritis NOS, Arthritis, ARTHRITIS, Arthritis - lumbosacral (GMS), Arthritis – spine, Arthritis associated with other disease, IP joint of toe, Arthritis of spine, Arthritis/arthrosis, Arthropathies and related disorders, Arthropathies NOS, Arthropathy – psoriatic, Arthropathy (GMS), Arthropathy NOS, Arthropathy NOS-hand, Arthropathy NOS, of multiple sites, Arthropathy NOS, of the ankle and foot, Arthropathy NOS, of the shoulder region, Arthropathy NOS, of unspecified site, Arthroscopic debridement of knee joint, Arthrosis of first carpometacarpal joint unspecified, Chronic arthritis, Elbow arthritis NOS, Elbow joint pain, Elbow osteoarthritis NOS, Erosive osteoarthrosis, Finger osteoarthritis NOS, Flare of rheumatoid arthritis, Foot arthritis NOS, Foot osteoarthritis NOS, Generalised arthritis, Generalised osteoarthritis – OA, Generalised osteoarthritis NOS, Generalised osteoarthritis of multiple sites, Generalised osteoarthritis of the hand, Generalised osteoarthritis-OA, Gout, GOUT, Gout NOS, Gouty arthritis, Gouty arthropathy, Gouty arthropathy, arthritis, osteoarthritis, rheumatoid arthritis, Hand arthritis NOS, Hip arthritis NOS, Hip osteoarthitis NOS, Hip osteoarthritis NOS, Inflammatory polyarthropathy, Inflammatory polyarthropathy NOS, Juvenile rheumatoid arthritis, Juvenile rheumatoid arthritis NOS, Knee arthritis NOS, Knee osteoarthritis NOS, Localised osteoarthritis, unspecified, NOS, Localised osteoarthritis, unspecified, of shoulder region, Localised osteoarthritis, unspecified, of the ankle and foot, Localised osteoarthritis, unspecified, of the hand, Localised osteoarthritis, unspecified, of the lower leg, Localised osteoarthritis, unspecified, pelvic region/thigh, Localised, primary osteoarthritis, Localised, primary osteoarthritis of elbow, Localised, primary osteoarthritis of the hand, Localised, primary osteoarthritis of the lower leg, Osteoarthritis, OSTEOARTHRITIS, Osteoarthritis - ankle/foot, Osteoarthritis - elbow joint, Osteoarthritis - hand joint, Osteoarthritis - hip joint, Osteoarthritis – knee, Osteoarthritis - knee joint, Osteoarthritis - knee joint, Osteoarthritis - knee joints, Osteoarthritis - knee joints, Osteoarthritis – NOS, Osteoarthritis - other joint, Osteoarthritis – spine, Osteoarthritis - wrist joint, Osteoarthritis -multiple, Osteoarthritis -multiple joint, Osteoarthritis -shoulder joint, Osteoarthritis (GMS), Osteoarthritis and allied disorders, Osteoarthritis cervical spine, Osteoarthritis NOS, Osteoarthritis NOS-hand, Osteoarthritis NOS, of 1st MTP joint, Osteoarthritis NOS, of acromioclavicular joint, Osteoarthritis NOS, of ankle, Osteoarthritis NOS, of ankle and foot, Osteoarthritis NOS, of elbow, Osteoarthritis NOS, of hip, Osteoarthritis NOS, of knee, Osteoarthritis NOS, of PIP joint of finger, Osteoarthritis NOS, of shoulder, Osteoarthritis NOS, of shoulder region, Osteoarthritis NOS, of subtalar joint, Osteoarthritis NOS, of the hand, Osteoarthritis NOS, of the lower leg, Osteoarthritis NOS, of unspecified site, Osteoarthritis NOS, of wrist, Osteoarthritis NOS, other specified site, Osteoarthritis NOS, pelvic region/thigh, Osteoarthritis of cervical spine, Osteoarthritis of knee, Osteoarthritis of lumbar spine, Osteoarthritis of spinal facet joint, Osteoarthritis of spine,

Osteoarthritis of thoracic spine, Osteoarthritis spine, Osteoarthritis, back, Osteoarthritis+allied disord, OSTEOARTHROSIS, OSTEOARTHROSIS FINGERS, OSTEOARTHROSIS KNEE(S), STEOARTHROSIS SPINE, Other juvenile arthritis, Palindromic rheumatism, PATELLO FEMORAL ARTHRITIS, Patellofemoral osteoarthritis, Pauciarticular juvenile rheumatoid arthritis, Periarthritis NOS, Periarthritis of shoulder, Periorbital oedema,Polyarthritis, Polyarthritis NOS, Polyarthritis NOS (GMS), Polyarthropathy NEC, Primary generalized osteoarthrosis, Pseudogout, Psoriatic arthritis, Psoriatic arthropathy, Psychiatric monitoring, Pyogenic arthritis of the pelvic region and thigh, Rheum. arth. - knee joint, Rheum. arth. - multiple joint, Rheumat.dis.- joints affected, Rheumatic pain, Rheumatism NOS – multiple, Rheumatism unspecified, Rheumatism/fibrositis NOS, Rheumatoid arthrit monitoring, Rheumatoid arthritis, RHEUMATOID ARTHRITIS, Rheumatoid arthritis - multiple joint, Rheumatoid arthritis annual review, Rheumatoid arthritis monitoring invitation first letter, Rheumatoid Arthritis NOS, Rheumatol. disorder monitoring, Septic arthritis, Sero negative arthritis, Sero negative polyarthritis, Sero-Negative Polyarthritis, Seronegative rheumatoid arthritis, Seropositive rheumatoid arthritis, unspecified, Shoulder arthritis NOS, Suspected inflammatory arthritis, Thumb osteoarthritis NOS, Toe osteoarthritis NOS, Undifferentiated inflammatory arthritis, Unspecified polyarthropathy of multiple sites, Unspecified polyarthropathy or polyarthritis, Unspecified polyarthropathy or polyarthritis NOS, Wrist arthritis NOS, Wrist osteoarthritis NOS

- **Asperger's**

Asperger's syndrome

- **Assault**

Domestic violence, Victim of crime and terrorism, Assault by fight, Assault, Assault - gun, larger gun, Assault by bodily force, Assault by bodily force, occurrence at home, Stabbing, Accident caused by gunshot wound NOS, Assault by cutting and stabbing instruments, Assault by unspecified means, At risk of domestic violence, Dog bite, Gunshot accident, History of domestic violence, Suspected assault - allegation made, Victim of domestic violence.

- **Back pain**

Central disc prolapse, Lateral spinal stenosis, Spondylolisthesis grade 1, Spondylolisthesis grade 2, Chronic back and neck problems, Facet joint of lumbar spine, Spinal nerve root, Spinal nerve root C5, Spinal nerve root L5, Spinal nerve root of lumbar spine, Spinal nerve root S1, Lower back injury, Other forms of scoliosis, Spondylopathies, Lumbar spine - no cord lesion, Abnormal Lumbar Spine, Acquired kyphosis, Acquired kyphosis NOS, Acquired spondylolisthesis, Acute back pain – lumbar, Acute back pain – thoracic, Acute back pain – unspecified, Acute back pain + sciatica, Acute back pain with sciatica, Anterior spinal and vertebral artery compression syndromes, Arachnoiditis, Back disorders NOS, back pain, Back pain, BACK PAIN, Back pain . has tender left, Back pain and sciatica left, Back pain – lower, Back pain - wedge fracture, Back pain 10 years at least, Back pain 12/12 at least no, Back pain 3 years MRI scan, Back pain chronic, Back pain CHRONIC, Back pain extensive, Back pain investigated at, Back pain no previous, Back pain off and on 5, Back pain scoliosis, ch back, Back pain since 93, Back pain since94, Back pain some, Back pain without radiat NOS, Back pain without radiat

NOS-accident (GMS), Back pain without radiation NOS, Back pain, restricted, Back pain, restricted spinal, Back pain, spinal movement, Back pain unspecified, Back sprain, Back sprain NOS, Back stiffness, Backache, Backache (GMS), Backache and neck pain, ex, Backache low, Backache symptom, Backache treated with, Backache with radiation, Backache with radiation down, Backache, Chronic. Backache, discussed, Backache, unspecified, Backache, Backache. Isq, low back pain, lumbar pain, upper back ache, Chronic low back pain, Coccygodynia, Collapse of lumbar vertebra, Congenital kyphosis, Congenital lumbosacral spondylolysis, Congenital spondylolisthesis, Decompression of spine NOS, Degeneration of lumbar spine, Degenerative cervical spinal stenosis, Degenerative disc disease NOS, Degenerative lumbar spinal stenosis, Degenerative spondylolisthesis, Denervation of spinal facet joint of lumbar vertebra NEC, Disc prolapse with myelopathy, Facet joint syndrome, back problem, Idiopathic scoliosis, Intervertebral disc disorders, Intervertebral disc prol. NOS, Intervertebral disc prolapse NOS, Kyphoscoliosis and scoliosis, Kyphoscoliosis or scoliosis NOS, LBP - low back pain, Low back pain, Lumbago, Lumbago with sciatica, Lumbalgia, Lumbar ache – renal, Lumbar back sprain, Lumbar back sprain (GMS), Lumbar disc degeneration, Lumbar disc disorder with myelopathy, Lumbar disc displacement, Lumbar disc displacement without myelopathy, Lumbar disc lesion – displaced, Lumbar disc lesion - displaced (GMS), Lumbar disc prolapse with cauda equina compression, Lumbar disc prolapse with myelopathy, Lumbar disc prolapse with radiculopathy, Lumbar discitis, Lumbar DXA scan result osteopenic, Lumbar DXA scan result osteoporotic, Lumbar spinal stenosis, Lumbar spondylosis, Lumbar spondylosis (GMS), Lumbar sprain, Lumber disc bulge, Lumbosacral spond + myelopathy, Lumbosacral spond-no myelopath. (GMS), Lumbosacral spondylosis with radiculopathy, Lumbosacral spondylosis without myelopathy, Lumbosacral sprain, Lumbosacral strain, Mechanical low back pain, Mechanical low back pain (Synergy code: @16CA), Multiple joint pain. ch back, Myelopathy NOS, Nerve root and plexus compressions in spondylosis, O/E - spine abnormal NOS, Osteoarthritis back&shoulder, Osteoarthritis, ch backache, Other and unspecified back disorders, Other back injuries, Other lumbar disc disorders, Pain In Back, Paraplegia, PID - prolapsed lumbar disc, Postural scoliosis, Prolapsed intervertebral disc without myelopathy, Prolapsed lumbar intervertebral disc, Prolapsed lumbar intervertebral disc with sciatica, Pulled back muscle, Sacrococcygeal sprain, Scheuermann's disease, Sciatica, SCIATICA, Sciatica rt, Scoliosis – acquired, Scoliosis associated with other condition, Scoliosis of thoracic spine, Single-level cervical spondylosis without myelopathy, Slipped intervertebral disc, Spasm of back muscles, Spinal cord compression, Spinal cord compression NOS, Spinal disorder NOS, Spinal injuries, Spondylitis NOS, Spondylolisthesis (GMS), Spondylolysis, Spondyloses, Spondylosis + allied disorders, Spondylosis and allied disorders, Spondylosis NOS, Sprain of other parts of back, Thoracic back pain, Thoracic disc degeneration, Thoracic discitis, Thoracic spondylosis, Vertebral column syndromes, Wedge compression # lumbar spine, Wedge Compression # Lumbar Spine, Wedge compression # of dorsal spine, Wedge Compression # Of Dorsal Spine

- **Blood deficiency**

Alpha trait thalassaemia, Anaemia unspecified, Anticoagulant therapy, Antiphospholipid syndrome, Aortic aneurysm, B12 injections - at surgery, Blood dyscrasia NOS, Blood pressure monitoring, Borderline blood pressure, Chronic venous insuffic.NOS, Chronic venous insufficiency NOS, Combined B12 and folate deficiency anaemia, ESR raised, Ferritin level low, Folate-deficiency anaemia, Folic acid deficiency, raised blood lipids,

Haemoglobin estimation, Haemoglobin low, Haemoptysis – symptom, Hypercholesterolaemia, Hypercholesterolaemia (GMS), Hyperkalaemia, Hyperlipidaemia, Hyperlipidaemia NOS, Hyperparathyroidism, Hyperprolactinaemia, Hypocalcaemia NEC, Hyponatraemia, Idiop thrombocytopenic purpura, Immunoglobulins, Impaired glucose regulation, Impaired glucose tolerance, Intramuscular injection of vitamin B12, Iron deficiency, Iron deficiency anaemia NOS, Iron deficiency anaemias, ITP - idiopathic thrombocytopenic purpura, Lymphocytosis, Lymphoedema, Macrocytic anaemia unspecified cause, Macrocytosis - no anaemia, Microcytic - hypochromic anaemia, Microcytic hypochromic anaemia, Mixed hyperlipidaemia, Monoclonal gammopathy of uncertain significance, Myelodysplastic and myeloproliferative disease, Neutropenia, Neutrophilia, Perthe's disease, Perthes' disease - osteochondritis of the femoral head, Plasma factor V level, Plasma testosterone level, Possible familial hypercholesterolaemia, Pure hypercholesterolaemia, Pure hypercholesterolaemia NOS, Secondary anaemia NOS, Serum cholesterol, Serum cholesterol raised, Serum cholesterol very high, Serum cortisol, Serum digoxin level, Serum ferritin high, Serum folate low, Serum iron level, Serum iron low, Serum testosterone, Serum triglycerides raised, Serum vitamin B12, Serum vitamin B12 low, Serum vitamin D, Serum vitamin D -Req, Serum zinc level low, Thrombophilia, Thrombophlebitis migrans, Thrombophlebitis NOS, Thrombophlebitis of a superficial leg vein NOS, Thrombosis of vein of leg, Vitamin B12 deficiency, Vitamin B12 deficiency anaemia, Vitamin D deficiency, Vitamin D insufficiency, Vomiting, Vomiting symptoms, White cell count.

- **Blood vessal conditions**

Cavernous haemangioma, Superficial femoral artery, Atherosclerosis, Behcet's syndrome, Behcets syndrome, Buerger's disease, Chilblains, Chronic peripheral venous hypertension, Deep vein thrombosis, Deep vein thrombosis leg, DVT - Deep vein thrombosis, DVT - not obstetric x 2 over past 2 yrs on, Embolism and thrombosis of the radial artery, False aneurysm, Familial, hypercholesterolaemia, Giant cell arteritis, Giant cell arteritis with polymyalgia rheumatica, Granulomatosis with polyangiitis, Deep Vein Thrombosis, Hereditary haemorrhagic telangiectasia, Ischaemia of legs, Ischaemic foot, Melaena, Nonpyogenic venous sinus thrombosis, Normocytic anaemia due to unspecified cause, phlebitis, pompholyx, Occlusion of posterior tibial artery, Oesophageal varices, Other peripheral vascular dis, Other specified peripheral vascular disease, Peripheral arterial disease, Peripheral ischaemia, Peripheral ischaemic vascular disease, Peripheral vascular dis. NOS, Peripheral vascular disease monitoring, Peripheral vascular disease NOS, Phlebitis NOS, Phlebitis of a superficial leg vein NOS, Polyarteritis nodosa, Portal vein thrombosis, Raynaud's disease, Raynaud's phenomenon, Raynaud's syndrome, Superficial vessel phlebitis and/or thrombophlebitis of leg, Telangiectasia, Varicose veins of legs, Varicose veins of the leg NOS, Varicose veins of the leg with eczema, Varicose veins of the leg with ulcer and eczema, Varicose veins of the legs

- **Brain dysfunction**

Cerebral palsy, Stroke, Demyelinating diseases of the central nervous system, Other cerebral infarction, Vascular dementia, Acute confusional state, Arnold - Chiari syndrome, Benign essential tremor, Benign intracranial hypertension, Brain injury NOS, Central demyelination of corpus callosum, Central pontine myelinosis, Central post-stroke pain, Cerebellar ataxia NOS, Cerebellar stroke syndrome, Cerebral aneurysm, nonruptured, Cerebral

degeneration due to multifocal leukoencephalopathy, Cerebral palsy with spastic diplegia, Cerebrovascular disease, Chiari's malformation, CNS diseases (GMS), Cognitive decline, Congenital cerebral palsy, Congenital cerebral palsy NOS, CVA - cerebral artery occlusion, CVA - cerebrovascular accid due to intracerebral haemorrhage, CVA - Cerebrovascular accident unspecified, CVA unspecified, Dandy - Walker syndrome, Epilepsy, Epilepsy medication review, Epilepsy NOS, Epileptic seizures – tonic, CVA/stroke, TIA, Haematoma NOS, Hydrocephalus, Hydronephrosis, Left sided CVA, Mild cognitive impairment, Motor neurone disease, Multiple sclerosis, Multiple sclerosis of the spinal cord, Parkinson's disease, Progressive supranuclear palsy, Stroke and cerebrovascular accident unspecified, Stroke Monitoring, Stroke unspecified, Subarachnoid haemorrhage, Suspected stroke, Systemic sclerosis, Transient ischaemic attack, Traumatic brain injury, Traumatic subarachnoid haemorrhage, Unspecified encephalopathy.

- **Bowel dysfunction**

Change in bowel habit, Rectal symptoms, Stool contents abnormal, Stoma care, Has ileostomy, Altered bowel habit, Bile acid malabsorption syndrome, Bleeding PR, Blood in stool, Bowel dysfunction, Bowel obstruction, Change in bowel habit, Chronic constipation with overflow, Clostridium difficile infection, Colitis - ulcerative (GMS), Collagenous colitis, Colon polyp, Colonic fistula, Colonic polyp, Colonic Polyp, Colovesical fistula, Constipated, Constipation, Constipation – functional, Constipation NOS, Constipation symptom, Crohn's colitis, Crohn's disease, Crohn's disease of the small bowel NOS, Drug induced constipation, Faeces: mucous present, Hirschsprung's disease, Ileal stricture, Incontinent of faeces, Incontinent of faeces symptom, Inflammatory bowel disease, Irritable bowel – IBS, Irritable bowel syndrome, Irritable bowel syndrome with diarrhoea, Irritable colon - Irritable bowel syndrome, Loose stools, Regional enteritis - Crohn's disease, Small bowel obstruction NOS, Soiling symptom.

- **Burning sensation**

Burning feet, Burning feet syndrome, Burning pain

- **Cancer**

Adenocarcinoma NOS, Adenocarcinoma, metastatic, Adenocarcinomas, Carcinoma, metastatic, Epithelioid mesothelioma malignant, Leiomyosarcoma, Lymphoma, Malignant lymphoma large cell, cleaved, diffuse, Malignant melanoma, Mesothelioma malignant, Myeloma, Neoplasm metastatic, Non Hodgkins lymphoma, Pancreatic adenomas and carcinomas, Papillary carcinoma, Renal adenoma/carcinoma, Sarcoma, Spindle cell sarcoma, Squamous cell carcinoma, Squamous cell carcinoma metastatic, Transitional cell papillomas and carcinomas, Family history of malignant neoplasm of breast, Adenocarcinoma cervix uteri stage 3 (GMS), Adenocarcinoma of lung, B-cell chronic lymphocytic leukaemia, Breast carcinoma, Breast carcinoma left, Ca female breast, Carcinoma, Carcinoma bladder, Carcinoma breast, Carcinoma breast left had, Carcinoma in situ of breast, Carcinoma in situ of bronchus or lung, Carcinoma in situ of cervix uteri, Carcinoma in situ of oral cavity, Carcinoma in situ of prostate, Carcinoma in situ of tongue, Carcinoma in situ of upper lobe bronchus and lung, Carcinoma of rectum, Chronic lymphatic leukaemia, Chronic myeloid leukaemia, Colonic cancer, Diffuse large B-cell lymphoma, prostate cancer, Hepatocellular carcinoma, Hodgkin lymphoma, Lung cancer, Malig neop larynx,

Malig neop of colon, Malig neop soft palate, Malignant lymphoma, Malignant melanoma of skin, Malignant neoplasm of anal canal, Malignant neoplasm of bronchus or lung, Malignant neoplasm of cervix uteri, Malignant neoplasm of cervix uteri, Malignant neoplasm of colon, Malignant neoplasm of connective and other soft tissue, Malignant neoplasm of connective and soft tissue of axilla, Malignant neoplasm of descending colon, Malignant neoplasm of female breast, Malignant neoplasm of female breast, Malignant neoplasm of floor of mouth, Malignant neoplasm of greater vestibular (Bartholin's) gland, Malignant neoplasm of labia minora, Malignant neoplasm of larynx, Malignant neoplasm of middle lobe, bronchus or lung, Malignant neoplasm of oesophagus, Malignant neoplasm of other site of cervix, Malignant neoplasm of ovary, Malignant neoplasm of pancreas, Malignant neoplasm of prostate, Malignant neoplasm of sigmoid colon, Malignant neoplasm of soft palate, Malignant neoplasm of stomach, Malignant neoplasm of subglottis, Malignant neoplasm of thyroid gland, Malignant neoplasm of tongue, Malignant neoplasm of tonsil, Malignant neoplasm of tonsillar fossa, Malignant neoplasm of upper lobe, bronchus or lung, Malignant neoplasm of urinary bladder, Multiple myeloma, Myelodysplasia, Oesophageal cancer, Prostate cancer care review, Rectal carcinoma, Renal malignant neoplasm, Suspected bladder cancer, Suspected lung cancer, Suspected malignancy.

- **Chest discomfort**

Chest discomfort, Chest lump, Chest pain, Chest pain, unspecified, Chest tightness, Chest injury, Intercostal myalgia, Intercostal neuropathy, Pleuritic pain, Retrosternal pain

- **Chronic intractable pain**

Chronic intractable pain, Other chronic pain, Myofascial pain syndrome, Polysymptomatic

- **Chronic regional pain syndrome**

Chronic regional pain syndrome, Complex regional pain syndrome, Complex regional pain syndrome type I, Sympathetic nerve dystrophy syndrome

- **Consultation**

Advice, Advice about treatment given, Advice to GP to start patient medication, Discussed with carer, Discussion, Discussion with colleague, DNA hospital appointment, Emergency appointment, Follow-up consultation, Fostering medical examination, Had a chat to patient, Had a discussion with patient, Home visit, Home visit elderly assessment, Home visit request by patient, Learning disabilities annual health assessment, Letter from consultant, Letter from specialist, Letter/report awaited, MED3 - doctor's statement, New patient consultation, New patient health check, New patient screen, New patient screen - problem identified, New patient screen admin, New patient screen admin, New patient screen done, New patient screen, NHS Health Check programme, Patient asked to come in, Patient given advice, Patient health questionnaire (PHQ-9) score, Patient medication advice, Patient non compliant with specific advice, Patient refuses hospital admit, Patient's condition deteriorating, Planned telephone contact, Telephone call to a patient, Telephone consultation, Telephone encounter, Telephone triage encounter

- **Cough**

Cough syncope, Haemoptysis, cough, Chesty cough, Chronic cough, Cough, Cough symptom, Coughing up phlegm, Dry cough, Nocturnal cough / wheeze, Persistent cough, Productive cough -clear sputum, Productive cough -green sputum, Productive cough, Productive cough-yellow sputum

- **Cramping**

Claudic.- intermittent, Claudication, Intermittent claudication, night cramps, hand cramps, leg cramps, cramps, cramping pain,

- **Dental complaints**

Dental health promotion, Wisdom tooth, Acute pericoronitis, Dental abscess, Dental caries, Dental infection, Dental symptoms, Gingival hyperplasia, Sensitive teeth dentine, Simple dental extraction, Simple extraction of tooth, Surgical removal of impacted wisdom tooth, Tooth symptoms, Toothache

- **Diabetes**

Hyperglycaemia, Impaired fasting glucose, Chronic painful diabetic neuropathy, Diabetes mellitus, Diabetic - poor control, Diabetic Charcot arthropathy, Diabetic nephropathy, Diabetic neuropathy, Diabetic on insulin, Diabetic polyneuropathy, Diabetic retinopathy screening, Insulin dependent diab mellit, Insulin treated Type 2 diabetes mellitus, Left diabetic foot – ulcerated, Type 1 diabetes mellitus, Type 1 diabetes mellitus with gastroparesis, Type 2 diabetes mellitus, Type 2 diabetes mellitus with exudative maculopathy, Type II diabetes mellitus

- **Drug misuse**

Drug addiction – opioids, Heroin addiction, Mental and behav dis due seds/hypntcs: withdrawal state, Mental and behav dis due to use opioids: dependence syndr, Analgesic abuse, Benzodiazepine dependence, Cocaine type drug dependence, Combined opioid with other drug dependence, Continuous opioid dependence, Diazepam dependence, Methadone dependence, Morphine dependence, Other drug psychoses, Other specified drug dependence, unspecified, Overdose of drug, Suspected drug abuse

- **Endometriosis**

Acute endometritis, Endometriosis, Endometriosis, Other endometriosis

- **ENT complaint**

Blocked ear, Difficulty in swallowing, Epistaxis, Acute infective otitis externa, Acute left otitis media, Acute otitis media with effusion, Acute pharyngitis, Acute pharyngitis, Acute rhinosinusitis, Acute right otitis media, Acute suppurative otitis media, Acute tonsillitis, Acute viral tonsillitis, Allergic rhinitis, Allergic rhinosinusitis, Barrett's oesophagus, Blocked nose, Buzzing in ear, post nasal drip, Calculus – salivary, Cholesteatoma of middle ear, Chronic otitis media with effusion, serous, Chronic rhinitis, Chronic rhinosinusitis, Chronic simple rhinitis, Chronic suppurative otitis media, Coryza – acute, Deafness, Difficulty swallowing solids, Dry mouth, Dysphagia, Ear drum perforation, Ear pain, Ear symptoms, Ear/nose/throat symptoms, Earache symptoms, Eustachian tube dysfunction, Glue ear, hearing problem, Has a sore throat, Has nose bleeds – epistaxis, Hearing difficulty, Hearing impairment, Hearing loss, High frequency deafness, Hoarse, Hoarseness symptom, Impacted cerumen (wax in

ear), Inflamed throat, Labyrinthitis, Mallory - Weiss tear, Meniere's disease, Nasal congestion, Nasal symptoms, Nasal symptoms, Nasal turbinate hypertrophy, Nose bleed symptom, Nose cellulitis/abscess, Nose symptoms, Nutcracker oesophagus, foreign body in ear, wax in ear, Oesophageal dysmotility, Otalgia, Other otitis externa, Other vocal cord disease, Otitis externa, Otitis externa, Otitis media, Perennial rhinitis, Perforation of oesophagus, Pharyngitis - acute-as above, red throat with (GMS), Ramsey - Hunt syndrome, Rhinitis – acute, Rhinitis – chronic, Spasm of oesophagus, Stricture of oesophagus, Suppurative and unspecified otitis media, Swallowing symptoms, Throat symptom, Tinnitus, Tinnitus symptom, Tinnitus symptoms, Tongue symptoms, Tonsillectomy, Tonsillitis, Tympanic membrane perforation, Ulcer of oesophagus, Unilateral earache, Unspecified otalgia, Viral labyrinthitis, Viral sore throat, Voice hoarseness, Wax in ear

- **Eye complaint**

Adherent prepuce, Amaurosis fugax, Anisocoria - unequal pupil diameter, Bilateral cataracts, Blind In Right Eye, Blurred vision, Cataract, Corneal abrasion, Dry eye syndrome, Dry eyes, Dry senile macular degeneration, Ectropion, Eye pain, Eye symptoms, Glaucoma, Has a red eye, Homonymous hemianopia, Hordeolum externum ( stye ), Itchy eye symptom, Ocular hypertension, Ophthalmic migraine, Optic neuritis, Primary open-angle glaucoma, Raised intra-ocular pressure, Retinal detachment, Scleritis, Seen by optician, Sticky eye, Thyroid eye disease, Unspecified amblyopia, Unspecified conjunctivitis, Watery eyes

- **Facial pain**

Face ache, Facial pain, Facial nerve (VII), Bell's (facial) palsy, Facial swelling, Facial weakness, facial injury, Orofacial dyskinesia, Stickler syndrome

- **Fever**

Fever symptoms, Hot flushes, Menopausal flushing, Menopausal or female climacteric state, Rigor – symptom, Scarlet fever, Temperature symptoms

- **Flu**

Flu like illness, Influenza vaccination, Seasonal influenza vaccination

- **Gastroenterology problems**

Gamma glutaryl transferase raised, Hepatomegaly, Nausea, Nausea and vomiting, Right upper quadrant pain, Other gastritis, Acid reflux, Acute cholecystitis, Acute gastritis, Acute pancreatitis, Acute pancreatitis, Anal fissure, Anal fissure and fistula, Anal pain, Anal symptoms, Angiodysplasia of colon, Autoimmune hepatitis, Balloon gastrostomy feeding, Biliary colic, Campylobacter enteritis, Cholecystitis, Cholelithiasis, Cholelithiasis, Chronic anal fissure, Chronic cholecystitis, Chronic deafness, Chronic gastritis, Chronic liver disease, Chronic pancreatitis, Cirrhosis - non alcoholic, Cirrhosis and chronic liver disease, Cirrhosis of liver, Coeliac disease, Diarrhoea, Diarrhoea & vomiting, symptom, Diarrhoea symptom, Diarrhoea symptoms, Divertic disease/both sml+lge intestin with perforat+abscess, Diverticular abscess, Diverticular disease, Diverticulitis, Diverticulitis, Diverticulitis of the colon, Diverticulosis, Diverticulosis of the colon, Duodenal diseases, Duodenal ulcer, Duodenal ulcer, Duodenal ulcer, Duodenal ulcer, Duodenitis, Dyspepsia, Dyspepsia-long hx.Scoped in, Enteritis

- presumed infectious origin, Exacerbation of ulcerative colitis, Fatty liver, Gallbladder calculus with acute cholecystitis, Gallbladder calculus without mention of cholecystitis, Gallstones, Gastric ulcer, Gastric ulcer, Gastritis and duodenitis, Gastritis unspecified, Gastro-oesophageal reflux, Gastroenteritis,Gastroenteritis - presumed infectious origin, Gastrointestinal symptoms, Gastrointestinal symptoms, Gastroscopy abnormal, Gastroscopy NEC, Gilbert's syndrome, GIT symptom changes, Gluten intolerance, colitis, peptic ulcer, Haematemesis, Heartburn, Heartburn symptom, Helicobacter eradication therapy, Helicobacter gastritis, Helicobacter pylori breath test, Helicobacter pylori gastrointestinal tract infection, Helicobacter pylori test positive, Helicobacter serology positive, History of acute pancreatitis, Hyperemesis gravidarum, Hyperemesis of pregnancy, Hyperhidrosis symptom, Indigestion, Indigestion symptoms, Laryngopharyngeal reflux, Liver cyst, Microscopic colitis, Nausea, Nausea symptoms, Non-alcoholic fatty liver, Nonalcoholic steatohepatitis, Oesophageal reflux, Oesophagitis, Other liver disorders, Pancreatitis, Percutaneous endoscopic gastrostomy feeding, Pernicious anaemia, Post cholecystectomy bile leakage, Reflux oesophagitis, Reflux oesophagitis (GMS), Reflux oesophagitis abdomen, Right upper quadrant pain, Seasickness, Suspected gallstones, Viral gastroenteritis, Wilson's disease

- **General aches and pains**

Allodynia, General aches and pains, Non cardiac chest pain, Pain, generalized, Aches and pains, generally unwell (GMS), Aching leg syndrome, Aching muscles, Aching pain, a pain, an ache, a pain, Chronic pain, Chronic pain review, Constant pain, Dyspareunia, Generalised pain [symptom], dyspareunia, Mastitis, Mastitis - non puerperal, Mastodynia - pain in breast, Muscle injury / strain, Muscle pain, Muscle sprain, Muscle strain, Night sweats, Night terrors, in pain, Pain, Pain and symptom management, Pain control, Pain in testicle, Pain management, Pain management (specialty), Pain relief, Pain relief by medication, Pain, generalized, Pain, generalized, Painful scar, Painful swallowing, Painful tongue, Persistent mastalgia, Premenstrual tension syndrome, Rectal bleeding, Rectus muscle sprain, Shaking, Soft tissue disorders

- **Groin discomfort**

Groin lump, Groin pain, Groin, Cellulitis and abscess of groin, Groin Pain, Groin sprain, Groin strain (GMS)

- **Gynecological or reproductive issues**

Fibroid uterus, Postnatal care, Vaginal prolapse, General contraceptive advice and counselling, Removal of coil, Removal of intrauterine contraceptive device, Sterilisation, Other specified, menopausal and perimenopausal disorders, Abnormal vaginal bleeding, unspecified, Bacterial vaginosis, p.v. bleeding, Candidal vulvovaginitis, Cervical neoplasia screen, Cervical neoplasia screening, Cervical nerve root injury - C7, Cervical smear due, Cervical smear overdue, Cervical smear screen, Cervical smear taken, Cervical spinal stenosis, Cold coagulation of lesion of cervix, Combined oral contraceptive, Contraception, Cyst of Bartholin's gland, Cystocele with second degree uterine prolapse, Cystocele without uterine prolapse, Delayed menstruation, Delayed period, Depo-provera injection given, Depot contraception, Divarication of recti, Dysfunctional uterine bleeding, Emergency contraception, Endometrial polyp, Fertility problem, Fibroids, First degree perineal tear during delivery, Full post-natal examination, General contraceptive advice, Genital prolapse, Gynaecological history, miscarriage,

painful periods, Heavy periods, High vaginal swab taken, Hot flushes – menopausal, Hydrosalpinx, Hysteroscopy NEC, Infertility investigation -fem, Infertility problem, Intermenstrual bleeding, Intermenstrual bleeding – irregular, Introduction of Mirena coil, Irregular menstrual cycle, Maternal P/N 6 week exam, Menopausal and postmenopausal disorders, Menopausal symptoms, Menopausal symptoms, Menopause, Menopause symptoms present, Menorrhagia, Menstruation disorder, Menstruation disorders, Miscarriage, Missed miscarriage, Missed period, Mittelschmerz - ovulation pain, Obstetric history, Oral contraception, Oral contraception, Oral contraceptive, Oral contraceptive repeat, Ovarian cyst, Ovarian cysts, Patient currently pregnant, Patient pregnant, Perimenopausal menorrhagia, Period disorders, Period pains, Phantom pregnancy, Polycystic ovarian syndrome, Post natal care, Postcoital bleeding, Postmenopausal atrophic vaginitis, Postmenopausal bleeding, Postnatal care, Postnatal exam. – maternal, Postnatal examination normal, Pregnancy complications, Premature menopause, Progestogen only oral contraceptive, Rectocele, Rectocele without uterine prolapse, Replacement of Mirena coil, Requests pregnancy termination, Second degree perineal tear during delivery, Secondary amenorrhoea, Secondary dysmenorrhoea, Separation of vulval adhesions, Sexually transmitted diseases, Termination of pregnancy, Therapeutic endoscopic operations on uterus, Third degree perineal tear during delivery, Threatened abortion, Thrush, Total abdominal hysterectomy, Total abdominal hysterectomy with conservation of ovaries, Trying to conceive, Unprotected intercourse, Unwanted pregnancy, Urine dipstick test, Urine pregnancy test positive, Uterine leiomyoma – fibroids, Uterovaginal prolapse, incomplete, Uterovaginal prolapse, unspecified, Vaginal discharge, Vaginal discharge symptom, Vaginal discomfort, Vaginal dryness, Vaginal hysterectomy, Vaginal irritation, Vaginal pain, Vaginal thrush, Vaginal wall prolapse without uterine prolapse, Vaginitis and vulvovaginitis, Vaginitis unspecified, Vulva sore, Vulval irritation, Vulval pain, Vulval sores, Vulvectomy, Vulvitis unspecified, Vulvodynia, Wishes to postpone menstruatn.

- **Headache**

Headache, Pain in head, Tension type headache, Cervicogenic headache, Chronic headache disorder, Tension type headache, a headache, Chronic paroxysmal hemicrania, Classical migraine, Cluster headache, Frontal headache, migraine, trigeminal neuralgia, Headache, Headache - post traumatic, Medication overuse headache, Migraine, Migraine – menstrual, Migraine, Migraine with aura, Muscular headache, Occipital headache, Other forms of migraine, Other specified trigeminal neuralgia, Paroxysmal hemicrania, Sinus headache, Temporal arteritis, Temporal headache, Tension headache

- **Heart condition**

Bumping of heart, Bradycardia, unspecified, Cardiac pacemaker in situ, Bradycardia, unspecified, Other hypertrophic cardiomyopathy, Acute coronary syndrome, Acute myocardial infarction, Acute non-ST segment elevation myocardial infarction, Acute pericarditis, Acute ST segment elevation myocardial infarction, Angina pectoris, Angina pectoris, Aortic regurgitation alone, cause unspecified, Aortic stenosis, Aortic valve disorders, Atrial fibrillation, Atrial fibrillation and flutter, Atrial flutter, Atrial septal defect, Cardiac arrhythmias, Cardiomyopathy, Cardiovascular symptoms, Congestive heart failure, Constrictive pericarditis, Coronary artery disease, First degree atrioventricular block, Heart failure, IHD - Ischaemic heart disease, Impaired left ventricular

function, Ischaemic heart disease, Left ventricular diastolic dysfunction, Left ventricular failure, Left ventricular hypertrophy, Left ventricular systolic dysfunction, MI - acute myocardial infarct, MI - acute myocardial infarction, Myocardial infarct INPAT AINTREE (GMS), Palpitations, Paroxysmal atrial fibrillation, Primary dilated cardiomyopathy, Primary prevention of ischaemic heart disease, QRISK2 cardiovascular disease 10 year risk score, Refractory angina, Sinus tachycardia, Stable angina, Suspected ischaemic heart disease, Valvular heart disease

- **Hormone replacement**

Hormone replace monitor admin, Hormone replacement therapy, Hormone Replacement Therapy ongoing treatment

- **Hypertension**

Palpitations, Raised blood pressure read, Raised blood pressure reading, Examination of blood pressure, Benign essential hypertension, Essential hypertension, Essential hypertension, hypertension, Hypertension, Hypertension (GMS), Hypertension annual review, Hypertension medication review, Hypertension monitored, Hypertension monitoring, Hypertension, Hypertensive disease, Hypertensive disease, blood pressure, blood pressure reading, BP borderline raised, Postural hypotension, White coat hypertension

- **Infection**

Gangrene, Abscess of axilla, Abscess of buttock, Cellulitis of breast, Perineal abscess, Abscess, Abscess of Bartholin's gland, Abscess of jaw, Abscess of labia, Abscess of vulva, Acute bacterial tonsillitis, Acute bilateral otitis media, Acute conjunctivitis, Acute follicular tonsillitis, Acute laryngitis, Allergic conjunctivitis, Allergy, unspecified, Antimalarial drug prophylaxis, Biliary sepsis, Blepharo conjunctivitis, Boil of axilla, Boil of vulva, Boils of multiple sites, Breast abscess, Breast infection, Candidal intertrigo, Candidiasis, Cervical discitis, Chest infection, Chest infection - pnemonia due to unspecified organism, Chest infection - unspecified bronchitis, Chest infection, Community acquired pneumonia, Conjunctivitis, Cutaneous cellulitis, Drainage of abscess, Drainage of perianal abscess, Epididymo-orchitis, Epidural intraspinal abscess, Eye infection, Flea bite, Fungal infection of skin, Fungal nail infection, Furuncle – boil, Gangrene of finger, Genital herpes unspecified, Genital warts, chronic ear infection, poliomyelitis, viral illness, Hand, foot and mouth disease, Having rigors, Hepatitis C, Herpes simplex, Herpes zoster, Herpes zoster ophthalmicus, HIV positive, Impetigo, Incision and drainage of abscess, Infected eczema, Infected insect bite, Infected joint prosthesis, Infected nailfold, Infected sebaceous cyst, Infected skin ulcer, Infected varicose ulcer, Infection ear, Infection finger, Infection foot, Infection toe, Infective endocarditis in diseases EC, Infective otitis externa, Ingrowing nail with infection, Insect bite, Insect Bites, Insect bites - non venomous, Intraspinal abscess, Ischaemic leg ulcer, Ischiorectal abscess, Local infection skin/subcut tissue, Major aphthous ulceration, Meticillin resistant staphylococcus aureus, Mouth ulcer, Mumps, Nail infection, Nasal infection, Nasopalatine cyst, Non-healing leg ulcer, ankle ulcer, infected toe, Right foot ulcer, ulcer on tongue, Wound infected, Onychomycosis, Oral aphthae, Oral candidiasis, Oral cavity, salivary gland and jaw diseases, Oral thrush, Pancreatic cyst, Paronychia of finger, Paronychia of toe, Penile candidiasis (thrush), Perianal abscess, Perianal candidiasis, Peritonitis, Peritonsillar abscess – quinsy, Pilonidal sinus/cyst, Pilonidal

sinus/cyst, Pneumococcal meningitis, Pneumonia or influenza, Post-traumatic wound infection, Postoperative infection, Postoperative stitch abscess, Postoperative wound abscess, Postoperative wound infection, unspecified, Psoas abscess, Sebaceous cyst, Sebaceous cyst – wen, Skin abscess, Skin and subcutaneous tissue infections, Splenic cyst, Syringomyelia, Syringomyelia/syringobulb, Throat infection – pharyngitis, Throat infection – tonsillitis, Tinea, Tinea corporis, Tinea cruris, Tinea pedis, Traumatic leg ulcer, Ulcer of skin, Viral infection, Whitlow, cold sore

- **Ingrowing toe nail**

Ingrowing great toe nail

- **Lump on body**

Axillary lump, Local superficial swelling, mass or lump, Local superficial swelling, mass or lump, Lump on hand, Lump on leg, Lump on shin, Lump stomach, Lump, localized and superficial, Swelling, mass or lump in neck, Breast lump present, Breast lump symptom, Dercum's disease, Dermoid cyst, External thrombosed haemorrhoids, Feeling of lump in throat, Haemorrhoids, Hernia – incisional, Hernia of abdominal cavity, Incisional hernia, Indirect inguinal hernia, Inguinal hernia, Internal haemorrhoids, simple, Left inguinal hernia, Lump in breast, Lump on neck, a lump, Piles – haemorrhoids, Rupture of Baker's cyst – knee, Sarcoidosis

- **Lupus**

Lupus erythematosus, Lupus nephritis, Systemic lupus erythematosis (GMS), Systemic lupus erythematosus

- **Lymphadenopathy**

Lymph node enlargement, Lymphadenopathy, Other nonspecific lymphadenitis, Acute lymphadenitis, Congenital lymphoedema, Follicular lymphoma, Follicular non-Hodgkin's lymphoma, Kikuchi disease, Milroy's disease, Non - Hodgkin's lymphoma, lymphadenopathy, cervical lymphadenopathy, Other lymphoedema

- **Malaise**

Malaise, Malaise and fatigue, Feels unwell, Malaise/lethargy, Sickness notification-of GP

- **Male genitourinary tract**

BPH - Benign prostatic hypertrophy, Chronic prostatitis, Epididymal cyst, Epididymitis, Erectile dysfunction, Haematospermia, Hydrocele, Impotence, Oligoasthenozoospermia, Orchitis, Penile disorders, Peyronie's disease, Phimosis, Premature ejaculation, Seen by urologist, Seminoma of testis

- **Medication requested**

Analgesics requested, Hospital prescription, Lost prescription, Medication requested, Patient requested treatment

- **Medication review**

Anticoagulant monitoring, Buprenorphine maintenance therapy, Initial post discharge review, Medicals/reports, Medication change to generic, Medication changed, Medication dispensed in error, Medication error, Medication recommenced, Medication started, New medication added, New medication commenced, On

repeat dispensing system, Ongoing review, Other medication management, Patient reviewed, Pct Anti-Coag Monitoring, Pill check, Polypharmacy, Polypharmacy medication review, Prescription collected by patient, Prescription given no examination of patient, Prescription issued for patient on holiday, Previously Active Medications imported via GP2GP, Warfarin monitoring, epilepsy medication review, hypertension med review, med review no surgery, med review with out patient, med review with patient, med review medical notes, med review done, med review by pharmacist, med review by Dr, med review done, med review.

- **Memory**

Unspecified dementia, Alzheimer's dementia unspec, Dementia in Alzheimer's disease, Alzheimer's disease, Carer of person with dementia, Memory assessment, Memory disturbance, Memory loss symptom, Mild memory disturbance

- **Mental health**

Irritability and anger, Work stress, Behavioural problems, Reactive depression, Agoraphobia, Anxiety, Anxiety reaction, Anxiety state, Attention deficit hyperactivity disorder, Bipolar affective disorder, Borderline schizophrenia, Chronic pain personality syndrome, Cyclothymia, Cyclothymic personality, Deliberate drug overdose / other poisoning, Delusional disorder, Depression NOS, Depressive disorder, Depressive episode, Depressive episode, unspecified, Dissocial personality disorder, Eating disorder, unspecified, Eating disorders, Emotionally unstable personality disorder, Endogenous depression without psychotic symptoms, Generalized anxiety disorder, Grief reaction, Induced psychotic disorder, Intentional self harm by other specified means, Mixed anxiety and depressive disorder, Moderate depressive episode, Neurotic depression, Obsessive - compulsive disorder, Panic disorder+agoraphobia, Paranoia, Post - traumatic stress disorder, Psychosis, Recurrent depressive disorder, Recurrent depressive disorder, currently in remission, Recurrent depressive disorder, unspecified, Schizoaffective disorder, unspecified, Severe depressive episode with psychotic symptoms, Severe depressive episode without psychotic symptoms, Trichotillomania, Acute reaction to stress, Acute stress reaction, Agitated, Agoraphobia with panic attacks, Agreeing on mental health care plan, Anger management counselling, Anger reaction, Anorexia nervosa, Antisocial or sociopathic personality disorder, Anxiety state, Anxiety state, Anxiety state unspecified, Anxiety states, Anxiety with depression, Anxiousness, Appetite loss – anorexia, Attempted suicide, Behaviour disorder, Bereavement, Bereavement reaction, Bipolar affective disorder, Borderline personality disorder, feeling depressed, Cause of overdose – deliberate, Chronic anxiety, Chronic depression, Confusion, Death of father, Death of mother, Death of spouse, Depressed, Depressed mood, Depression, Depression annual review, Depression interim review, Depression, Depression stable,mother, Depressive disorder, Depressive symptoms, Domestic stress, Emotional upset, Emotionally unstable personality, Endogenous depression, Family bereavement, Family problems, Fear of flying, Feeling stressed, Flashbacks, Forgetful, Generalised anxiety disorder, Grief reaction, deliberate self harm, depression, psychiatric disorder, Irritable, Life crisis, Low mood, Medication counselling, Mental health review, Mini mental state score, Mixed anxiety and depressive disorder, Mixed bipolar affective disorder, Moderate depression, Neurotic (reactive) depression, Neurotic depression reactive type, anxious, Other personality disorders, Other post-traumatic stress disorder, Panic attack, Paranoid psychosis, Paranoid schizophrenia, Personality disorder,

Personality disorders, Postnatal depression, Reactive depression (GMS), Recurrent anxiety, Recurrent depression, Restless, Schizo-affective schizophrenia, SCHIZOPHRENIA, Schizophrenia, Schizophrenic disorders, Schizophrenic psychoses, Seasonal affective disorder, Single major depressive episode, moderate, Stress at home, Stress at work, Stress counselling, Stress related problem, Suicidal ideation, Symptoms of depression, Tearful, Visual disturbances, Worried

- **Multiple symptoms**

Multiple symptoms

- **Musculoskeletal pain**

Musculoskeletal chest pain, Musculoskeletal pain, Musculoskeletal symptoms, Soft tissue injuries, Acromioclavicular joint, Anterior cruciate ligament, Arm, Gastrocnemius, Gluteus, Gluteus medius, Greater trochanter, Hip joint, Ischial tuberosity, Knee joint, Lip, Nose, Patellofemoral joint, Posterior horn of medial meniscus, Prepatellar bursa, Pubic symphysis, Rib cage, Rotator cuff, Sacroiliac joint, Scapular region, Shoulder joint, Soft tissue, Sole of foot, Third metatarsal, Trapezius, Trochanter of femur, unspecified, Ulnar collateral ligament, Foot problem, Problem knee, Toe problem, Dependence on wheelchair, Unspecified limb or other problem, Arthrosis, Dystonia, unspecified, Inflammatory myopathy, not elsewhere classified, Injuries involving multiple body regions, Injuries to the ankle and foot, Injuries to the knee and lower leg, Mixed connective tissue disease, Other bursitis of knee, Other disorders of patella, Other osteonecrosis, Unspecified injury of shoulder and upper arm, Unspecified multiple injuries, ankle, Clavicle, Femur, Abnormal gait, Ache in joint, Achilles bursitis, Achilles tendinitis, Acquired ankle or foot deformity, Acquired deformity, Acromio-Clavicular Dislocation, Acute exacerbation of gout, Acute meniscal tear, lateral, Acute meniscal tear, lateral, bucket handle tear, Acute meniscal tear, medial, Acute meniscal tear, medial, posterior horn, Adhesive capsulitis of the shoulder, Amputation, Amputation above knee, Amputation below knee, Amputation great toe, Amputation hallux, Amputation of leg, Amputation of leg, Amputation of toe, Amputation through knee, Ankle and foot sprain, Ankle joint pain, Ankle pain, Ankle pathological dislocation, Ankle sprain, Ankle stiff, Ankle swelling, ,Ankle/foot joint pain, Ankle/foot joint pain long, Ankylosing spondylitis, Ankylosing spondylitis the, Aquired cavus foot deformity, Arm bruise, Arm pain, Arthralgia, Arthralgia - ankle/foot, Arthralgia - lower leg, Arthralgia – shoulder, Arthralgia - site unspecified, Arthralgia NOS, Arthralgia of 1st MTP joint, Arthralgia of acromioclavicular joint, Arthralgia of hip, Arthralgia of IP joint of toe, Arthralgia of knee, Arthralgia of multiple joints, Arthralgia of sacro-iliac joint, Arthralgia of shoulder, Arthralgia of sternoclavicular joint, Arthralgia of the ankle and foot, Arthralgia of the hand, Arthralgia of the lower leg, Arthralgia of the pelvic region and thigh, Arthralgia of the shoulder region, Arthralgia of unspecified site, Arthralgia of wrist, Avascular bone necrosis, Avascular necrosis of bone, Avascular necrosis of other bone, Avascular necrosis of the head of femur, Avascular necrosis of the head of humerus, Avascular necrosis-bone, Axial spondyloarthritis, Axillary nerve injury, Axillary pain, Bilateral dysplastic hip, Brachial (cervical) neuritis, Brachial neuritis - bilaterastretch testing and (GMS), Brachial neuritis - rom neck nad shoulder nad (GMS), Breast soreness, Breast tenderness, Bunion, Bursitis NOS, Bursitis of hip, Bursitis of the knee, stiffness, Calcaneal spur, Calcific tendinitis, Calcifying tendinitis of the shoulder, Calf injury, Carpal tunnel syndrome, Cervical cord injury without evidence of spinal bone injury,

Cervical disc, Cervical disc degeneration, Cervical disc disorder with radiculopathy, Cervical disc displacement, Cervical disc displacement without myelopathy, Cervical disc prolapse with myelopathy, Cervical disc prolapse with radiculopathy, Cervical radiculitis, Cervical rib syndrome, Chondrocalcinosis, Claw hand – acquired, Cleidocranial dysostosis, Closed flail chest, Clubfoot, Complete division extensor tendon hand, Complete tear, knee, anterior cruciate ligament, Congenital hammer toe, Congenital talipes equinovarus, Contusion chest wall, Contusion knee, Costochondral joint syndrome, Costochondritis, Costochondritis, CTS - Carpal tunnel syndrome, Cubital tunnel syndrome, de Quervain's disease, De Quervain's disease, Developmental dysplasia of the hip, DHS - Dynamic hip screw primary fixation of neck of femur, Diffuse idiopathic skeletal hyperostosis, Disability, Disabled, Disc prolapse with radiculopathy, Dupuytren's contracture, Dupuytren's disease of palm, Dynamic hip screw primary fixation of neck of femur, Dysplastic hip, Dystonia, unspecified, Effusion of knee, Ehlers-Danlos syndrome, Ehlers-Danlos syndrome type III, Emery-Dreifuss muscular dystrophy, Endocr./nutrit/metabol.disease, Extensor tenosynovitis of wrist, Facioscapulohumeral muscular dystrophy, Feet deformities, Female pelvic inflammatory diseases, Femoroacetabular impingement, Finger trigger, Forestier's disease, Gluteal tendinitis, gout, knee problem kissing, Hallux rigidus – acquired, Hallux valgus – acquired, Hallux valgus osteotomy, Hamstring sprain, Hand rheumatism, Heberdens' nodes, Hemiplegia, Hereditary spastic paraplegia, Hip # - closed reduct. (GMS), Hip DXA scan result osteopenic, Hip girdle aches, Hip prosthesis loose, Hypophosphataemia, Iliotibial band syndrome, Klippel-Feil syndrome, Knee gives way, Knee joint effusion, Kyphoscoliosis-acquired, Kyphoscoliosis/scoliosis, Lateral epicondylitis, Lateral epicondylitis – elbow, Lateral epicondylitis of the elbow, Left sided weakness, Medial epicondylitis of the elbow, Medial meniscus derangement, Meniscus derangement, Meniscus derangement NOS (GMS), Metatarsalgia, Mobility, Mobility poor, Moderate frailty, Multiple epiphyseal dysplasia, Multiple joint pain, Multiple joint pain,but right, Multiple joint pain, multiple joint pains, Multiple stiff joints, Muscular dystrophy, Musculoskelet/connectiv tissue (GMS), Musculoskelet/connectiv tissue. (GMS), Musculoskeletal and connective tissue diseases, Musculoskeletal and connective tissue diseases, Musculoskeletal pain – joints, Musculoskeletal pain (GMS), Musculoskeletal pain, Myalgia or myositis, Myalgia unspecified, Myalgia/myositis, Myalgic encephalomyelitis, Myalgic, Encephalomyelitis, Myopathy or muscular dystrophy, Myositis unspecified, Myotonia congenita (Thomsen's disease), Neck disorder NOS (GMS), Neck pain, Neck pain, Neck sprain, Neck sprain, Neck sprain, unspecified, joint movement painful, joint swelling, limping gait, muscle tone spastic, shoulder joint abn, Old anterior cruciate ligament disruption, Old tear of posterior horn of medial meniscus, Olecranon bursitis, Ollier's disease, Osteitis deformans - Paget's, Osteochondritis dissecans, Osteochondritis, Osteochondritis of knee, Osteomyelitis NOS upper tibia, Osteopenia (GMS), Osteopenia L-spine on Dexa (GMS), Osteoradionecrosis of jaw, Other acute meniscus tear, Other and unspecified kyphosis, Other ankle injury, Other chest wall injuries, Other elbow injuries, Other finger injuries, Other finger injuries, unspecified, Other foot injury, Other hip injuries, Other joint symptoms, Other knee injury, Other knee, leg, ankle and foot injuries, Other leg injury, Other limb-girdle muscular dystrophy, Other lip injuries, Other neck injuries, Other nose injuries, Other peripheral enthesopathies, Other shoulder injuries, Other symptoms – shoulder, Other tenosynovitis of hand or wrist, Other tenosynovitis of the hand, Other tenosynovitis of the wrist, Other thigh injuries, Other valgus foot deformities, Other wrist injuries, Paget's disease, Paget's disease of bone, PAIN FOOT, PAIN HIP, Pain Im Multiple Joints, Pain in arm, Pain

in buttock, Pain in cervical spine, Pain in coccyx, Pain in elbow, Pain in eye, Pain in joint, Pain in joint – arthralgia, Pain in left leg, Pain in leg, Pain in limb, Pain in limb multiple (GMS), Pain in lower limb, Pain in lumbar spine, Pain in penis, Pain In Right Arm, Pain In Right Leg, Pain in thoracic spine, Pain in upper limb, Pain in wrist, Painful arc syndr – shoulder, Painful arc syndrome, Painful Elbow, Painful Right Knee, Partial tear, knee, anterior cruciate ligament, Patellar tendinitis, Patellofemoral disorder, Patellofemoral maltracking, Perforated diverticulum unspecified, Pes planus – acquired, Phobic disorder, Piriformis syndrome, Polycythaemia vera, Polymyalgia, Polymyalgia rheumatica, Polymyositis, PREPATELLAR BURSA, Prepatellar bursitis, Psoas tendinitis, Pubic symphysis separation, Radial styloid tenosynovitis, Reflex sympathetic dystrophy, Revision repair of rotator cuff, Rib pain, Rib sprain, Rib sprain, Rib sprain unspecified, Right hemiparesis, Rotator cuff shoulder syndrome and allied disorders, Rotator cuff sprain, Rotator cuff syndrome, Rotator cuff syndrome unspecify, Rotator cuff syndrome, unspecified, Rupture Achilles tendon, Rupture quadriceps tendon, Rupture supraspinatus tendon, Sacroiliac disorder, Sacroiliac ligament sprain, Sacroiliac sprain, Sacroiliac sprain rt with, Sacroiliac strain, Sacroiliitis, Seen in musculoskeletal clinic, Severe frailty, Shoulder syndrome, Shoulder tendonitis, Spasm of muscle, Specific disability rehab, Staghorn calculus, Subacromial impingement, Superficial injury chest wall NOS, without major open wound, Superficial injury of foot, Supraspinatus syndrome, Supraspinatus tendinitis, Supraspinatus tendonitis, Symphysis pubis separation, Synovitis and tenosynovitis, Synovitis of knee, Synovitis or tenosynovitis, Synovitis/tenosyn.- wrist, Temporomandibular joint disord, Temporomandibular joint disorder, Temporomandibular joint disorders, Temporomandibular joint-pain-dysfunction syndrome, Tendinitis, Tendon injury – hand, Tendon injury to hand, Tendon rupture, Tendonitis, Tenodesis, Tibialis posterior tendinitis, Torticollis, Trigger finger – acquired, Trigger thumb, Trochanteric bursitis, Trochanteric tendinitis, Unilateral dysplastic hip, Unilateral leg oedema, Wrist joint pain, Wrist pain, Wrist sprain, Wry neck, Wry neck symptom, Wry neck/torticollis, Cervical spond.- no, Cervical spond.- no myelopathy. **Cervical Spondylosis**: Cervical spond.with, Cervical spond.with myelopathy, Cervical spondylosis, CERVICAL SPONDYLOSIS, Cervical spondylosis (GMS), Cervical spondylosis with myelopathy, Cervical spondylosis with radiculopathy, Cervical spondylosis with vascular compression, Cervical spondylosis without myelopathy, Multiple-level cervical spondylosis without myelopathy, O.A.Cervical. **Mechanical Pain** - Gait abnormality, Jaw pain, Titubation, Genitofemoral nerve, Reduced mobility, Anterior chest wall pain, Anterior dislocation of shoulder, Anterior knee pain, Anterior shin splints, Atypical chest pain, Bone pain, a neck symptom, pain in big toe, renal pain, pelvic pain, Calf pain, Central chest pain, Cervical myelopathy, Cervicalgia, Cervicalgia - pain in neck, Chest pain, Chest pain, Chest wall pain, Chondromalacia patellae, Closed dislocation cervical spine, Closed traumatic dislocation of shoulder, Coccyx sprain, Congenital hip dysplasia, Difficulty in walking, Dislocation of elbow, Dislocation of finger or thumb not otherwise specified, Dislocation of hip, Dislocation of knee, Dislocation of shoulder, Dislocation of thumb, Dislocation or subluxation of knee, Dislocation or subluxation of shoulder, Elbow pain, Finger injury, Finger pain, Flank pain, Flat foot, Flexion deformity of finger, Foot drop, Foot pain, Foot sprain, Frozen shoulder, Full thickness rotator cuff tear, Golfer's elbow, dislocated shoulder, knee problem, significant knee disorder, Hand joint pain, Hand joint stiff, Hand operation, Hand pain, Heel pain, Hip joint pain, Hip joint pain (Left), Hip pain, Housemaids' knee, Hypermobility syndrome, Impingement syndrome of shoulder, Joint disorder of shoulder region, Joint disorders, Knee – dislocated, Knee joint pain, Knee joint pain Both, Knee joint pain both knees, Knee

joint pain both, full, Knee joint pain, lt side ? OA, Knee pain, Knee sprain, Knee sprain, Left flank pain, Left iliac fossa pain, Leg pain, Locking knee, Loose body in elbow joint, Loose body in knee, MSG:Ankle pain, Proctalgia fugax, Rectal pain, Rectal prolapse, Recurrent joint dislocation, of the shoulder region, Release of contracture of shoulder joint, Restless legs syndrome, Right flank pain, Shoulder joint pain, Shoulder pain, Shoulder pain (GMS), Shoulder sprain, Shoulder sprain (GMS), Shoulder sprain, Shoulder strain, Sore bottom, Sore gums, Sore lip, Sore mouth, Sore mouth – symptom, Sore Neck, Sore throat, Sore throat symptom, Sprain of knee and leg, Sprain of medial collateral ligament of knee, Sprain of shoulder and upper arm, Sprain of wrist and hand, Sprain shoulder/upper arm, Sprain, ankle joint, lateral, Sprain, quadriceps tendon, Sprain, tendocalcaneus (Achilles tendon), Sprains and strains, Sprains and strains of joints and adjacent muscles, Stiff neck, Stiff neck symptom, Symptom: ankle/foot, Symptom: chest wall, Tennis elbow, Tennis elbow – epicondylitis, Testicular hypogonadism, Testicular lump, Testicular pain, Testicular swelling, Thigh pain, Throat pain, Throat soreness, Thumb pain, Toe pain, Unstable ankle, Weakness of arm, Weakness of leg, Weakness symptoms. **Fibromyalgia**: Fibromyalgia, Query Fibromyalgia. **Bone fracture**: Osteochondral, Rehabilitation following fracture, Fract of other and unspec parts of lumbar spine & pelvis, Fracture of other parts of shoulder and upper arm, Fracture of shoulder and upper arm, unspecified, Fractures of other skull and facial bones, Arm fracture, Closed Colles' fracture, Closed fracture ankle, bimalleolar, Closed fracture ankle, lateral malleolus, Closed fracture ankle, trimalleolar, Closed fracture ankle, trimalleolar, low fibular fracture, Closed fracture ankle, unspecified, Closed fracture cervical vertebra, burst, Closed fracture cervical vertebra, transverse process, Closed fracture distal phalanx, toe, Closed fracture distal radius, extra-articular, other type, Closed fracture distal tibia, Closed fracture distal tibia, extra-articular, Closed fracture finger proximal phalanx, base, Closed fracture lumbar vertebra, Closed fracture lumbar vertebra, wedge, Closed fracture metatarsal, Closed fracture metatarsal base, Closed fracture metatarsal shaft, Closed fracture multiple ribs, Closed fracture navicular, Closed fracture of calcaneus, Closed fracture of cervical spine, Closed fracture of cervical spine - no spinal cord lesion, Closed fracture of clavicle, Closed fracture of distal fibula, Closed fracture of elbow, unspecified part, Closed fracture of femur, intertrochanteric, Closed fracture of foot, Closed fracture of great toe, Closed fracture of lumbar spine - no spinal cord lesion, Closed fracture of neck of femur NOS, Closed fracture of pelvis NOS, Closed fracture of proximal humerus, anatomical neck, Closed fracture of proximal humerus, unspecified part, Closed fracture of radius and ulna, lower end, Closed fracture of seventh cervical vertebra, Closed fracture of spine, unspecified, Closed fracture of the distal humerus, Closed fracture of the distal radius unspecified, Closed fracture of the patella, Closed fracture of the proximal humerus, Closed fracture of the proximal tibia, Closed fracture of tibia and fibula, proximal, Closed fracture olecranon, extra-articular, Closed fracture olecranon, intra-articular, Closed fracture pelvis, multiple pubic rami – stable, Closed fracture pelvis, single pubic ramus, Closed fracture proximal humerus, greater tuberosity, Closed fracture proximal phalanx, toe, Closed fracture radius and ulna, distal, Closed fracture radius, head, Closed fracture radius, neck, Closed fracture rib, Closed fracture shaft of tibia, Closed fracture thoracic vertebra, Closed fracture thoracic vertebra, spondylolysis, Closed fracture thoracic vertebra, wedge, Closed fracture triquetral, Closed fracture-dislocation of pelvis, Closed fracture-dislocation shoulder, Closed fracture-dislocation, ankle joint, Closed fracture-dislocation, hip joint, Closed fracture-dislocation, knee joint, Closed fracture-dislocation, tarsometatarsal joint, Closed reduction of dislocation of patella, Closed reduction of

fracture of shoulder, Congenital dislocation and subluxation of the hip, Congenital dislocation of hip, Elbow fracture – closed, Finger fracture, Fracture NOS, Fracture of acetabulum, Fracture of ankle, Fracture of ankle, NOS, Fracture of bones NOS, Fracture of calcaneus, Fracture of clavicle, Fracture of coccyx, Fracture of femur, NOS, Fracture of fibula alone, Fracture of great toe, Fracture of humerus, Fracture of humerus NOS, Fracture of lateral malleolus, Fracture of lower end of humerus, Fracture of lower end of radius, Fracture of lower leg, part unspecified, Fracture of lower limb, Fracture of lumbar vertebra, Fracture of mandible, closed, Fracture of metacarpal bone, Fracture of metatarsal bone, Fracture of nasal bones, Fracture of neck of femur, Fracture of one or more phalanges of foot, Fracture of patella, Fracture of radius AND ulna, Fracture of radius NOS, Fracture of rib, Fracture of sacrum, Fracture of scaphoid, Fracture of shaft of tibia, Fracture of spine without mention of spinal cord injury, Fracture of spine without mention of spinal cord lesion NOS, Fracture of sternum, Fracture of thoracic vertebra, Fracture of thumb, Fracture of tibia, Fracture of tibia and fibula, Fracture of tibia AND fibula, Fracture of tibia and fibula, NOS, Fracture of tibial plateau, Fracture of transverse process spine - no spinal cord lesion, Fracture of unspecified bones, Fracture of upper limb, Fracture or disruption of pelvis, Fracture tibial plateau, Fracture-dislocation or subluxation shoulder, Fractures, Fragility fracture, Fragility fracture due to unspecified osteoporosis, fragility fracture, vertebral fracture, Heel bone fracture, Hip fracture, Hip fracture NOS, Leg fracture, Malunion of fracture, Metatarsal bone fracture, Multiple fractures of foot, Multiple fractures of ribs, Multiple fractures of thoracic spine, Nonunion of fracture, Open fracture ankle, trimalleolar, Open fracture-dislocation, ankle joint, Os calcis fracture, Osteoporotic vertebral collapse, Other fracture of femur, Periprosthetic fracture, Primary open reduction fracture bone & intramedull fixation, Rib fracture NOS, Stress fracture, Temporal bone fracture, Toe fracture, Vertebroplasty of fracture of spine, Wrist fracture – closed. **Loin Pain**: Loin pain, loin pain, Left Loin Pain. **Pelvic Pain**: Pelvic pain, Pelvic and perineal pain, Pelvic mass, Acetabulum, Acetabular labrum tear, Bony pelvic pain, Other pelvic pain – female, PID, PID - pelvic inflammat disease, PID - pelvic inflammatory disease

- **Neuropathy**

Other chorea, Autonomic neuropathy due to diabetes, Brachial radiculitis, Meralgia paraesthetica, Mitochondrial myopathy not elsewhere classified, Morton neuroma, Morton's metatarsalgia, Myasthenia gravis, Nerve root and plexus compressions in other dorsopathies, Nerve root and plexus disorders, Nerve root or plexus disorder, Neuralgia unspecified, Neuralgia/neuritis - lower leg, Neurofibromatosis - Von Recklinghausen's disease, Neurofibromatosis type 1, Neurological symptom changes, Neuroma of amputation stump, Neuropathic pain, Numbness of hand, clonus, paraesthesia in hands, Other idiopathic peripheral neuropathy, Peripheral neuropathy, Phantom limb syndrome with pain, Polyneuropathy, Post-encephalitic syndrome, Post-herpetic neuralgia, Postherpetic neuralgia, Postzoster neuralgia, Quadriplegia, Radiculopathy, Relapsing and remitting multiple sclerosis, Right Neuropathic Pain, Secondary progressive multiple sclerosis, Sjogren - Larsson syndrome, Spasmodic torticollis, Spastic hemiplegia, Spastic paraplegia, Tetraplegia, Thoracic outlet syndrome, Transverse myelitis, Tremor symptom, Trigeminal nerve disorders, Trigeminal neuralgia, Ulnar nerve entrapment, Ulnar neuritis, Ulnar neuropathy

- **Not medically related**

Insurance medical, Other reasons for encounter, Global developmental delay, Other and unspecified problems related to employment, Acquired hypothyroidism, Acupuncture, Address instruction, Administration, Awaiting clinical code migration to EMIS Web, Benefits Assessed, Complaints about care, Computer summary updated, Discharge from intermediate care, Discharged from hospital, Do not attempt CPR (DNACPR) form in place, Driving licence application signed, DS1500 Disability living allowance report declined, Eligible for integrated care pathway, eMED3 (2010) new statement issued not fit for work, Failed encounter, Failed encounter - message left on answer machine, Foreign travel advice, FP10(MDA) issued, Funny turn, General builder, General chemist, Going to travel abroad, Has anticipatory care plan, History relating to military service, Homeless, Housebound, Jehovah's witness, Jury exempt form asked for, Letter encounter, MED3 issued - back to work, MED3 issued to patient, MED5 issued to patient, No follow-up, Patient self discharge, Patient's next of kin, Photosensitiveness, Poor compliance, Social problem, Social worker, Theft, Third party encounter, Vulnerable adult, Vulnerable family

- **Numbness**

Numbness

- **Osteoporosis**

Osteopenia, Acute osteomyelitis, Chronic osteomyelitis, Idiopathic osteoporosis, Idiopathic osteoporosis with pathological fracture, Osteophyte, Osteoporosis, Osteoporosis + pathological fracture lumbar vertebrae, Osteoporosis + pathological fracture thoracic vertebrae, Osteoporosis prevent, Unspecified osteomyelitis, Vertebral osteoporosis

- **Pins and needles**

Paraesthesia, paraesthesia, Has pins and needles, Has tingling sensation

- **Prosthetic replacement**

Total hip replacement, Total knee replacement, Charnley total hip replacement, Hybrid prosthetic replacement of hip joint using cement, Primary total knee replacement, Primary total prosthetic replacement of hip joint, Primary uncemented total hip replacement, Revision cemented total hip replacement, Revision of total knee replacement, Revision of total prosthetic replacement of hip joint, Revision total prosthetic replacement of shoulder joint, Thompson hemiarthroplasty of hip joint using cement, THR - Other total prosthetic replacement of hip joint, THR - Total prosthetic replacement hip joint without cement, THR - Total prosthetic replacement of hip joint using cement, TKR - Other total prosthetic replacement of knee joint, TKR - Total prosthetic replacement knee joint without cement, TKR -Total prosthetic replacement of knee joint using cement, Total hip replacement, Total knee replacement, Total prosthetic replacement of elbow joint, Total prosthetic replacement of hip joint, Total prosthetic replacement of hip joint not using cement, Total prosthetic replacement of hip joint using cement, Total prosthetic replacement of hip joint using cement, Total prosthetic replacement of knee joint using cement, Total prosthetic replacement of knee joint using cement, Total prosthetic replacement of shoulder joint, Unicompartmental knee replacement

- **Referral**

Neurosurgical referral, Orthopaedic referral, Patient awaiting procedure, Refer for X-ray, Refer to counsellor, Refer to geneticist, Refer to occupational therap, Refer to pain clinic, Referral for dual energy X-ray photon absorptiometry scan, Referral for echocardiography, Referral for further care, Referral to hearing aid clinic, Referral to respiratory physician, Referral to speech and language therapy service, Seen in bariatric surgery clinic, Seen in cardiology clinic, Seen in GP's surgery, Seen in hospital out-pat, Seen in neurology clinic, Seen in pain clinic, Seen in rheumatology clinic

- **Repeat prescription**

Issue of repeat prescription, Issue of repeat prescription for medication, Medication repeat prescript, Repeat prescription issue, Drug prescription, Medication given, Repeat medication check, Repeat prescription, Repeat prescription monitoring, Repeated prescription, Urgent request for repeat prescription

- **Respiratory problems**

Breathlessness, Pleuritic pain, Pulmonary nodule, Respiratory system and chest symptoms, Shortness of breath, Stridor, Acute bronchitis, Acute dry pleurisy, Acute exacerbation of asthma, Acute exacerbation of chronic obstructive airways disease, Acute infective exacerbation of chronic obstructive airways disease, Acute lower respiratory tract infection, Acute respiratory infections, Acute tracheobronchitis, Acute upper respiratory tract infection, Alpha-1-antitrypsin deficiency, Asthma, Asthma attack, Asthma, Atelectasis, Bacterial pneumonia, Bird-fancier's lung, Blood in sputum – haemoptysis, Breathless - mild exertion, Breathless - moderate exertion, Breathlessness, Bronchial asthma, Bronchiectasis, Bronchiectasis, Bronchitis unspecified, Bullous emphysema with collapse, Chronic asthma with fixed airflow obstruction, Chronic bronchitis, Chronic obst. pulm. Dis, Chronic obstr. airways disease, Chronic obstructive lung disease, Chronic obstructive pulm, Chronic obstructive pulmonary disease, Chronic obstructive pulmonary disease annual review, Chronic obstructive pulmonary disease monitoring, COAD - chr.obstr.airway dis, Compression of oesophagus, COPD self-management plan given, Difficulty breathing, Diffuse pulmonary fibrosis, Emphysema, Emphysema, Empyema, End stage chronic obstructive airways disease, Exacerbation of cystic fibrosis, Extrinsic asthma – atopy, asthma, pneumonia, pulmonary embolus, Hospital acquired pneumonia, Idiopathic pulmonary fibrosis, Interstitial lung disease, Issue of chronic obstructive pulmonary disease rescue pack, Lobar pneumonia due to unspecified organism, Lower limb spasticity, Lower resp tract infection, LTOT - Long-term oxygen therapy, Lung disease, Mild chronic obstructive pulmonary disease, Moderate chronic obstructive pulmonary disease, expiratory wheeze, Occupational asthma, Pleural effusion, Pleural plaque disease due to asbestosis, Pleurisy, Pneumonia due to unspecified organism, Pneumothorax, Pulmonary embolism, Pulmonary sarcoidosis, Recurrent bronchiectasis, Recurrent upper respiratory tract infection, Respiratory disease monitoring, Respiratory symptoms, Respiratory tract infection, Severe chronic obstructive pulmonary disease, Shortness of breath, Shortness of breath symptom, SOBOE, Suspected chronic obstructive pulmonary disease, Traumatic pneumothorax, Tuberculosis, Upper resp tract infection (GMS), Upper resp. tract infect. NOS, Upper respiratory infect.NOS, Upper respiratory infection, Upper respiratory tract infec. (GMS), Upper respiratory tract infection, Very severe chronic obstructive pulmonary disease, Viral induced wheeze, Viral upper respiratory tract infection, Wheezing, Wheezy bronchitis

- **Seizure**

Seizure, 2 to 4 seizures a month, Complex partial epileptic seizure, Had a fit, Hallucinations, Non-epileptic attack disorder, Partial epilepsy with impairment of consciousness

- **Shingles**

Shingles, Shingles, Shingles vaccination

- **Sinustis**

Acute frontal sinusitis, Acute maxillary sinusitis, Acute sinusitis, Acute sinusitis, Chronic sinusitis, Chronic sinusitis, Pain in sinuses, Sinus congestion, Sinusitis, Sinusitis - acute

- **Skin complaints**

Burning of skin, Flushing, Formication, Hyperhidrosis, Jaundice, Rash and other nonspecific skin eruption, Rash and other nonspecific skin eruption, Spots, Tingling of skin, Capillary haemangioma, Dermal naevus, Allergic skin reaction, Leg Ulcer, Leg ulcer – venous, Pressure sore, Skin of umbilicus, Bullous disorders, acne rosacea, Acne vulgaris, Acne unspecified, Actinic keratosis, Alopecia areata, Angular cheilitis, Angular stomatitis and cheilitis, Arterial leg ulcer, Asteatosis cutis, Athlete's foot, Atopic dermatitis/eczema, Balanitis, Basal cell carcinoma, Birth mark unspecified, Blepharitis, Blister of anus, Blister of foot, Blister of hand without mention of infection, Blister of lower leg, Boil, Bruise trunk, Bruises easily, Bruising symptom, Bullous pemphigoid, Burns, a rash, dry skin, hair loss, itching, Callosity on foot, Callosity under metatarsal head, Callus, Cellulitis and abscess, Cellulitis and abscess of foot, Cellulitis and abscess of leg excluding foot, Cellulitis and abscess of leg, Cellulitis and abscess of lower leg, Cellulitis and abscess of shoulder, Cellulitis and abscess of thigh, Cellulitis and abscess of toe, Cellulitis, Cellulitis of arm, Cellulitis of foot, Cellulitis of leg, Cellulitis of skin area excluding digits of hand or foot, Cellulitis, external ear, Cellulitis/abscess-forearm, Climacteric keratoderma, Cold sore (herpetic), Contact dermatitis, Contact dermatitis and other eczemas, Contact dermatitis, Corns, Corns and callosities, Cutaneous horn, Cystic acne, Darier's disease - keratosis follicularis, Dermatitis, Dermatitis/dermatoses, Dermatophytosis including tinea or ringworm, Dermatophytosis of foot, Discoid eczema, Discoid lupus erythematosus, Disseminated lupus erythematosus, Eczema, Eczemas, Erythema nodosum, Excessive sweating, Filiform wart, Fistula-in-ano, Folliculitis, Foot ulcer, Guttate psoriasis, Gynaecomastia, Haematoma of leg, Haematoma with intact skin, Hair loss, Halitosis, Hand eczema, Hand warts, Hard corn, Hidradenitis, Hidradenitis suppurativa, Hydradenitis suppurativa, Hypertrophic scar, Intertrigo, Inversion of nipple, Irritant contact dermatitis, Itch, Jaundice – symptom, Keloid scar, Laceration, Laceration – leg, Laceration, Laceration of arm, Leg bruise, Leg ulcer, Leg ulcer, Lichen planus, Lichen sclerosus et atrophicus, Melanoma in situ of back, Minor aphthous ulceration, Mole of skin, Nail clippings, Nail deformity, Nail disease, Necrotising fasciitis, Nummular dermatitis, allergic rash, bruising, cracked skin of feet, dry skin, itchy rash, rash present, skin cyst, skin lesion, skin tags, Onychogryphosis, Onycholysis, Other acne, Other specified skin disorder, Panniculitis, Papilloma of skin, Perianal irritation, Plantar fascial fibromatosis, Plantar fasciitis, Pompholyx unspecified, Porphyria cutanea tarda, Prickly heat – miliaria, Prurigo nodularis (Hyde's disease), Pruritus and related conditions, Pruritus ani, Pruritus, Pruritus vulvae, Psoriasis, Psoriasis (GMS), Psoriasis, Psoriasis-scalp-long history (GMS), Pustular psoriasis, Pyoderma gangrenosum, Recurrent boils, Rosacea, Rosacea, Scabies, Scalds, Scalp itchy, Scalp psoriasis, Scaly scalp,

Sclerodactyly, Scleroderma, Seborrhoea capitis, Seborrhoeic dermatitis, Seborrhoeic dermatitis capitis, Seborrhoeic eczema, Seborrhoeic keratosis, Seborrhoeic wart, Skin care, Skin flap and skin graft operations, Skin flap, Skin lesion, Skin symptoms, Skin tag, Skin tag, Solar keratosis, Spontaneous bruising, Sunburn, Superficial pressure sore, Sweat rash, Sweating symptom, Thinning of hair, Tight foreskin, Traumatic haematoma, Tylosis palmaris et plantaris, Urticaria, Varicose eczema, Verruca plantaris, Verrucae – warts, Viral warts, Warts - viral

- **Smoking**

Keeps trying to stop smoking, Moderate smoker - 10-19 cigs/d, Nicotine replacement therapy, Smoking cessation advice, Smoking cessation therapy, Trying to give up smoking

- **Spina Bifida**

Lumbar spinal meningocele, Spina bifida, Spina bifida occulta

- **Spinal stenosis**

Intervertebral disc stenosis of neural canal, Spinal stenosis, Spinal stenosis, Spinal stenosis of unspecified region

- **Supportive care**

Supportive care

- **Surgery/treatment**

Amputation, Post-cardiac surgery, Postoperative care, Spinal surgery, Carpometacarpal joint of thumb, Kidney donor, Liver transplanted, Removal of orthopaedic screws, Ventriculoperitoneal shunt catheter in situ, Other fusion of spine, Abdominoplasty and liposuction, Akin's osteotomy, Ankle joint operations, Anticoagulant prophylaxis, Aortic aneurysm repair, Appendicectomy, Arthroscopic partial lateral meniscectomy, Arthroscopic partial medial meniscectomy, Arthroscopic removal of loose body from knee joint, Arthroscopic subacromial decompression, Arthroscopic total medial meniscectomy, Arthroscopic trimming of lateral meniscus, Arthroscopy, Arthroscopy, Arthroscopy of knee, Aspiration of fluid from knee joint, Bilat. salpingo-oophorectomy, Bilateral mastectomy, Bilateral vasectomy for contraception, Blind sac closure of external auditory canal, Bone graft of mandible, Bone operations, Bunionectomy, Bypass aorta anastomosis axillary artery bi femoral arteries, Bypass bifurc aorta by anastom aorta to femoral artery, Bypass of superior mesenteric artery, Carpal tunnel decompression under local (GMS), Carpal tunnel release, Cerebral artery aneurysm operations, Check cystoscopy using flexible instrument, Cholecystectomy, Cls red+int fxn proximal femoral #+screw/nail device alone, Colectomy and ileostomy, Colonoscopy abnormal, Colonoscopy planned, Colostomy, Complex reconstruction of hindfoot, Coronary art bypass graft ops, Coronary artery bypass graft operations, Correction of ptosis of eyelid, Cranioplasty using acrylic material, Creation of defunctioning ileostomy, Creation of ileostomy, Cubital tunnel release, Diagnostic arthroscopy of knee, Diagnostic arthroscopy of shoulder joint, Diagnostic colonoscopy, Diagnostic hysteroscopy and endometrial biopsy, Diagnostic laparoscopy, Diagnostic laparoscopy of female pelvis, Duodenum operations, Elective caesarean delivery, Emergency appendicectomy, Emergency caesarean section, Endarterectomy of carotid artery, Endoscopic meniscectomy of knee, Endoscopic retrograde cholangiopancreatography, Enterotomy and removal of gallstone, Epidural anaesthetic, Examination

of rectum under anaesthetic, Excision biopsy of skin lesion, Excision of ganglion, Excision of ganglion of ankle, Excision of ganglion of knee, Excision of lesion of ovary, Excision of lipoma, Excision of sebaceous cyst, Excision of segment of left lower lobe, Exploratory laminectomy, Exploratory laparotomy, Exploratory thoracic laminectomy, Eye operations, Femoral hernia repair, FESS/Therapeutic endoscopy of nose and sinus, Foot joint operations, Forceps delivery, Fusion of first metatarsophalangeal joint, Fusion of first metatarsophalangeal joint of toe, Fusion of joint, Fusion of joint of cervical spine, Global parathyroidectomy, Spinal surgery, bariatric operative procedure, immunosupressive therapy, nephrectomy, splenectomy, Haemorrhoidectomy, Hallux excision arthroplasty, Hemicolectomy, Hill repair of hiatus hernia and gastropexy, Hip joint operations, Ileocaecal resection, Ileostomy formed, Implantation of cardiac pacemaker system, Implantation of dual chamber cardiac pacemaker system, Implantation of internal cardiac defibrillator, Injection of steroid into knee joint, Injection of steroid into shoulder joint, Injection of steroid into trochanteric bursa, Injection of therapeutic substance into joint, Insertion of vagal nerve stimulator, Internal fixation of bone, Intramuscular injection, Introduction of tension free vaginal tape, Jaw and temporomandibular joint operations, Knee joint operations, Knee: meniscectomy, Lambrinudi Operation Right, Laminectomy, Laminectomy approach to lumbar spine, Laminectomy approach to thoracic spine, Laminectomy. (GMS), Laparoscopic bilateral female sterilisation, Laparoscopic cholecystectomy, Laparoscopic gastric bypass, Laparoscopic Nissen fundoplication using abdominal approach, Laparotomy, Large loop excision transformation zone, Left hemicolectomy, Left hemiparesis, Left salpingoophorectomy, Lobectomy of lung, Localised fusion of joints of hindfoot, Localised fusion of joints of midfoot and forefoot, Lower uterine segment caesarean section (LSCS), Lumbar facet joint injection, Lumpectomy of breast, Mastectomy of left breast, Mastectomy of right breast, Minor surg done – cryotherapy, Minor surgery done, Minor surgery done – cautery, Minor surgery done – injection, Minor surgery done – other, Minor surgery done + claimable, Mitral valve repair, Mitral valve replacement (GMS), Monk hemiarthroplasty hip, Nasal polypectomy, Nasal polyps, Nasojejunal feeding, Nephrectomy, Nephrostomy, Nerve block NEC, Non obstetric encircling suture of cervical os, Nose operations, Nursing care – injections, Operation on intervertebral disc, Operations on hydrocele, Operations, procedures, sites, OS other primary decompression operations on lumbar spine, Osteotomy, Osteotomy of bone of foot, Osteotomy of first metatarsal, Osteotomy of foot, Other arthroplasty, Other bypass of femoral artery or popliteal artery, Other caesarean delivery, Other fixation of bone, Other graft of bone, Other laparoscopic female sterilisation, Other open pyeloplasty, Other operations on bowel, Other operations on haemorrhoid, Other primary fusion of joint, Other prosthetic hemiarthroplasty of hip, Other reconstruction of ligament, Other right hemicolectomy, Other specified cemented hemiarthroplasty of shoulder, Other specified operations on foot joint, Other specified operations on shoulder joint, Other specified primary lumbar discectomy, Other specified repair of recurrent incisional hernia, Other total prosthetic replacement of hip joint, Other total prosthetic replacement of joint, Other total prosthetic replacement of knee joint, Ovarian cystectomy, Panproctocolectomy, Parastomal hernia, Partial gastrectomy, Partial lobectomy of lung, Pelvic floor repair, Percut transluminal balloon angioplasty one coronary artery, Percutaneous transluminal angioplasty of femoral artery, Phacoemulsification lens insertion prosthetic replacement, Pilonidal sinus operations, Plastic repair of quadriceps tendon, Plastic repair of rotator cuff of shoulder, Plastic surgery, Pneumococcal vaccination given, Pneumonectomy operations, Post operative

monitoring, Post-operative pain, Posterior repair, Postoperative complication, Postoperative pain, Postoperative seroma, Postsurgical hypothyroidism, Prim anterior cervical spine corpectomy reconstruction HFQ, Prim post interspin lumb fuse, Primary anterior excis cervical IV disc & interbody fusion, Primary arthrodesis of joint NEC, Primary cemented hemiarthroplasty of hip, Primary cemented total knee replacement, Primary decompress thoracic spinal cord fusion thorac spine, Primary decompression operation on cervical spine, Primary decompression operations on lumbar spine, Primary fusion of joint of lumbar spine, Primary inguinal hernia repair, Primary laminectomy excision of cervical intervert disc, Primary laminectomy excision of lumbar intervertebral disc, Primary laparoscopic repair of inguinal hernia, Primary lumbar discectomy, Primary lumbar microdiscectomy, Primary microdiscectomy of lumbar intervertebral disc, Primary posterior fusion of lumbar spine, Primary repair of tendon, Primary transforaminal interbody fusion joint lumbar spine, Prmy open red+int fxn prox femoral #+screw/nail+plate device, Prmy open reduction of #+internal fixation with plate, Prosthetic replacement of mitral valve, Prosthetic uncemented hemiarthroplasty of shoulder, Proximal row carpectomy, Radical hysterectomy with conservation of ovaries, Radical nephrectomy, Radical prostatectomy without pelvic node excision, Reconstruction of anterior cruciate ligament of knee, Release of trigger finger, Removal of gastric band, Removal of plate from bone, Repair of recurrent incisional hernia, Repair of umbilical hernia, Replacement of aortic valve, Replacement of aortic valve, Resurfacing arthroplasty, Resurfacing of joint, Reversal of Hartmann's procedure, Reversal of ileostomy, Revision cemented hemiarthroplasty of shoulder, Revision of bypass for coronary artery, Revision of fundoplication of stomach, Revision uncemented hemiarthroplasty of hip, Revisional lumbar discectomy, Revisional lumbar microdiscectomy, Rhinoplasty, Right salpingoophorectomy, Rigid oesophagoscopic dilation of oesophagus, Rotator cuff decompression - open acromioplasty, Sampling of axillary lymph nodes, Septoplasty of nose, Septorhinoplasty, Shoulder joint operations, Shoulder joint operations, Sigmoid colectomy, Simple arthrodesis, Simple mastectomy, Simple nephrectomy – other, Splenectomy, Standard circumcision, Subacromial decompression, TAH - Tot abdom hysterectomy and BSO - bilat salpingophorect, Tenotomy, Therapeutic arthroscopic operations on cavity of knee joint, Thoracoscopic video-assisted approach to thoracic cavity, Tibial osteotomy, Total cholecystectomy, Total colectomy, Total gastrectomy, Total lobectomy of left lower lobe, Total lobectomy of right upper lobe, Total nephrectomy, Total nephrectomy, Total splenectomy, Tracheostomy, Transplantation of liver, Transurethral prostatectomy, Trapeziumectomy, Traumatic arthropathy of shoulder, Triple therapy helicobacter pylori, TURBT - Transurethral resection of bladder tumour, Tympanoplasty, Uci total replacement of knee joint using cement, Unilateral recurrent inguinal hernia – simple, Ureteroscopy, Vasectomy requested, Ventriculocisternostomy, Whipple pancreaticoduodenect, Whipple pancreaticoduodenectomy

- **Suspected condition**

Suspected condition

- **Swelling/inflammation**

Dependent oedema, Peripheral oedema, Acquired (chronic) lymphoedema, Acute prostatitis, Baker's cyst, Bloating symptom, scrotal swelling, a swelling, Finger swelling, Ganglion of foot, Ganglion of wrist, Ganglion unspecified, Leg swelling, Leg swelling symptom, ankle oedema, leg oedema, oedema not present, oedema of

ankles, oedema of feet, oedema of legs, scrotal swelling, submandibular swelling, Oedema, Osgood schlatter's dis, Osgood-Schlatter's dis - osteochondrosis of tibial tubercle, Pitting oedema, Popliteal bursitis, Reactive arthropathy unspecified, Salivary gland disease, Swelling, Swelling of calf, Swollen calf, Swollen foot, Swollen hand, Swollen joint, Swollen knee, Swollen legs, Swollen lower leg, Swollen nose, Swollen thumb, Ulcerative colitis, Ulcerative colitis and/or proctitis, Wegener's granulomatosis

- **Testing**

Abnorm.liver function test, Abnormal liver function test, LFT's abnormal, Adult screening, Angiogram, Angular cheilitis, Awaiting results, Blood sample taken, Blood test due, Breast examination, Computerised tomograph scan, CT scan brain – normal, ECG abnormal, ECG: Q-T interval prolonged, Echocardiogram, Echocardiogram abnormal, Echocardiogram normal, Helicobacter breath test, HEp-2 cell autoantibody screening test, Inform patient of results, Investigation result, Laboratory test requested, Liver function test, Liver function tests, Liver function tests abnormal, Magnetic resonance imaging of lumbar spine, Magnetic resonance imaging of lumbar spine abnormal, MRI of knee, MRI of lumbar spine, MRI of shoulder, MRI scan abnormal, Partially informed of test results, Patient informed - test result, Plain X-ray abdomen, Plain X-ray hand, Plain X-ray knee normal, Platelet count abnormal, Scaphoid X-ray, Screening, Standard chest X-ray, Standard chest X-ray abnormal, Test result to pat.by 'phone, Test result to pat.personally, Test result to patient, Thyroid function test, Thyroid function tests abnormal, Tuberculosis screening, U-S gallbladder scan, U-S pelvic scan

- **Therapeutic prescription**

Therapeutic prescription

- **Thyroid issues**

Acquired hypothyroidism, Thyroid disorder, Graves' disease, Hyperthyroidism, Hypopituitarism, Hypothyroidism, Hypothyroidism, Nontoxic multinodular goitre, Subclinical hypothyroidism, Thyrotoxicosis, TSH level

- **Tiredness or sleep**

Drowsiness, Fatigue, Lassitude, Lethargy, Post polio exhaustion, Sleep disturbances, Sleeping problem, tired all the time, Cannot sleep – insomnia, Chronic fatigue syndrome, Chronic fatigue syndrome, Excessive sleep, Fatigue, Insomnia, Insomnia symptom (GMS), Lethargic, Lethargy – symptom, Myalgic encephalomyelitis, Obstructive sleep apnoea, Persistent insomnia, Poor sleep pattern, Sleep apnoea, Sleep disorders, Snoring symptoms, Tired all the time, Tiredness symptom, Transient insomnia

- **Tumour**

Adenoma, Aggressive fibromatosis, Carcinoid tumour, Carcinoid tumours, Cartilaginous exostosis, Melanocytoma of eyeball, Meningiomas, Neuroendocrine carcinoma, Neuroendocrine neoplasm, Neurofibroma, Neurofibromas, Oligodendroglioma, Osteoma, Paraganglioma, Schwannoma, Acoustic neuroma, Benign neoplasm of spine, Cerebral meningioma, Lipoma, Lipoma of abdominal wall, Lipoma of back, Liver

metastases, Multiple congenital exostosis, Parotid lump, Phaeochromocytoma, Pituitary adenoma, Sacrococcygeal disorders not elsewhere classified, Spinal meningioma

- **Urinary system complaints**

Urgency of micturition, Acute retention of urine, Albuminuria, Fowler's Syndrome, Incontinence of urine, Microalbuminuria, Raised PSA, Renal colic, Retention of urine, Slowing of urinary stream, Continence assessment, Urinary incontinence, Other specified disorders of bladder, Urolithiasis, Acquired cyst of kidney, Acute kidney injury, Acute kidney injury stage 1, Acute kidney injury stage 3, Acute pyelonephritis, Attention to urinary catheter, Benign prostatic hypertrophy, Bladder calculus, Bladder disorders, Bladder outflow obstruction, Blood in urine – haematuria, Burch colposuspension, Calculus of kidney, Catheter complications, Cauda equina syndrome, Chronic cystitis, Chronic interstitial cystitis, Chronic kidney disease, Chronic kidney disease stage 2, Chronic kidney disease stage 3, Chronic kidney disease stage 3A without proteinuria, Chronic kidney disease stage 3B, Chronic kidney disease stage 3B with proteinuria, Chronic kidney disease stage 4, Chronic kidney disease stage 5, Chronic renal failure, CKD stage 3 with proteinuria, CKD stage 3A with proteinuria, CKD stage 3B without proteinuria, CKD stge 3A wthout proteinuria, CKD with GFR category G2 & albuminuria category A1, CKD with GFR category G3a & albuminuria category A1, Cystitis, Degree of urinary incontinence, Detrusor instability, Dysuria, End stage renal failure, Frank haematuria, Frequency of micturition, renal disease, Haematuria, Hydronephrosis with pelviureteric junction obstruction, Impaired renal function disorder, Incontinence of urine, Indwelling urethral catheter, Irritable bladder, Kidney calculus, Lower urinary tract symptoms, Microscopic haematuria, Micturition frequency, Micturition stream, Mild lower urinary tract symptoms, Nocturia, Nocturnal enuresis, Nonspecific urethritis, kidney stone, Overactive bladder, Polycystic kidney disease, Polycystic kidney disease, Polyuria, Prostatism, Prostatitis, Puerperal endometritis, Pyelonephritis unspecified, Recurrent urinary tract infection, Recurrent UTI, Reflux – vesicoureteric, Renal calculus, Renal calculus, Renal colic, Renal dialysis, Renal function monitoring, Renal haematoma without mention of open wound into cavity, Renal impairment, Renal profile, Renal stone, Stress incontinence, Stress incontinence – female, Suspected UTI, Transitional cell papilloma of bladder, Unstable bladder, Ureteric colic, Ureteric stone, Urethral diverticulum, Urge incontinence of urine, Urgency of micturition, Urinary frequency, Urinary symptoms, Urinary tract infection, Urinary tract infection, site not specified, Urinary tract infection site not specified,

- **Vertigo**

Acute vertigo, Dizziness, Light-headedness, Vertigo NOS, Benign paroxysmal positional vertigo, Benign paroxysmal positional vertigo or nystagmus, Dizziness symptom, Feels off balance

- **Viral illness**

Viral illness

- **Weight issues**

Abnormal loss of weight, Abnormal weight gain, Abnormal weight loss, Abnormal weight loss – symptom, Body mass index 30+ - obesity, Body mass index 40+ - severely obese, Complaining of weight loss, Health education -

weight management, Morbid obesity, Under weight, Obese class III (BMI equal to or greater than 40.0), Obesity, Obesity hypoventilation syndrome, Obesity monitoring, Wants to lose weight, Weight decreasing, Weight increasing, Weight monitoring, Weight symptom

- **Whiplash injury**

Whiplash injury

- **Wound care**

Pressure sore, Wound management, Open wound of other parts of hip and thigh, Dressing of wound, wound healing, wound necrotic, Open wound of finger(s), Open wound of leg, Open wound of lip, Post-operative wound care, Pressure sore, Venous ulcer of leg, Wound care, Wound observation

- **Other**

Dizzyness, History/symptoms, Breast Disorders, Syncope, Unsteady symptom, Spleen enlargement Clinical Opiate Withdrawal Scale, Down's Syndrome, Lack of Libido, Medically unexplained symptoms, Sicca (Sjogern's) syndrome, Anosmia loss of smell, Blackout, Electric Shock, Addison's Disease, Analgesia Present, Angiotensin converting enzyme inhibitor not tolerated, Ascites, Autism, Best interest decision made on behalf of patient, Cold Hands, Gender reassignement patient, General symptoms, Loss of appetite, Raised immunological level, Serious Diagnosis, Statin decline

## APPENDIX 6: Brands of opioid medication prescribed

| Prescribed Drug | Opioid | Include/Exclude |
|---|---|---|
| Alfentanil | Alfentanil | Exclude |
| Co-proxamol | Dextropropoxyphene | Exclude |
| Diamorphine | Diamorphine | Exclude |
| Galenphol | Pholdocine | Exclude |
| Nurofen | Nurofen | Exclude |
| Oxylan | Oxycodone | Exclude |
| Pavacol-D | Pholdocine | Exclude |
| Pholcodine | Pholdocine | Exclude |
| Abtard | Oxycodone | Include |
| Aspirin/Codeine | Codeine | Include |
| Bupeaze | Buprenorphine | Include |
| Buprenorphine | Buprenorphine | Include |
| Butec | Buprenorphine | Include |
| BuTrans | Buprenorphine | Include |
| Co-codamol | Codeine | Include |
| Co-codaprin | Codeine | Include |
| Codeine | Codeine | Include |
| Codipar | Codeine | Include |
| Co-dydramol | Dihydrocodeine | Include |
| DF118Forte | Dihydrocodeine | Include |
| DHCcontinus | Dihydrocodeine | Include |
| Dihydrocodeine | Dihydrocodeine | Include |
| DurogesicDTrans | Fentanyl | Include |
| Effentora | Fentanyl | Include |
| Fencino | Fentanyl | Include |
| FentalisReservoir | Fentanyl | Include |
| Fentanyl | Fentanyl | Include |
| Hapoctasin | Buprenorphine | Include |
| Hydromorphone | Hydromorphone | Include |
| Kapake | Codeine | Include |
| Longtec | Oxycodone | Include |
| Marol | Tramadol | Include |
| Matrifen | Fentanyl | Include |
| MaxitramSR | Tramadol | Include |
| Meptazinol | Meptazinol | Include |
| Methadone | Methadone | Include |
| MethadoneHydrochloride | Methadone | Include |
| MezolarMatrix | Fentanyl | Include |
| Migraleve | Codeine | Include |
| Morphgesic | Morphine Sulphate | Include |
| Morphine | Morphine Sulphate | Include |
| MorphineSulfate | Morphine Sulphate | Include |

| | | |
|---|---|---|
| MSTcontinus | Morphine Sulphate | Include |
| MSTcontinusSuspension | Morphine Sulphate | Include |
| MXL | Morphine Sulphate | Include |
| Oramorph | Morphine Sulphate | Include |
| Oxycodone | Oxycodone | Include |
| Oxycodone/Naloxone | Oxycodone | Include |
| OxyContin | Oxycodone | Include |
| OxyNorm | Oxycodone | Include |
| Palexia | Tapentadol | Include |
| Panadol | Codeine | Include |
| Panitaz | Buprenorphine | Include |
| Paracetamol/Dihydrocodeine | Dihydrocodeine | Include |
| Pethidine | Pethidine | Include |
| Physeptone | Methadone | Include |
| Reletrans | Buprenorphine | Include |
| Reltebon | Buprenorphine | Include |
| Remedeine | Dihdrocodeine | Include |
| Sevodyne | Buprenorphine | Include |
| Sevredol | Morphine Sulphate | Include |
| Shortec | Oxycodone | Include |
| Solpadeine | Codeine | Include |
| Solpadol | Codeine | Include |
| Subutex | Buprenorphine | Include |
| Tapentadol | Tapentadol | Include |
| Targinact | Oxycodone | Include |
| Temgesic | Buprenorphine | Include |
| Tephine | Buprenorphine | Include |
| Tradorec | Tramadol | Include |
| Tramacet | Tramadol | Include |
| Tramadol | Tramadol | Include |
| Tramadol/Paracetamol | Tramadol | Include |
| TramquelSR | Tramadol | Include |
| TramuliefSR | Tramadol | Include |
| Transtec | Buprenorphine | Include |
| Tylex | Codeine | Include |
| Yemex | Fentanyl | Include |
| Zamadol | Tramadol | Include |
| Zapain | Codeine | Include |
| Zeridame | Tramadol | Include |
| Zomorph | Morphine Sulphate | Include |
| Zydol | Tramadol | Include |

## APPENDIX 7: MED calculations for each opioid

| DrugName | Generic Opioid | Conversion into daily morphine equivalent dose |
|---|---|---|
| Bupeaze, Hapoctasin, Transtec | Buprenorphine | 35mcg/h = 90mg morphine/day 52.5mcg/h = 130mg morphine/day 70mcg/h = 180mg morhpine/day |
| Buprenorphine, Subutex | Buprenorphine | 0.4mg or 2mg or 8mg sublingual tablets total aily dose multiplied by 80 |
| Butec, BuTrans, Panitaz, Reletrans, Reltebon, Sevodyne | Buprenorphine | 5,10,15,20 version available. 15, 30, 45 and 60mg respectively |
| Temgesic, Tephine | Buprenorphine | 0.2mg and 0.4mg sublingual tablets total aily dose multiplied by 80 |
| Codeine, Co-codamol, Co-codaprin, Codipar, Kapake, Migraleve, Panadol, Solpadeine, Solpadol, Tylex, Zapain | Codeine | Adding all mg of codeine and divide by 10 |
| Remedeine, Co-dydramol, DF118Forte, DHCcontinus, Paracetamol/Dihydrocodeine | Dihdrocodeine | Adding all mg of dihydrocodeine and divide by 10 |
| DurogesicDTrans, Fencino, FentalisReservoir, Matrifen, MezolarMatrix, Yemex | Fentanyl | Multiply patch size time 24 and multiply times 100 then divide by 3 for oral 24h dose. See reference for official conversation |
| Effentora | Fentanyl | Short acting: bioavailability 65% +/- 20% add daily amount of fentanyl and multiply by 85 and then by 100 and divide by 3 for oral 24h MED |
| Hydromorphone | Hydromorphone | Adding all mg of hydrocodone and multiply by 7 |
| Meptazinol | Meptazinol | Add all mg of meptazinol and multiply by 0.03. This is very rarely used and might be excluded |
| Methadone, MethadoneHydrochloride, Physeptone | Methadone | Add all mg of methadone which will equal MED. Tricky as at higher doses this might move to 1 in 10 or even 1 in 20. |
| Morphgesic, Morphine, MorphineSulfate, MSTcontinus, MSTcontinusSuspension, MXL, Oramorph, Sevredol, Zomorph | Morphine Sulphate | Add all mg over 24 hours |
| Abtard, Longtec, Oxycodone, Oxycodone/Naloxone, OxyContin, OxyNorm, Shortec, Targinact | Oxycodone | calculate daily dose by adding all oxycodone (short acting and long acting) taking in 24 hours and multiply by 2 |
| Pethidine | Pethidine | Add mg over 24h and divide by 5. |
| Tapentadol, Palexia | Tapentadol | Add all mg of tapentadol and divide by 50. |
| Tramadol, Marol, MaxitramSR, Tradorec, Tramacet, Tramadol/Paracetamol, TramquelSR, TramuliefSR, Zamadol, Zeridame, Zydol | Tramadol | Add all mg of tramadol and multiply by 0.15 |

## APPENDIX 8: NHS HRA ethics approval for Study 2

Health Research Authority

**North West - Greater Manchester South Research Ethics Committee**

3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

17 April 2018

Dr Helen Poole
Faculty of Science
Tom Reilly Building, Byrom Street
Liverpool
L3 3AF

Dear Dr Poole

| | |
|---|---|
| **Study title:** | **Reducing the use of opioids for chronic non-cancer pain: Patient and Health Professionals views** |
| **REC reference:** | **18/NW/0217** |
| **IRAS project ID:** | **242720** |

Thank you for your letter of 10 April 2018, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

**Conditions of the favourable opinion**

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).*

*Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.*

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of management permissions from host organisations.*

**Registration of Clinical Trials**

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

**Approved documents**

The documents reviewed and approved by the Committee are:

| *Document* | *Version* | *Date* |
|---|---|---|
| Covering letter on headed paper [Interview Schedule Patients] | 1.0 | 27 February 2018 |
| Interview schedules or topic guides for participants | 1 | 27 February 2018 |
| Interview schedules or topic guides for participants | 1 | 27 February 2018 |
| Interview schedules or topic guides for participants [Response to Provisional] | | 10 April 2018 |
| Interview schedules or topic guides for participants [Interview Schedule Health Professionals] | 1.0 | 27 February 2018 |
| IRAS Application Form [IRAS_Form_05032018] | | 05 March 2018 |
| IRAS Checklist XML [Checklist_05032018] | | 05 March 2018 |
| Letters of invitation to participant | v1 | 27 February 2018 |
| Participant consent form | 1 | 27 February 2018 |
| Participant information sheet (PIS) | 1 | 27 February 2018 |
| Participant information sheet (PIS) | 1 | 27 February 2018 |
| Research protocol or project proposal | 1 | 05 March 2018 |
| Summary CV for Chief Investigator (CI) | 1 | 27 February 2018 |
| Summary CV for student | V1 | 05 March 2018 |
| Summary CV for student | 1 | 05 March 2018 |
| Summary CV for student | 1 | 05 March 2018 |
| Summary CV for supervisor (student research) | | |

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**After ethical review**

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

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

**Feedback**

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

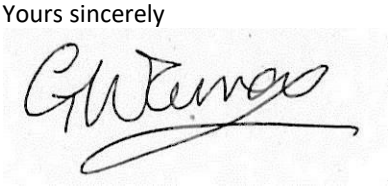
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our RES Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

| 18/NW/0217 | Please quote this number on all correspondence |
|---|---|

With the Committee's best wishes for the success of this project.

Yours sincerely



pp
Vice-Chair Richard Hovey
Email: nrescommittee.northwest-gmsouth@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Dr Dave Harris
Dave Watling, The Walton Centre NHS Foundation Trust

## APPENDIX 9: HCP email invite


Dear …… [name]

I'm sending you this email to let you know about an ongoing study and to invite you to consider participating. It's a qualitative study to explore the experiences of health care professionals involved in the care of patients with chronic non-cancer pain who are taking or have taken opioid medication for their pain. I've attached an information sheet with further details of the study. If you have any questions, I'm happy to answer them or there are contact details for other members of the research team on the sheet attached.

With best wishes

Dr Bernhard Frank

## APPENDIX 10: HCP Participant information sheet Study 2

# HCP PARTICIPANT INFORMATION SHEET

**Title of Project**: Reducing the use of opioids for chronic non-cancer pain (CNCP): Patient and Health Professionals views.

**Name of Researchers and School/Faculty**: Dr Helen Poole, Emma Begley, Alison Moffatt, Hannah Riley, Dr Cathy Montgomery (School of Natural Science and Psychology, Faculty of Science), Professor Harry Sumnall (Public Health Institute, Faculty of Education Health and Community) and Dr Bernhard Frank (Pain consultant, The Walton Centre NHS).

You are being invited to be take part in a brief one to one interview as part of a research study. Before you decide whether you would like to take part it is important that you read this information sheet to understand why the research is being done and what it involves. Please let me know if anything is unclear or if you would like more information.

**1. What is the purpose of the study?**

Researchers at Liverpool John Moores University are working with Health Professionals at The Walton Centre NHS Foundation Trust, South Sefton CCG and Southport and Formby CCG on a study to explore patient and health professionals views about using, reducing or discontinuing high dose opioid medications. We want to know about the benefits and challenges of managing patients taking opioid medications as well as those wishing to or needing to reduce or stop these medications.

When we've interviewed patients and health professionals to find out their views, we'll use the information to help us develop an intervention to help support health professionals and patients who want to reduce or stop taking high doses of opioid medication.

**2. Who can take part?**

**You are eligible to take part if:**

a. You are aged over 18 years.
b. You are a health professional/practitioner/pharmacist who is currently or recently (in the past 2 years) been involved with diagnosing/supporting and/or prescribing opioids (such as, dihydrocodeine, codeine, co-codamol, tramadol, oxycodone) for chronic non-cancer pain relief.
c. You can converse in English.

**You are not eligible to take part if:**

a. You are under 18 years old.
b. You are not involved in the pharmaceutical care or management of patients with CNCP.

**3. Do I have to take part?**

No. Your participation is voluntary and it is up to you to decide whether you take part or not.

Once you read this information sheet, and had the opportunity to ask any questions, we will ask you to sign a consent form if you do decide to take part.

Please note that you are free to withdraw at any time without having to provide reason. A decision to withdraw will not affect your rights or any future treatment or service you receive.

**4. What will happen to me if I take part?**

If you would like to take part, please contact the researcher (Emma Begley, E.K.Begley@2017.ljmu.ac.uk) to register your interest in the study. You will be given the opportunity to ask any questions you may have. We will then ask for written consent prior to any face-to-face interviews; however if you decide to participate via

telephone or skype you will be sent a consent form via post or email and asked to sign and return it prior to interview.

The study will consist of a face-to-face interview, lasting around 60 minutes. The interview will take place in a location of your choice or alternatively, arrangements made to conduct the interview via telephone or skype.

The interview will include questions around, discussing the challenges and barriers to adhering to clinical guidelines and recommendations, raising the issue of reducing or changing your patients' current opioid prescription, your views on the effectiveness of opioid medication to treat chronic pain and your perceptions of alternative non-drug therapies.

Your interview will be audio-recorded, transcribed and then analysed. The data will be used to inform behavioural interventions for treating CNCP patients. Everything you say will be kept confidential and will be anonymised prior to analysis.

**5. What do I have to do?**

You will need to contact a member of the research team to agree to take part. Please contact Emma Begley via email on e.k.begley@2017.ljmu.ac.uk or via telephone on 07516860587.

**6. Are there any risks / benefits involved?**

There are no intended personal benefits. However, the information we collect might help develop improved treatment options for patients with CNCP.

There are no anticipated risks associated with taking part in the study. If at any time you feel uncomfortable with the interview, you can decline to answer a question, and the interview would be stopped so you could have time to decide whether you want to continue.

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

Yes. The details of your participation will remain strictly confidential. You will be asked to provide the researcher with a signed consent form. This will be stored securely in a locked research office and kept separate to any research data (i.e. interview recordings and transcripts).

All interviews will be audio-recorded, encrypted and transferred onto a password-protected computer. Anonymity will be ensured by using pseudonyms such as 'Health Professional 1' or 'Patient 1' to differentiate between transcripts and quotes during the analysis. Copies of your transcript will be made available on request.

All personal data will be destroyed after use, less than 3 months after the study ends. Digital recordings will also be securely deleted from any recording equipment used. Research data will be kept securely for up to 5 years and then shredded/erased.

You have the right to withdraw from the study at any time.

**8. What will happen to the results of the research study?**

Once the data has been analysed, a summary of the results will be provided on request, with an opportunity to provide feedback. The results will inform a further research project designed to investigate alternative behavioural treatments for CNCP patients. The results may be used in future presentations, reports and peer-reviewed publications.

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

The study is organised and funded by Liverpool John Moores University and the Pain Relief Foundation and works closely in collaboration with The Walton Centre, Liverpool.

**10. Who has reviewed the study?**

The study has received ethical approval from LREC (IRAS reference number 24270, approved 17/4/18)

**11. Contact**

To register your interest in the study or if you have any questions please contact a member of the research team: Emma Begley on e.k.begley@2017.ljmu.ac.uk or primary investigator Helen Poole on h.m.poole@ljmu.ac.uk.

If you have any concerns regarding your involvement in this research, please discuss these with a member of the research team in the first instance. If you wish to make a complaint, please contact researchethics@ljmu.ac.uk and your communication will be re-directed to an independent person as appropriate.

Thank you for taking the time to read this information sheet

## APPENDIX 11: Consent form

**Appendix 3:** Participant consent form

# LIVERPOOL JOHN MOORES UNIVERSITY

# PARTICIPANT CONSENT FORM

**Title of project**: Reducing the use of opioids for chronic non-cancer pain (CNCP): Patient and Health Professionals views

**Name of Researchers and School/Faculty:** Dr Helen Poole, Emma Begley, Alison Moffatt, Hannah Riley, Dr Cathy Montgomery (School of Natural Science and Psychology, Faculty of Science), Professor Harry Sumnall (Public Health Institute, Faculty of Education Health and Community) and Dr Bernhard Frank (Pain consultant, The Walton Centre NHS).

Please confirm the following by ticking the boxes:

1. I confirm that I have read and understand the information provided. 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 a reason and that this will not affect my legal rights. ☐
3. I understand that any personal information collected during the study will be anonymised and remain confidential. ☐
4. I understand that the interview will be audio-recorded and I am happy to proceed. ☐
5. I understand that parts of our conversation may be quoted in future publications and or presentations but that these quotes will be made anonymous (your name and details will not be used). ☐
6. I agree to take part in the interview for the above study. ☐

Name of Participant Date Signature

Name of Researcher Date Signature

## APPENDIX 12: Patients Participant Information Sheet Study 2

# PARTICIPANT INFORMATION SHEET

**Title of Project:** Reducing the use of opioids for chronic non-cancer pain (CNCP): Patient and Health Professionals views

**Research team:** Dr Helen Poole, Emma Begley, Alison Moffatt, Hannah Riley, Dr Cathy Montgomery (School of Natural Science and Psychology, Faculty of Science), Professor Harry Sumnall (Public Health Institute, Faculty of Education Health and Community) and Dr Bernhard Frank (Pain consultant, The Walton Centre NHS).

*You are being invited to be take part in a brief one to one interview as part of a research study. Before you decide whether you would like to take part, it is important that you read this information sheet to understand why the research is being done and what it involves. Please let me know if anything is unclear or if you would like more information.*

- **What is the purpose of the study?**

Researchers at Liverpool John Moores University are working with Health Professionals at The Walton Centre NHS Foundation Trust, South Sefton CCG and Southport and Formby CCG on a study to explore patients views of taking pain medication for non-cancer pain. We are particularly interested in hearing patient experiences of taking, reducing or discontinuing to take opioid medications. We want to know about the benefits and challenges of taking or stopping these sorts of medicines.
When we've interviewed patients and health professionals to find out their views, we'll use the information to help us develop an intervention to help support health professionals and patients who want to reduce or stop taking high doses of opioid medication.

**Who can take part?**

**You are eligible to take part if:**

**a.** You are aged over 18 years.
**b.** You are currently or have recently (in the past two years) received treatment for a chronic non-cancer pain.
**c.** You have no other major co-morbid or psychological disorders.
**d.** You can converse in English.

- **You are not eligible to take part if:**
  a. Under 18 years old.
  b. You have cancerous pain.
  c. You have acute pain.
  d. You have not received opioid treatment in the past two years to manage pain.
  e. You have other major medical conditions or psychiatric disorders.

- **Do I have to take part?**

No. Your participation is voluntary, and it is up to you to decide whether you take part or not. Once you read this information sheet, and had the opportunity to ask any questions, we will ask you to sign a consent form if you do decide to take part.

Please note that you are free to withdraw at any time without having to provide reason. A decision to withdraw will not affect your rights or any future treatment or service you receive.

- **What will happen to me if I take part?**

If you would like to take part, please contact the researcher (Emma Begley, E.K.Begley@2017.ljmu.ac.uk) to register your interest in the study. You will be given the opportunity to ask any questions you may have. We will then ask for written consent prior to any face-to-face interviews; however if you decide to participate via telephone or skype you will be sent a consent form via post or email and asked to sign and return it prior to interview.

The study will consist of a face-to-face interview, lasting around 1 hour (60 minutes). The interview will take place in a location of your choice or alternatively, arrangements made to conduct the interview via telephone or skype.

The interview will include questions around: discussing your treatment journey, your views on the effectiveness of opioid medication, your perceptions as to the long-term outlook for your treatment plan and what your perceptions of the barriers and challenges on treating your diagnoses.

Your interview will be audio-recorded, transcribed and then analysed. The data will be used to inform behavioural interventions for treating chronic non-cancer pain patients. Everything you say will be kept confidential and will be anonymised prior to analysis.

- **What do I have to do?**

You will need to contact a member of the research team to agree to take part. Please contact Emma Begley via email on e.k.begley@2017.ljmu.ac.uk or via telephone on 07516860587.

- **Are there any risks / benefits involved?**

There are no intended personal benefits. However, the information we collect might help develop improved treatment options for patients with chronic non-cancer pain.

There are no anticipated risks associated with taking part in the study. However, talking about your pain and or medication can be somewhat upsetting. If at any time you feel uncomfortable with the interview, you can decline to answer a question, and the interview would be stopped so you could have time to decide whether you want to continue. If you feel distressed and would find it useful, the researcher will provide you with information about services that may offer you support. Additionally if you would like to speak to a member of the clinical team, the researcher will make a referral for someone to contact you.

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

Yes. The details of your participation will remain strictly confidential. You are requested to provide the researcher with a signed consent form. This will be stored securely in a locked research office and kept separate to any research data (i.e. interview recordings and transcripts).

All interviews will be audio-recorded, encrypted and transferred onto a password-protected computer. Anonymity will be ensured by using pseudonyms such as 'Health Professional 1' or 'Patient 1' to differentiate between transcripts and quotes during the analysis. Copies of your transcript will be made available on request.

All personal data will be destroyed after use, less than 3 months after the study ends. Digital recordings will also be securely deleted from any recording equipment used. Research data will be kept securely for up to 5 years and then shredded/erased.

You have the right to withdraw from the study at any time.

- **What will happen to the results of the research study?**

Once the data has been analysed, a summary of the results will be provided on request, with an opportunity to provide feedback. The results will inform a further research project designed to investigate alternative behavioural treatments for CNCP patients. The results may be used in future presentations, reports and peer-reviewed publications.

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

The study is organised and funded by Liverpool John Moores University and the Pain Relief Foundation and works closely in collaboration with The Walton Centre, Liverpool.

- **Who has reviewed the study?**

The study has received ethical approval from IREC (IRAS reference number 242720, approved 17/4/18).

- **Contact**

To register your interest in the study or if you have any questions please contact a member of the research team**:** Emma Begley on e.k.begley@2017.ljmu.ac.uk or the primary investigator Helen Poole on h.m.poole@ljmu.ac.uk.

**If you have any concerns regarding your involvement in this research, please discuss these with a member of the research team in the first instance. If you wish to make a complaint, please contact researchethics@ljmu.ac.uk and your communication will be re-directed to an independent person as appropriate.**

***Thank you for taking the time to read this information sheet***

## APPENDIX 13: HCP interview guide

**Script for Researcher**

*Thank you for agreeing to the interview today, as already mentioned in the participant information sheet given to you, I am interested in talking to you about your experience prescribing or dispensing opioid medication for chronic non-cancer pain patients.*

***Firstly can you highlight for me whether you:***

Prescribed opioid medication

Dispensed opioid medication

Support patients being treated with opioids?

Q1) Can you tell me briefly about your role and if you have any specific interest in the treatment or practice of chronic non-cancer pain?

**Probe: what is your involvement in the diagnosis or management of CNCP patients? Are there any specific management routes taken for these patients? Do you follow clinical guidelines?**

How do you discuss with patients your concerns regarding high dose medicines/ long term prescription/dose reduction?

**Probe: medication review/do you need more help with this, like what?**

What difficulties do you encounter when dispensing opioid medication to patients?

**Probe:any systems/pathways in place where you can direct your concerns/ problem paients?**

What are the main challenges you deal with, with CNCP patients?

What have been the most rewarding and challenging encounters when treating your patients?

**Probe: conflict/disagreements/care plans or proceedures?**

Are there any regulations/ guidance policies in place you don't agree with or feel need updating?

Follow questions below (**skip Q4**)

What are your views on the current policies and guidelines for prescribing opioids?

**Probe: how could they be improved? Do you need addtional support adhearing to them?**

What concerns do you have over prescription opioids and how effective do you think they are?

**Probe: consider long and short term**

How easy/difficult do you find sticking to clinical practice guidelines?

**Probe: do they limit how you would like to treat patients? How do you over come this?**

What advice would you give to other people who are thinking of weaning off their prescription?

Do you ever find it difficult to write a prescription? can you tell me about this?

**Probe: instances where patients lose/misue their prescription?**

***Please go to Q2.***

Q2) What do you think the challenges/difficulties are from a patients point of view when they come to see you about their condition/pain/current prescription?

Q3) Can you discuss whether patients are given sufficient information about their medication and to what extent you believe they fully understand it all?

   a. Probe: Is there anything you think should be done differently?

Q4) Are there any key reasons why you would choose not to prescribe or treat a patient with opioids?

   a. Probe: do you offer any alternative treatments and could there be any additional support in place to help these decisions?
   b. Probe: to what extent do you believe patients would benefit from alternative medication? What and why?

Q5) If a patient had concerns about opioid treatment, how do you manage those concerns?

   a. Probe: how do you manage patients who insist on an alternative modes of treatment or wish to change dose or discontinue treatment before you think they are ready?

Q6) How effective do you think opioid medication is for treating chronic pain? Please consider long-term/short-term prescriptions.

   a. Probe, cases where they have worked well – why do you think this is?
   b. Probe, cases where they have not worked – why do you think this is?

Q7) Do you think there need for more research carried on the use opioids for CNCP? Like what?

Q8) We are interested in the communication between practitioners and other health professionals who are involved with treating CNCP patients, can you describe the communication you have with other health professionals? Is there need for better communication?

   a. Probe: how do you think this could be improved?

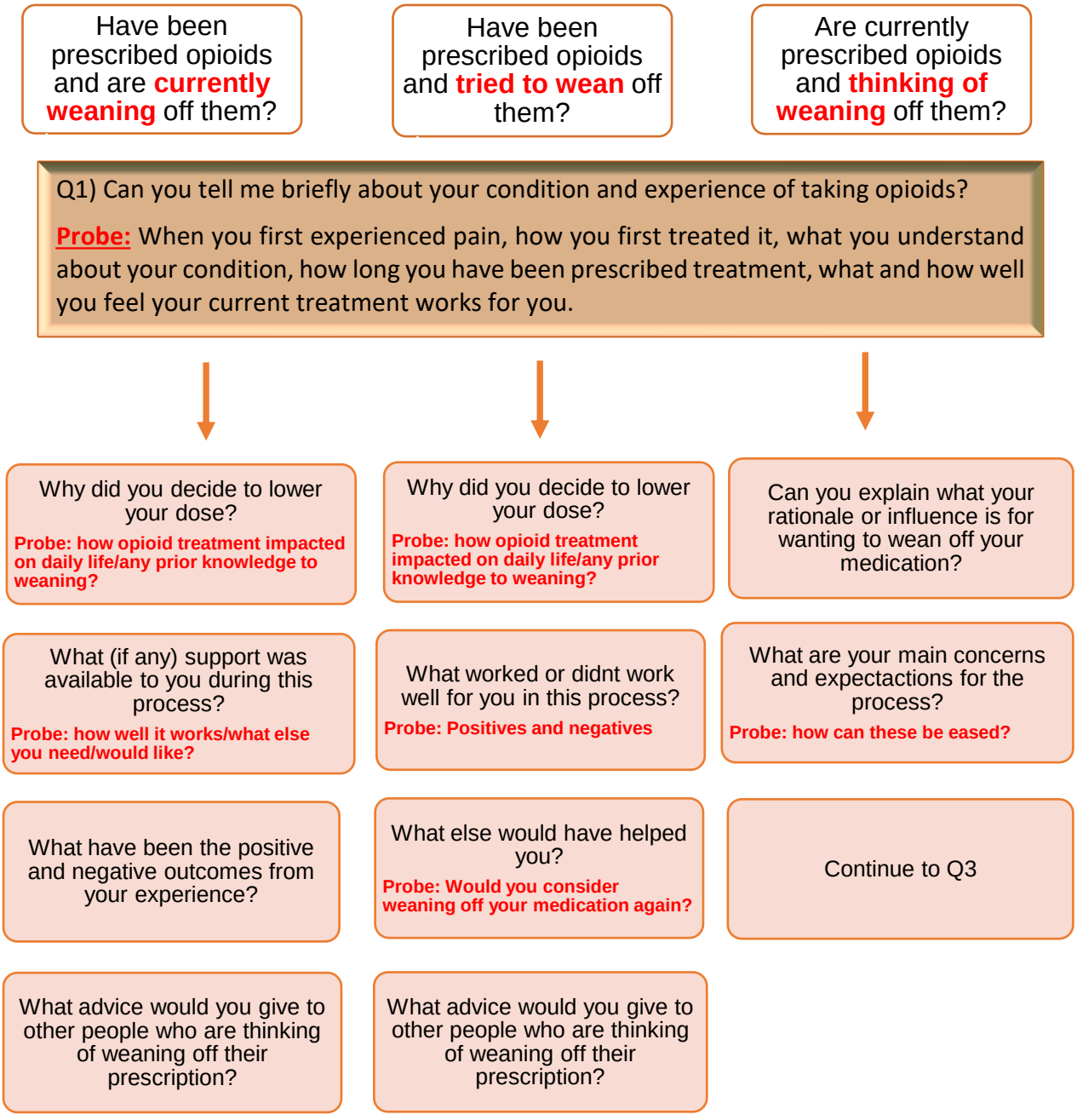
Q9) In your experience how open are patients to experimenting with alternative treatment and what do you think is needed to encourage and retain this?

## APPENDIX 14: Patient interview guide

**Script for Researcher**

*Thank you for agreeing to the interview today, as already mentioned in the participant information sheet given to you, I am interested in talking to you about your experience with opioid medication. This includes prescribed medication such as: codeine, co-codamol, tramadol, dihydrocodeine, morphine, oxycodone and fentanyl just to name a few.*

***Firstly can you highlight for me whether you:***




***Please go to Q3.***

Q2) Can you tell me briefly about your condition and experience of taking opioids? E.g. When you first experienced pain, how you first treated it, what you understand about your condition, how long you have been prescribed treatment, what and how well you feel your current treatment works for you.

Q3) What methods of treatment do you feel worked best? Why?

   a. Probe about lifestyle at that time? Active? Working? Mindset (i.e. were you motivated to try new things/positive/negative thinking/emotionally charged/timeline of condition e.g. early/later stages of diagnoses?)

Q4) Have you ever used, been offered or queried alternative treatment? E.g. exercises/stretching, physiotherapy or acupuncture? If so, what did you use? If not, why?

   a. Probe about when you used them? Why did you choose to change course of treatment? How well did they work for you?
   b. What anxieties, if any, do you have around changing your course of treatment? How might those anxieties be reduced or prevented?

Q5) How does your opioid treatment affect your daily life? Does it cause you any problems?

Q6) How do you feel if you do not take your medication?

Q7) How do you think you might feel if you stopped taking your medication altogether?

Q8) Are these problems enough to make you want to stop taking your pain medicine or source alternative treatment? At what point did you/would you decide to seek alternative treatment?

Q9) On a scale of 1-10 (1 = totally unsatisfied and 10= completely satisfied) how satisfied are you with your current treatment plan?

   a. Probe why, what are the positive/negative outcomes. Take note of point in scale and if it reflects patients reasoning.

Q10) Can you describe your long-term ideal outcome? i.e. do you see an endpoint to your treatment? What does this look like?

   a. Probe what are your expectations from your current treatment, how does it make you feel when your expectations are not met? What would you like to change?

Q11) What barriers and challenges do you feel you face when coming to see your GP regarding your pain?

Q12) What do you think the challenges/difficulties are for your doctor when they are consulting your condition and course of action?

Q13) Would you consider taking part in a trial of an alternative treatment aimed at reducing or possibility terminating your opioid prescription?

Q14) Is there anything else you would like to add about your experience with prescription opioids?

## APPENDIX 15: Coding framework for HCPs

| Codes | Sub-theme | Theme | Example extracts |
|---|---|---|---|
| External communication, internal communication, issues with communication, methods of communication, risk communication | Communication | Health Care system | "*There's a massive shortage of GPs the turnover is so high that' we're not consistently able to get communication with the same person*" HCP13, Nurse.<br>"*The nurse will then see them and make recommendations for the GP, again we are slaves to the GP implementing that and making those changes longer term*" HCP10 Clinical psychologist<br>"*I'm very uniquely placed that I have access to all the alternative therapies* (right) *available; pain physiotherapy, pain psychology, pain rehabilitation, neuromodulation which all, all these therapies I use regularly to, to take my patients down on opioids*" HCP19 Pain consultant. |
| Diffusion of responsibility, HCP role identity | Defining roles | | |
| Referral process, access to treatment, levels of care | Referral | | |
| Impact of pain, patient identity, patients in treatment, HCP input into treatment | "This isn't me" patients identity crisis | Working with patients | "*Often patients will say things like "this isn't me, you know I was never like this, this is not my life you know, I've changed completely, even my personality has changed*" HCP10.<br><br>"*I don't think anybody is given enough information. We certainly don't give them leaflets… unless they take the leaflet out* [of the medication box] *and actually read it which the majority of them don't do*" HCP24, GP. |
| Patient's knowledge, education and training | Patient's knowledge | | |
| Pharmacological treatment, Non-pharmacological treatment, pain management | Initiating treatment | Treatment | "*Within the health care setting in primary care there aren't really any alternative treatments, I mean people can go to the voluntary sector and get acupuncture, massage and things like that but we aren't providing that service to them*" HCP26, GP.<br><br>"*Opioids they only last for so long…I don't think they're effective in most of our patients*" HCP13, Nurse.<br><br>"*We can either refer them to the drug services… or we say to them do you want us to do it* [weaning]*… actually the best thing really is just get refer to one of the drug addiction services they are the best people to deal with that I think erm rather than the GP*" HCP25, GP |
| Efficacy of treatment | Efficacy of treatment | | |
| Refining treatment, capacity | Opioid weaning | | |

# APPENDIX 16: Transcript extract HCP24, GP

R: So I will follow on with the next question, we were talking about ammm, oh that was it, when patients come in with high dose medications, do you have any additional help or support around, you said that you were talking about referrals onto secondary care and that [P24: Yeah], do you need, so for your role here do you think you need extra support around those patients

P24: yeah so, the person you spoke to [refers to another participant], so he works with the other practice and he reviews all their chronic pain patients now we don't have a service like that and I think if we could get someone like that, that would be absolutely fantastic [R: magic], absolute magic and partly because he has I think half an hour to talk to a patient with chronic pain and a lot of this with chronic pain patients is mental health and a lot of that is they just need time to sit and talk to you. And I think if we had that and we had that across the board I think that would be fantastic and it would take a lot of service pressure away from secondary care as well because you could manage those patients a whole lot more in primary care

**Commented [EB1]:** Coded at:
- Defining roles (capacity; HCP role identity)
- Patient characteristics (impact of pain)
- HCS (level of care)
- Treatment (refining treatment)

R: yeah and manage expectations and stuff like that...

P24: yeah, yeah. And you would have that follow through. The problem with them just seeing a GP is firstly, they will jump from one GP to another to get medication or just with different symptoms. These chronic patients usually have masses of comorbidities whether that is mental health or other comorbidities or a mixture of the two amm and so different GP's see them and there just you know just waffling on about all sorts of different things about this pain and that pain and just to get a history a clear history if you've not seen them and you don't know them or if you've not seen them for ages is very difficult so to do that in 10 minutes, to get clarity in 10 minutes is incredibly difficult so the default probably is 'oh lets give you a bit of this' and then you can come back and see me and they will never come back and see you they will go back and see someone else and start the whole process again, get more medication and then they will come back and see you in another 6 months where you start the whole process all over again. Whereas if one person is seeing them, both people know whats going on, so even the person, the patient will also know as well they can't play the system, they know me, I know them, I'm not going to get passed them, I need to you know, they know where I've came from last time I saw them two weeks ago and so I can't make something up. Amm I think that would be really important you know amm for these types of patients continuity is incredibly important and giving them a bit of time [R: seems to be key], yeah with someone who has insite into that pharmacology you know, I don't know, see we have practice nurses as well amm nurse practitioners, I don't necessarily think that, sorry if we had a nurse practitioner or GP even who had that interest and could give them that time then that's different but I think they need that medical knowledge, medication knowledge specifically amm and I think pharmacists are really good there because they have that sort of pharmacology background into what the drug is actually doing and I think partly educating the patient is helpful because a lot of patients like to know well this works like that and that works like that and so forth if we combine the two it might give you a better result rather than you just having 3 times the amount of opioids [R: yeah] and if that is explained to them with that time a lot of people will say yeah okay we will go ahead with that. Whereas with a lot of GP's in 10 minutes they are just like right take this and off you go please.

**Commented [EB2]:** Coded at:
- Facets for treatment (patients in treatment, HCP input into treatment, education/training)
- HCS (level of care, practice specific approach)
- Patient characteristics (impact of pain, patient knowledge)
- Treatment (redefining treatment)
- Defining roles (capacity, diffusion of responsibility, HCP role identity)

## APPENDIX 17: Coding framework for CNCP patients

| Codes | Sub-theme | Theme | Example extracts |
|---|---|---|---|
| Engagement in treatment, non-pharmacological treatment, access to treatment, referral | Initiating treatment | The treatment journey | "*I've got to do whatever they ask me to do and what they think is best for me. Because otherwise I'm, things aren't going to get any better*" P17. |
| Using opioids, medication review, | Adherence to treatment | | "*I was getting a month's supply off them, and they were going within a week, I just needed them constantly*" P23. |
| Understanding medical decisions, communication with HCP, consistency, HCP knowledge, review of the HCS (positive and negative experiences) | Communicating with HCPs | | "*You've got one person* [HCP] *telling you one thing and another person* [HCP] *telling you another*" P15.<br><br>"*I find it hard to relate really to the actual doctors here with the opioid medication, they don't seem to understand*" P6. |
| Ability to function and quality of life, diagnosis and co-morbidities, identity | Self-identity & QOL | Living with opioids | "*I didn't want to interact with anybody, I didn't want to speak to anybody, I didn't want to go nowhere. It affected my relationship, erm, it really did just turn me to basically a vegetable*" P9. |
| Efficacy or opioids, efficacy of other treatment, feelings toward opioids, side effects, emotional responses to treatment, anxiety about treatment, preconceived judgements | Are opioids worth it? | | "*When I was on the opioids, I was able to carry on, a normal life doing the things that I wanted to do, I was a lot more active*" P17. |
| Self-management of pain, future outlook | Self-management | | "*I mean they might be ok for a week or 10 days but anything longer than that You get used to the… painkillers Are the wrong name because sometimes they don't kill any pain*" P3.<br><br>"*I think the thing that works best is just sort of pacing round really, because there's not one that works best*" P12. |
| Weaning approach, opioid replacement, stages of engagement | Approach to weaning | Weaning experience | "*With the best will in the world at the present moment I can't come down off this Zormorph*" P15. |
| Hitting a wall | Hitting a wall | | "The positives were, it got me off the opioids, to me the negatives were I'm still in pain and nobody would treat me" p9 |
| Post weaning, advice to other patients | Post weaning | | |
| Support | Support | | "*I think you need somebody, because we had nobody, it was basically right get on with it and come and see us in three months*" P12. |

# APPENDIX 18: Transcript extract from CNCP P12

**Appendix X: Transcript extract CNCP P12**

INT: the first time you did it [reduce dose], the Doctor, the GP suggested reducing it down, was their any other kind of support available for you in terms of somebody being there while you were going through it all?

PPT: No

INT: And do you think it's something that you might benefit from?

PPT: I think you need somebody, because we had nobody, I mean when Dr X did it with us, it was basically right get on with it and come and see us in three months, but there was nobody. You could do with like a District Nurse or somebody calling in just to check you are ok.

**Commented [EB1]:** Coded at: Interaction with HCS (room for improvement)

**Commented [EB2]:** Coded at: Weaning experience (support)

INT: Just somebody touching base with you and letting you know, you know what it's going to be a rough ride for the next week or so but it's going to get better or just kind of keeping an eye on you really?

PPT: Somebody, because we were, I'm serious, we were going through hell and my husband was saying, this is enough now, this is enough now and if he had somebody to come in and say look this is how it's supposed to be or yes this is what will happen but it will pick up. Give it another two days, or three days and it will be better then, then it would have worked. But we had no time span, no, yes it's meant to be like this, but my head honestly, I was crawling the floor. Thinking back, it was really, really bad and you just don't know, you don't know.

**Commented [EB3]:** Coded at: Weaning experience (stages of engagement, support)

INT: and do you think the treatment that you're on now, you're on a few different bits that you mentioned there, do you think it works? How well do you think it works for you?

PPT: I think there's got to be something better, I think there's got to be, because we still haven't been told why this is happening. Even from the very beginning we were saying well why's this happened, even from the very first beginning like all my bones were black, erm I had really sore bones right from the go. All I was given was medication to mask it, and we were never told why, why I felt like this.

**Commented [EB4]:** Coded at: Are opioids worth it (efficacy of treatment);

Living with pain (diagnosis and co-morbidity)

INT: Have you ever been offered a pain management program?

PPT: Yes I went to that.

INT: And how did you get on there?

PPT: It was okay, a bit fluffy. I've been to a couple actually.

**Commented [EB5]:** Coded at: The treatment journey (engagement in treatment, non-pharmacological treatment)

## APPENDIX 19: The APEASE criteria

| Criterion | Description |
|---|---|
| **Affordability** | All interventions have an implicit or explicit budget. Regardless of how effective or cost-effective it may be, if it cannot be afforded it does not matter. An intervention is considered affordable if it is within an accepted budget and can be delivered and accessed by all for whom it is relevant. |
| **Practicability** | The extent to which an intervention can be delivered as designed and intended, determines how practicable it is. For example, an intervention may be effective when delivered by highly trained staff with resources, however this may differ in routine clinical practice. |
| **Effectiveness and cost effectiveness** | Effectiveness of an intervention refers to its effect size in relation to its objectives in a real-world context. This differs from efficacy which considers the effect size of an intervention when delivered under optimal conditions in comparative evaluations. Cost-effectiveness refers to the ratio of effect to cost, in regard to the difference in timescales between intervention delivery and intervention effect. For example, if two interventions are effective, the most cost-effective should be chosen. If one is more effective, but less cost-effective other issues such as affordability are factored into the decision making. |
| **Acceptability** | Acceptability refers to the extent an intervention is judged to be appropriate by relevant stakeholders, including the general public. Acceptability may differ for different stakeholders, however interventions that limit agency on part of the target group are only deemed acceptable for more serious problems (Bioethics, 2007) |
| **Side effects/safety** | An intervention may be effective and practicable but have unwanted side-effects or unintended consequences. These need to be considered when deciding whether or not to proceed. |
| **Equity** | An important consideration is the extent to which an intervention may reduce or increase the disparities in standard of living, wellbeing or health between different sectors of society. |

(Michie, Atkins, & West, 2014; p23-24)

## APPENDIX 20: Prioritising behaviours according to impact and outcome

| Potential target behaviours to wean CNCP patients off opioid prescriptions in primary care | Impact of behaviour change | Likelihood of changing behaviour | Spillover score | Measurement score |
|---|---|---|---|---|
| **Patient Weaning** | | | | |
| Get support from a HCP | Very promising | Very promising | Very promising | Very promising |
| Get support from family and peers | Quite promising | Quite promising | Quite promising | Unpromising |
| Agree a weaning plan with HCP | Very promising | Quite promising | Very promising | Very promising |
| Adhere to weaning plan | Very promising | Quite promising | Very promising | Very promising |
| Agree a contingency/relapse plan | Very promising | Very promising | Quite promising | Very promising |
| Understand the risks of long-term opioid use | Very promising | Very promising | Very promising | Quite promising |
| Informed expectation of weaning | Very promising | Very promising | Very promising | Quite promising |
| Understand the mechanisms of pain | Quite promising | Quite promising | Quite promising | Very promising |
| Make the most of your HCP appointments | Unpromising | Unpromising | Unpromising | Unpromising |
| Attend opioid weaning support groups | Quite promising | Quite promising | Quite promising | Very promising |
| Learn relevant coping strategies to reduce psychological distress | Very promising | Quite promising | Very promising | Very promising |
| Learn relevant coping strategies to self-manage pain | Very promising | Very promising | Very promising | Very promising |
| Use coping strategies as part of daily routine | Very promising | Quite promising | Very promising | Very promising |
| **HCP delivering care** | | | | |
| Prepare patients engaging in a weaning plan (i.e. inform them and manage expectations) | Very promising | Very promising | Very promising | Very promising |
| Offer regular and consistent support | Very promising | Quite promising | Very promising | Very promising |
| Develop patients understanding of the risks of long-term opioid use and mechanisms of pain | Very promising | Quite promising | Very promising | Very promising |
| Tailor weaning plans to suit patients | Very promising | Very promising | Very promising | Very promising |
| Consider continency/relapse manage plans | Very promising | Very promising | Very promising | Very promising |
| Manage patients fear and anxieties around weaning | Very promising | Quite promising | Very promising | Quite promising |
| Develop patients coping/self-management skills | Very promising | Quite promising | Very promising | Quite promising |
| Encourage group support | Very promising | Quite promising | Very promising | Quite promising |

| Potential target behaviours to wean CNCP patients off opioid prescriptions in primary care | Impact of behaviour change | Likelihood of changing behaviour | Spillover score | Measurement score |
|---|---|---|---|---|
| Indicated prescribing (i.e. rotate opioids to optimise weaning/manage withdrawal) | Very promising | Very promising | Very promising | Very promising |
| Review and monitor opioid prescriptions | Very promising | Quite promising | Very promising | Very promising |
| Improve HCP skills to better manage pressure from patients | Very promising | Quite promising | Very promising | Quite promising |
| Encourage patients to practice learnt techniques and strategies | Very promising | Quite promising | Very promising | Quite promising |
| **Health Care System** | | | | |
| Deliver training for HCPs supporting patients weaning | Very promising | Quite promising | Very promising | Very promising |
| Provide access/available of support services | Very promising | Quite promising | Very promising | Very promising |
| Improve the availability or access to community prescriptions | Very promising | Unpromising | Very promising | Very promising |
| Improve communication between different levels of care involved in patient's treatment | Very promising | Quite promising | Very promising | Very promising |
| Optimise HCPs in the community to provide MDT support | Very promising | Quite promising | Very promising | Very promising |
| | | | | |
| **Family and friends** | | | | |
| Stay informed and updated with the weaning progress | Unpromising | Unpromising | Unpromising | Unpromising |
| Encourage patients practice of learnt techniques and skills to manage pain and weaning experience | Quite promising | Quite promising | Quite promising | Unpromising |
| Understand the weaning process and difficulty the patient may face | Unpromising | Unpromising | Unpromising | Unpromising |
| Provide a sense of security and support for patient | Quite promising | Unpromising | Unpromising | Unpromising |

## APPENDIX 21: Intervention functions and BCTs selected for each target behaviour

| **Intervention function (COM-B component)** | **Frequently used BCTs (and consideration of relevant less frequently used BCTs)** | **Is the BCT relevant for HCPs or patients and does it meet the APEASE criteria?** | | |
|---|---|---|---|---|
| | | *Adherence to weaning* | *Fear and anxiety* | *Information and support* |
| **Education**<br><br>**(Psychological capability and Reflective motivation)** | Information about social and environmental consequences | No | No | No |
| | Information about health consequences | Yes - both | Yes - both | Yes – HCP only |
| | Feedback on behaviour | No | No | No |
| | Feedback on outcome(s) of the behaviour | No | No | No |
| | Prompts/cues | Yes – HCP only | Yes – HCP only | Yes – HCPs only |
| | Self-monitoring of behaviour | Yes - both | Yes - both | No |
| | Information about emotional consequences (less used BCT) | Yes - both | Yes - both | Yes – HCP only |
| | Self-monitoring of outcomes of behaviour (less used BCT) | Yes - patients only | Yes - patients only | No |
| | Information about others approval (less used BCT) | Yes – both | Yes – both | Yes - both |
| **Persuasion**<br><br>**(Reflective motivation)** | Creditable source | Yes – patients only | Yes – patients only | Yes -patients only |
| | Information about social and environmental consequences | No | No | No |
| | Information about health consequences | Yes – both | Yes - both | No |
| | Feedback on behaviour | Yes – patients only | Yes – patients only | No |
| | Feedback on outcome(s) of behaviour | Yes – patients only | Yes – patients only | No |
| | Information about emotional consequences (less used BCT) | Yes – patients only | Yes – patients only | No |
| **Training**<br><br>**(Psychological capability, Social opportunity, Reflective motivation, Automatic motivation)** | Demonstration of the behaviour | No | Yes – both | No |
| | Instruction on how to perform a behaviour | Yes – both | Yes – both | No |
| | Feedback on the behaviour | Yes – HCPs only | Yes – HCPs only | No |
| | Feedback on the outcome(s) of behaviour | Yes – HCPs only | Yes – HCPs only | No |
| | Self-monitoring of behaviour | Yes – patients only | Yes – patients only | No |
| | Behavioural practice/rehearsal | No | Yes – patients only | No |
| | Habit reversal (less used BCT) | No | Yes – patients only | No |

| **Intervention function (COM-B component)** | **Frequently used BCTs (and consideration of relevant less frequently used BCTs)** | **Is the BCT relevant for HCPs or patients and does it meet the APEASE criteria?** | | |
|---|---|---|---|---|
| | | *Adherence to weaning* | *Fear and anxiety* | *Information and support* |
| **Environmental restructuring (Social opportunity, Physical opportunity)** | Adding objects to the environment | No | No | No |
| | Prompts/cues | Yes – HCPs only | Yes – patients only | No |
| | Restructuring the physical environment | No | No | No |
| | Restructure the social environment (less used BCT) | No | No | Yes–patients only |
| **Modelling (Social opportunity, Reflective motivation)** | Demonstration of the behaviour | No | Yes – patients only | Yes – patient only |
| **Enablement**<br><br>**(Psychological capability, Social opportunity, Reflective motivation, Automatic motivation)** | Social support (unspecified) | Yes-HCP only | Yes-HCP only | No |
| | Social support (practical) | No | Yes-patient only | Yes-patient only |
| | Goal setting (behaviour) | Yes – both | Yes – both | Yes-patient only |
| | Goal setting (outcome) | Yes – both | Yes-patient only | No |
| | Adding objects to the environment | Yes-HCP only | No | Yes-HCP only |
| | Problem solving | Yes - both | Yes - both | No |
| | Reduce negative emotion (less used BCT) | Yes- both | Yes-patient only | Yes-patient only |
| | Action planning (includes relapse management and coping planning) | Yes – both | Yes – both | No |
| | Self-monitoring of behaviour | No | No | No |
| | Restructuring the physical environment | No | No | No |
| | Review behaviour goal(s) | Yes-both | Yes-both | No |
| | Review outcome goal(s) | Yes-both | Yes-both | No |

# APPENDIX 22: Ethics for Study 3 feedback

Dear Emma

Thank you for registering your study as minimal risk.

**Emma Begley, PGR - An online workshop investigating recommendations for an opioid weaning intervention for Chronic Non-Cancer Pain patients in primary care (Cathy Montgomery)**

**UREC opinion: Favourable ethical opinion**

**UREC reference: 20/NSP/041**

Conditions of the favourable opinion

Prior to the start of the study.

- Covid-19. Studies that involve face-to-face activity – you must ensure participant facing documents explain the potential risks of participating in the study which are associated with Covid-19, how the risks will be mitigated and managed.

After ethical review.

- The study is conducted in accordance with the Minimal Ethical Risk Guiding Principles
- You must ensure the information included in the participant facing documents are always current and informed by ongoing risk assessments and any changes to current practices.
- Where any substantive amendments are proposed to the protocol or study procedures further ethical opinion must be sought (https://www.ljmu.ac.uk/ris/research-ethics-and-governance/research-ethics/university-research-ethics-committee-urec/amendments)
- Any adverse reactions/events which take place during the course of the project are reported to the Committee immediately by emailing FullReviewUREC@ljmu.ac.uk
- Any unforeseen ethical issues arising during the course of the project will be reported to the Committee immediately emailing FullReviewUREC@ljmu.ac.uk

Please note that favourable ethics opinion is given for a period of five years. An application for extension of the ethical opinion must be submitted if the project continues after this date.

**Research Governance Approval.**

This email also constitutes LJMU Research Governance Approval of the above referenced study on the basis described in the minimal risk registration form, supporting documentation and any clarifications received, subject to the conditions specified below.

Conditions of Approval

- Compliance with LJMU Health and Safety Codes of practice and risk assessment policy and procedures and LJMU Code of Practice for Research
- Ensure the study is covered by UMAL
- Covid-19. Compliance with LJMU's travel restrictions
- Covid-19. Studies that involve any face-to-face research activity have the appropriate risk assessment in place – the risk assessment is signed by the school Director or nominated other, revised, resigned and reissued when required and sent to the Safety, Health and Environment Department by email to SHE@ljmu.ac.uk

- Covid-19. Studies that involve any face-to-face research activity meet Covid-19 practices which are current at the time the research activity takes place.
- Where relevant, appropriate gatekeeper / management permission is obtained at the study site concerned.
- The LJMU logo is used for all documentation relating to participant recruitment and participation e.g. poster, information sheets, consent forms, questionnaires.
- The study consent forms, study data/information, all documents related to the study etc. will be accessible on request to a student's supervisory team and/or to responsible members of Liverpool John Moores University for monitoring, auditing and data authenticity purposes.

Yours sincerely

**Mandy Williams, Research Support Officer**

**(Research Ethics and Governance)**

**Research and Innovation Services**

**Exchange Station, Tithebarn Street, L2 2QP**

**t: 01519046467 e: a.f.williams@ljmu.ac.uk**

**https://www2.ljmu.ac.uk/RGSO/93042.htm**

**https://twitter.com/LJMUEthics**

## APPENDIX 23: HCP email invite for Study 3

Dear XXX,

I thought I would get in touch with you as you expressed some interest in hearing about further research around the work I am doing on opioid weaning. Using the findings of the research interviews I done last year, exploring your experiences of managing patients with chronic non-cancer pain; we have developed a number of intervention recommendations to help reduce or discontinue opioid use, where opioids are not indicated as a beneficial treatment option.

In order to establish their suitability and feasibility, we are hosting online workshops designed to explore the views and feedback of health care professionals. Is this something you would be interested in participating in? The workshop would require one hour of your time and will be held online. I have attached a participant information sheet and a consent form which you would be asked to complete if you are interested in taking part.

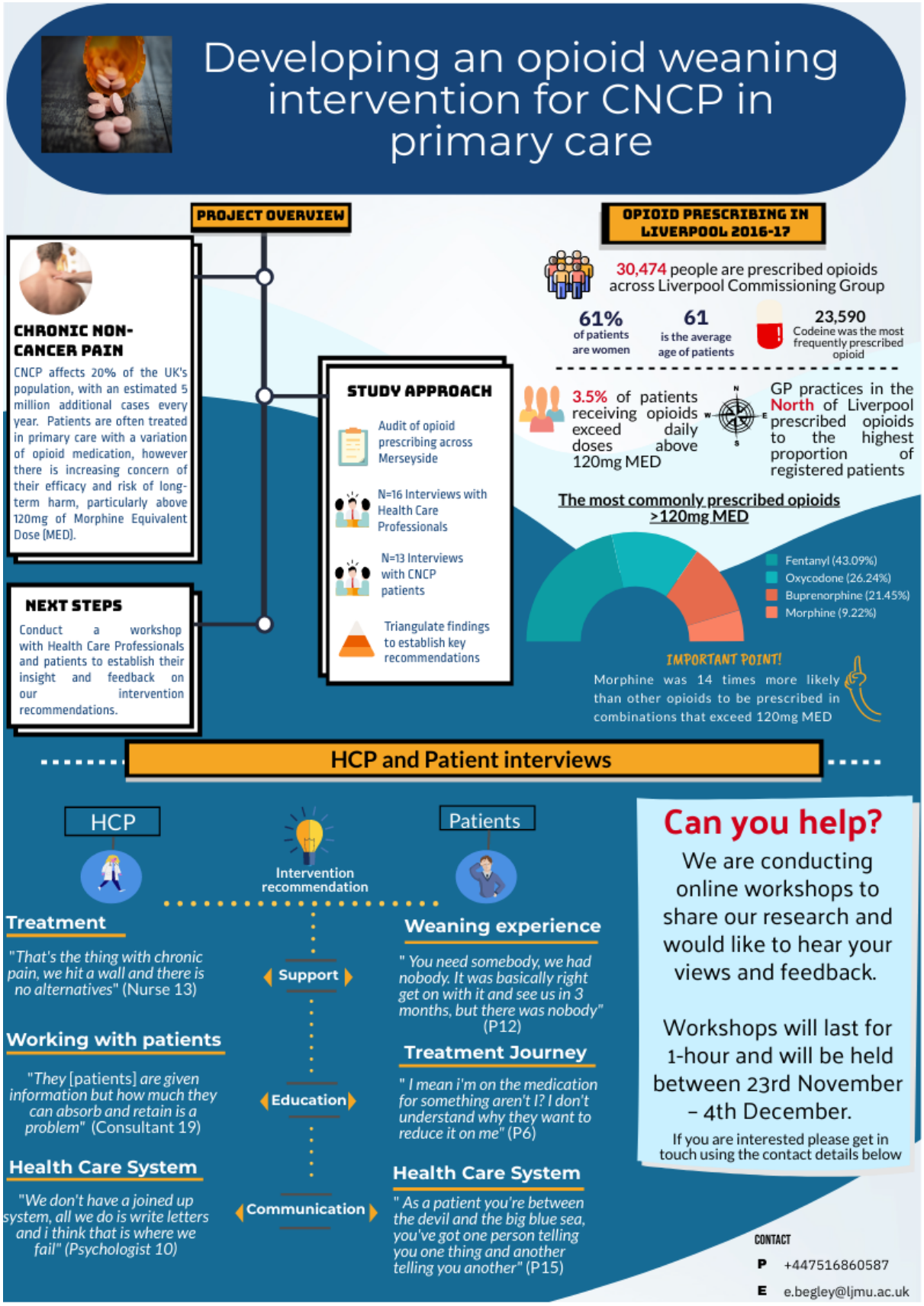
If you have any questions about the workshop, don't hesitate to contact me.

Kind regards,

Emma Begley (BSc, MSc)
PhD researcher

School of Natural Science and Psychology
Byrom Street Campus
Liverpool John Moores University

## APPENDIX 24: Study 3 recruitment poster for HCP Study 3



## APPENDIX 25: Recruitment poster for Patients Study 3

## APPENDIX 26: Participant Information Sheet for HCP Study 3

### LIVERPOOL JOHN MOORES UNIVERSITY
### PARTICIPANT INFORMATION SHEET

**An online workshop investigating recommendations for an opioid weaning intervention for Chronic Non-Cancer Pain patients in primary care**

*You are being invited to be take part in an online workshop as part of a research study. Before you decide whether you would like to take part, it is important that you read this information sheet to understand why the research is being done and what it involves. Please let me know if anything is unclear or if you would like more information.*

- **Meet the research team:**



Emma Begley
PhD Researcher
LJMU


Dr Cathy Montgomery


Dr Helen Poole
School of Psychology, LJMU


Prof. Harry Sumnall
Public Health Institute
LJMU


Dr Bernhard Frank
Pain Consultant
The Walton Centre, NHS


**The purpose of this study**

Online workshops are being conducted to explore Health Care Professional (HCP) views on recommendations for a proposed opioid weaning intervention for Chronic-Non-Cancer (CNCP) patients in primary care. We are specifically interested to know the relevance and feasibility of the recommendations for your everyday practice. The information gathered will be used to refine our recommendations and inform approaches aimed at supporting both HCPs and patients to reduce or discontinue high dose opioid medication.

**You have been invited to take part if you are:**

- Aged 18 years+
- A HCP with current (past 2 years) experience of treating or supporting CNCP patients.
- Available for one hour between the 23rd November – 4th December to take part in an online workshop.

**You cannot take part in this study if:**

- You cannot converse in English.
- Live outside of England.
- Are not involved in the management or care of patients with CNCP.

**IMPORTANT**
Your participation is completely voluntary, and it is up to you to decide whether you take part or not. Once you read this information sheet and had the opportunity to ask any questions, we will ask you to sign a consent form, should you decide to take part. You are however free to withdraw at any time without having to provide a reason. A decision to withdraw will not affect your rights or your professional position.

- **What will happen if I decide to take part?**

First

If you would like to take part, please contact lead researcher (Emma Begley, E.Begley@ljmu.ac.uk) to register your interest in the study and an opportunity to talk through the study procedure and any questions.

Second

We will then ask for your written consent and identify a date between the 16th – 20th November when you are available for an hour. Following this, we will send you out an email link for the pre-agreed date and time providing you with access to join the workshop.

Third

You will be invited to attend one-one-hour workshop, alongside a maximum of 4 other participants (5 participants in total per-workshop). We will allocate you to a workshop based on your availability during the 16th-20th November, depending on study interest alternative dates may be discussed with the lead researcher. Workshops will be conducted online using Microsoft Teams, which you will need access to prior to your scheduled workshop. The format of the workshop will include: an overview of the study, a presentation of the conceptualised recommendations, followed by your participation in an open discussion. The aim of the discussion will be to explore your insights of the acceptability, suitability and feasibility of managing and delivering the intervention recommendations aiming to reduce or discontinue high dose opioid prescriptions among CNCP patients in primary care.

- **Will I be recorded and how will the recorded media be used?**

All workshops will be recorded, this is essential to your participation, but you should be comfortable with the recording process and are free to withdraw at any time. The video recordings made during this study will be used only for analysis. No other use will be made of them without your written permission.

- **Are there any risks / benefits involved?**

There are no intended personal benefits. However, the design of the workshop is co-productive, the nature of this encourages collaboration from those involved and offers the opportunity to gain knowledge and insight from sharing experiences. It is hoped that this work will also help develop improved intervention strategies for opioid weaning among CNCP patients.

There are no anticipated risks associated with taking part in the study. If at any time you feel uncomfortable with the discussions, you can decline to engage or leave the workshop.

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

Yes. The details of your participant will remain strictly confidential. We will not tell anyone you have taken part in the focus group, although there is of course a possibility that another member of the group might recognise you. We will also not name you in any reports or publications and in addition all participants in the focus group will be asked to respect the confidentiality of their fellow participants. If preferred participants can use a pseudonym and turn off their camera upon joining the workshop.

Consent forms and recorded workshops will be encrypted and stored separately on a password-protected computer. No reference will be made to specific participants during data analysis. All personal data will be destroyed after use, less than 3 months after the study ends. Digital recordings will also be securely deleted from any recording equipment used. Research data will be kept securely for up to 5 years and then shredded/erased.

- **What will happen to the results of the research study?**

Once the data has been analysed, it will be used to refine recommendations for an intervention designed to reduce or discontinue prescription opioids among CNCP patients in primary care. A summary of the results will be made available upon request. The results may also be used in future presentations, reports and peer-reviewed publications.

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

The study is organised and funded by Liverpool John Moores University and the Pain Relief Foundation and work is carried out in collaboration with The Walton Centre, Liverpool.

- **Who has reviewed the study?**

The study has received ethical approval from LJMU REC: **20/NSP/040**

- **Contact**

To register your interest in the study or if you have any questions please contact Emma Begley on e.k.begley@2017.ljmu.ac.uk.

**If you have any concerns regarding your involvement in this research, please discuss these with a member of the research team in the first instance. If you wish to make a complaint, please contact researchethics@ljmu.ac.uk and your communication will be re-directed to an independent person as appropriate.**

***Thank you for taking the time to read this information sheet***

## APPENDIX 27: Participant Information Sheet for patients for Study 3

### LIVERPOOL JOHN MOORES UNIVERSITY
### PARTICIPANT INFORMATION SHEET

An online workshop investigating recommendations for an opioid weaning intervention for Chronic Non-Cancer Pain patients in primary care

*You are being invited to be take part in an online workshop as part of a research study. Before you decide whether you would like to take part, it is important that you read this information sheet to understand why the research is being done and what it involves. Please let me know if anything is unclear or if you would like more information.*

- **Meet the research team:**

Emma Begley
PhD Researcher
LJMU

Dr Cathy Montgomery
School of Psychology, LJMU

Dr Helen Poole

Prof. Harry Sumnall
Public Health Institute
LJMU

Dr Bernhard Frank
Pain Consultant
The Walton Centre, NHS

**The purpose of this study**

Online workshops are being conducted to explore patient views on recommendations for a proposed opioid weaning intervention for Chronic-Non-Cancer (CNCP) in primary care. We are specifically interested to know the relevance and feasibility of the recommendations for your everyday practice. The information gathered will be used to refine our recommendations and inform approaches aimed at supporting both Health Care Professionals and patients to reduce or discontinue high dose opioid medication.

**You are invited to take part if you are:**

- Aged 18 years+
- Patients currently or recently (past 2 years) treated with opioids for CNCP.
- Available for one hour between the 23rd November – 4th December to take part in an online workshop.

**You cannot take part in this study if:**

- You have other co-morbid or psychological disorders.
- You cannot converse in English or live outside of England.
- You have cancerous pain.

**IMPORTANT**
Your participation is completely voluntary, and it is up to you to decide whether you take part or not. Once you read this information sheet and had the opportunity to ask any questions, we will ask you to sign a consent form should you decide to take part. However, you are free to withdraw at any time without having to provide a reason. A decision to withdraw will not affect your rights or any future treatment or service you receive.

- **Next steps if you decide to take part:**

Firstly

If you would like to take part, please contact lead researcher (Emma Begley, E.Begley@ljmu.ac.uk) to register your interest in the study and an opportunity to talk through the study procedure and ask any questions.

Second

We will then ask for your written consent and identify a date between the 16th – 20th November when you are available for an hour. Following this, we will send you out an email link for the pre-agreed date and time providing you with access to join the workshop.

Thirdly

You will be invited to attend one-one-hour workshop, alongside a maximum of 4 other participants (5 participants in total per-workshop). We will allocate you to a workshop based on your availability during the 16th-20th November, depending on study interest alternative dates may be discussed with the lead researcher. Workshops will be conducted online using Microsoft Teams, which you will need access to prior to your scheduled workshop. The format of the workshop will include: an overview of the study, a presentation of the conceptualised recommendations, followed by your participation in an open discussion. The aim of the discussion will be to explore your insights of the acceptability, suitability and feasibility of the intervention recommendations aimed at reducing or stopping high dose opioid prescriptions for CNCP.

- **Will I be recorded and how will the recorded media be used?**

All workshops will be recorded, this is essential to your participation, but you should be comfortable with the recording process and are free to withdraw at any time. The video recordings made during this study will be used only for analysis. No other use will be made of them without your written permission.

- **Are there any risks / benefits involved?**

There are no intended personal benefits. However, the design of the workshop is co-productive, the nature of this encourages collaboration from those involved and offers the opportunity to gain knowledge and insight from sharing experiences. It is hoped that this work also help develop improved intervention strategies for opioid weaning among CNCP patients.
There are no anticipated risks associated with taking part in the study. However, talking about your pain and or medication can be somewhat upsetting. If at any time you feel uncomfortable with the workshop discussions, you can decline to engage or leave the workshop at any point. If you feel distressed and would find it useful, the researcher will provide you with information about services that may offer you support.

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

Yes. The details of your participation will remain strictly confidential. Anonymity will be ensured by offering participants to pseudo their name and turn off camera visibility upon joining the workshop. Participants will still be able to hear each other but personal identification will be hidden. Consent forms and recorded workshops will be encrypted and stored separately onto a password-protected computer. No reference will be made to specific participants during data reporting.

All personal data will be destroyed after use, less than 3 months after the study ends. Digital recordings will also be securely deleted from any recording equipment used. Research data will be kept securely for up to 5 years and then shredded/erased.

- **What will happen to the results of the research study?**

Once the data has been analysed, it will be used to refine recommendations for an intervention designed to reduce or discontinue prescription opioids among CNCP patients in primary care. A summary of the results will be made available upon request. The results may also be used in future presentations, reports and peer-reviewed publications.

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

The study is organised and funded by Liverpool John Moores University and the Pain Relief Foundation and works closely in collaboration with The Walton Centre, Liverpool.

- **Who has reviewed the study?**

The study has received ethical approval from LJMU REC: **20/NSP/040**

- **Contact**

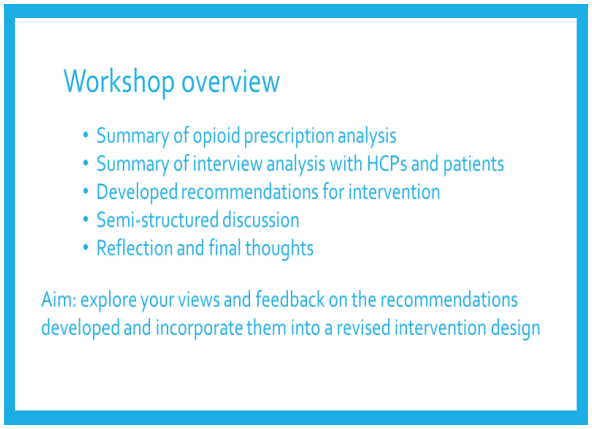
To register your interest in this study or if you have any questions please contact Emma Begley on e.begley@ljmu.ac.uk.

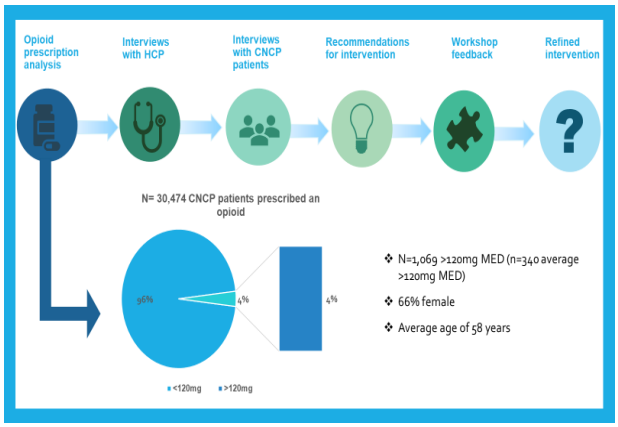
**If you have any concerns regarding your involvement in this research, please discuss these with a member of the research team in the first instance. If you wish to make a complaint, please contact researchethics@ljmu.ac.uk and your communication will be re-directed to an independent person as appropriate.**

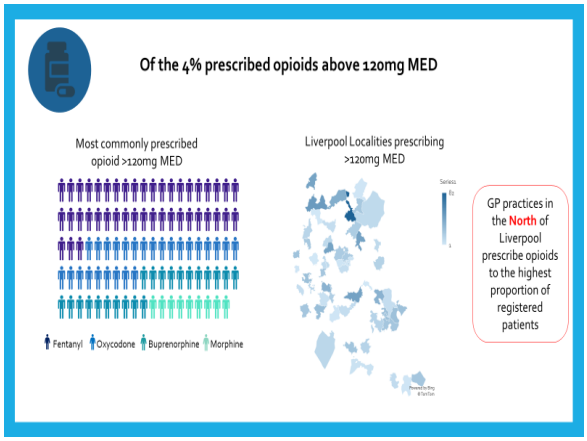
***Thank you for taking the time to read this information sheet***

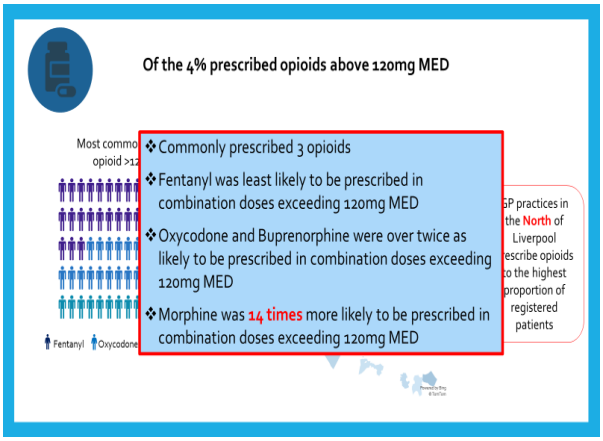
# APPENDIX 28: PowerPoint Presents for HCPs and Patients

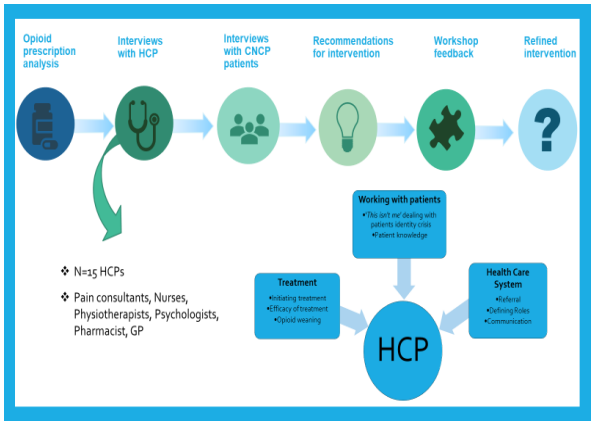


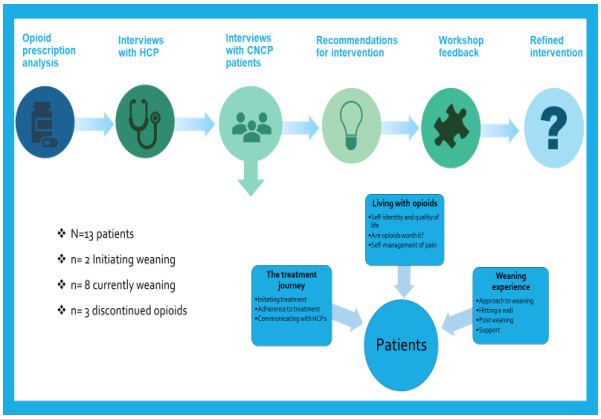


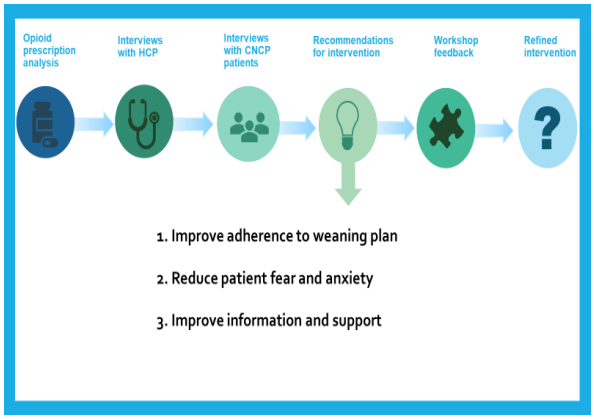



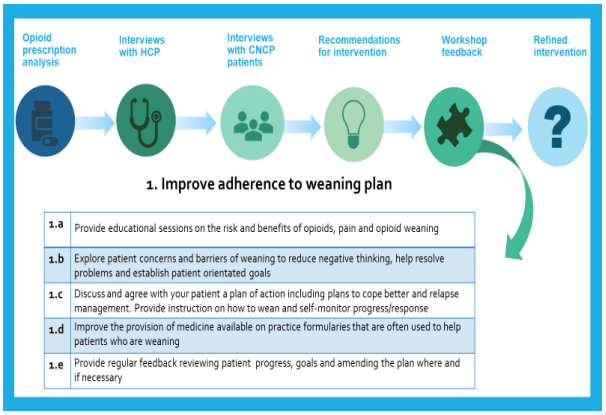



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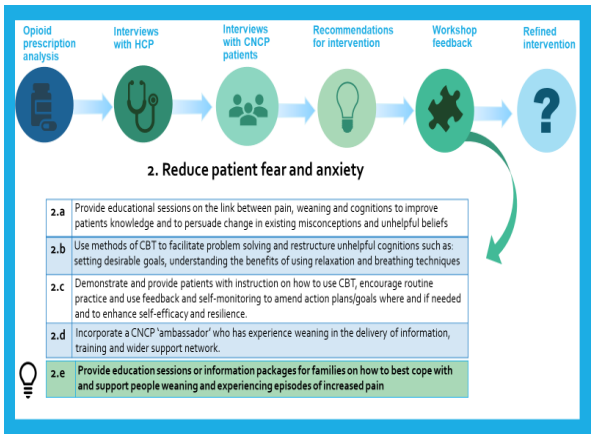


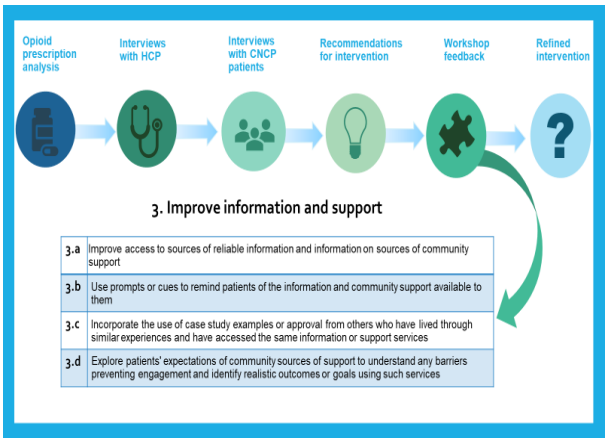


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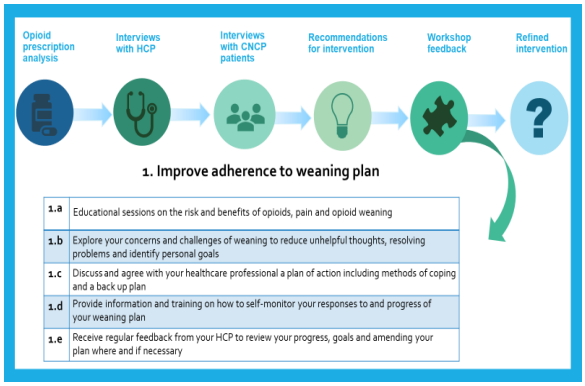


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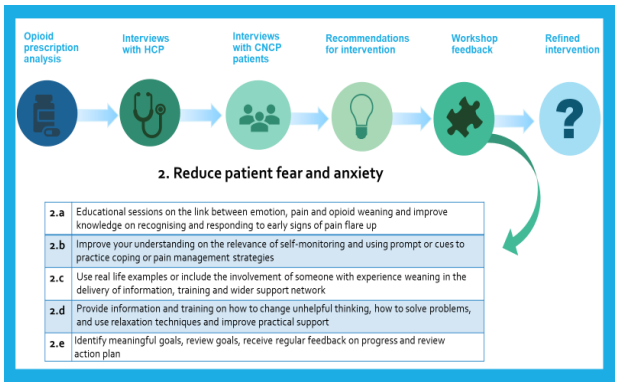


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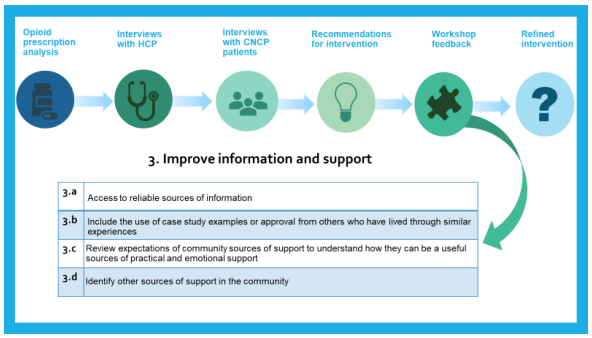


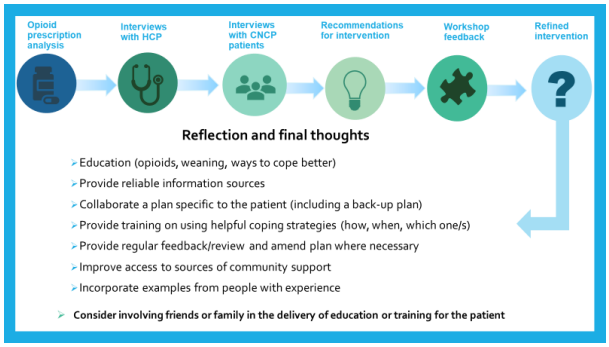


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