Enhancing the role of UK community pharmacy staff in the prevention of prescription and over-the-counter opioid misuse: developing intervention strategies using established behaviour change models

A thesis submitted in partial fulfilment of the degree of Doctor of Philosophy

By

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Abstract

Background:

Opioids are associated with half of all registered drug poisoning deaths in the UK, yet the rate at which opioids are prescribed remains high. Furthermore, over-the-counter (OTC) opioids can be obtained from pharmacies without a prescription. Community pharmacists have a role to play in preventing opioid misuse since they are responsible for dispensing opioids to patients. This study was aimed at developing strategies for intervention to help enhance community pharmacists' roles in the prevention of prescription and OTC opioid misuse.

Methods:

The research involved three studies- a systematic review and two qualitative research. The systematic review was carried out according to PRISMA guidelines and set out to review literature on the barriers and facilitators of community pharmacists' involvement in prescription and OTC opioid misuse prevention. The Qualitative studies were carried out by conducting one-to-one interviews with 36 participants (Study 2: 28 community pharmacy staff, Study 3: eight policymakers) via Zoom. The Capability, Opportunity, Motivation, and Behaviour (COM-B) model which is used for identifying factors that influence behaviour, and the Behaviour Change Wheel (BCW) model used in developing strategies for intervention were used in classifying identified themes. For the systematic review, database search in Ovid MEDLINE, Embase, Scopus, Web of Science, CINAHL, and APA PsycINFO were carried out and narrative synthesis utilising the COM-B model was used for analysis. Data obtained from the qualitative studies were thematically analysed.

Findings:

Ten articles were included in the review. Barriers and facilitators identified were classified as capabilities (knowledge and skill), opportunities (such as relationship with prescribers, time) and motivation (pharmacists' attitude). Themes identified from the pharmacy staff interviews were mapped to the COM-B model to identify 22

potential areas for intervention while 13 Behaviour Change Techniques (BCT) to target each of these areas were identified from all three studies using the BCW model. These enabled the development of strategies that could help enhance the potential targets, thus enhancing community pharmacists' roles in the prevention of opioid misuse. These strategies are education and training, collaboration with GPs, change in OTC opioid regulatory practices, and support from commissioners.

Conclusion:

This research has identified strategies for intervention that could help to enhance community pharmacists' roles in the prevention of opioid misuse. This finding has provided a baseline for future research on the development of feasible, effective, and cost-effective interventions following the Medical Research Council (MRC) framework.

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List of abbreviations

Abbreviation	Term
ACT	Accredited Checking Technicians
API	Active Pharmaceutical Ingredient
APTUK	Association of Pharmacy Technicians UK
AUR	Appliance Use Review
BCT	Behaviour Change Techniques
BCTTv1	Behaviour Change Techniques Taxonomy version 1
BCW	Behaviour Change Wheel
BMI-MTM	Brief Motivational Intervention-Medication Therapy Management
CCGs	Clinical Commissioning Groups
CD	Controlled drugs
CHM	Commission on Human Medicine
COM-B	Capability, Opportunity, Motivation and Behaviour
COVID-19	Coronavirus disease 2019
CPCF	Community Pharmacy Contractual Framework
CPCS	Community Pharmacist Consultation Service
CPD	Continuing Professional Development
GP	General practitioner
GPhC	General Pharmaceutical Council
HAT	Heroin Assisted Treatment
HCP	Health care professionals
HCV	Hepatitis C Virus
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
ICB	Integrated Care Boards
ICS	Integrated care systems
IPA	Interpretative Phenomenological Analysis
IPE	Interprofessional education
JBI	Joanna Briggs Institute
LPC	Local Pharmaceutical Committee
MCA	Medicines counter assistant
MESH	Medical Subject heading
MUR	Medicine Use Review
NENCICB	North East North Cumbria Integrated Care Board
NHS	National Health Service
NMS	New Medicine Service
NSAIDs	Non-steroidal anti-inflammatory drugs
OTC	Over-the-Counter

P	Pharmacy medicines
PCN	Primary care networks
PDMP	Prescription Drug Monitoring Programmes
PMR	Patient Medication Record
POMI	Prescribed Opioid Misuse Index
PQS	Pharmacy Quality Scheme
PRISMA	Preferred Reporting Item for Systematic Reviews and Meta-Analysis
PROSPERO	International Prospective Register of Systematic Reviews
PSNC	Pharmaceutical Services Negotiating Committee
PWID	People who inject drugs
ROOM	Routine Opioid Outcome Monitoring
RPS	Royal Pharmaceutical Society
RTPM	Real time prescription monitoring
S/NVQ	Scottish/National Vocational Qualification
SAC	Stoma Appliance Customisation
SBIRT	Screening, Brief Intervention and Referral to Treatment
SDCRs	Supervised Drug Consumption Rooms
SMR	Structured Medication Review
TA	Thematic analysis
TARGET	Treat Antibiotic Responsibly, Guidance, Education and Tools
UK	United Kingdom
USA	United States of America
UTI	Urinary Tract Infection

Declaration

I hereby declare that this research was carried out by me, Ogochukwu Fidelia Offu, on registration for the Doctor of Philosophy (PhD) degree at Newcastle University. I certify that this work has not been previously submitted, in part or in whole, for the award of any other degree in any university or tertiary institution of learning. I diligently prepared this thesis in line with 'Newcastle University's guidelines for the submission and format of theses' and is not based on collaborative research. To the best of my knowledge, I have duly referenced all resources that have been used in this research and were previously published or written by another person.

Note from the author

The terms ‘pharmacists’ and ‘pharmacy staff’ are used interchangeably in the thesis. The terms ‘pharmacy’ and ‘pharmacies’ refer to the community pharmacy while ‘pharmacists’ and ‘pharmacy staff’ refer to staff that work in community pharmacy.

The term ‘drug clinics’ was adopted in this research and refers to drug rehabilitation centres, drug addiction treatment centres and similar centres where persons that are addicted to opioids are treated.

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Chapter 1 Introduction

1.1 Introduction

This doctoral thesis presents research that comprises a systematic review and two qualitative studies. The research provides intervention strategies that could enhance community pharmacists' roles in the prevention of prescription and over-the-counter (OTC) opioid misuse. In this chapter, I present a brief background to this research, give an overview of opioid misuse prevention services that could be carried out by community pharmacists, explain community pharmacy practice in the United Kingdom (UK) and the National Health Service (NHS) long term plan regarding community pharmacy, describes community pharmacy stakeholders, and details the Royal Pharmaceutical Society (RPS) recommendation for pharmacists' roles in the provision of opioid misuse. The chapter ends with a summary of the chapter and a structure of the thesis.

1.2 Background to the study

1.2.1 Opioid misuse

Opioids are a group of drugs that are obtained from the opium poppy plant, scientifically known as Papaver somniferum (Alcohol and Drug Foundation, 2023; National Institute on Drug Abuse, 2021b). Opioids can be obtained either legally or illegally worldwide. Examples of opioids that can be obtained legally in the UK are prescription opioids which require presenting a prescription written by a certified health professional to a pharmacist who dispenses the medication. Examples of prescription opioids are morphine, fentanyl, pentazocine, codeine, hydrocodone, oxycodone, pethidine, and tramadol. Another group of opioids that can be obtained legally is those that can be obtained OTC from pharmacies and sold under the supervision of the pharmacist, also called pharmacy medicines (P) (Medicines and Healthcare products Regulatory Agency, 2023).

The OTC opioids include cough syrups containing codeine, and paracetamol tablets with codeine. Prescription and OTC opioids are medically used as analgesics and

cough suppressants. Misuse of opioids, either when overdosed or taken for a long period, can cause dependence, addiction, respiratory depression, withdrawal symptoms, coma and death (National Institute on Drug Abuse, 2021a; U.S. Department of Justice, 2022). People can also obtain them illegally to help relieve pain if they feel that their prescription is not sufficient. Opioids are also obtained illegally for recreational purposes, to achieve a state of intense pleasure or euphoria, also known as a 'high'. The procurement of prescription opioids through illegal means is made possible by the diversion of potent opioids such as fentanyl, oxycodone, methadone, and hydrocodone (American Society of Addiction Medicine, 2016). Diversion could occur at any point of supply of opioids from the manufacturer to wholesaler, from wholesaler to pharmacy, and from pharmacy to patient (Department of Health and Human Services, 2016). An opioid that is generally obtained illegally and has no medicinal value is heroine (American Society of Addiction Medicine, 2016).

Misuse of drugs is defined as the use of drugs for non-medical or illegal purposes (World Health Organization, 1994). Misuse also includes the use of a prescription in a different way from the directions given by the prescriber, taking another person's prescription, even if it is to treat a medical condition, and taking the medication to feel intense pleasure (National Institute on Drug Abuse, 2021c; United Nations Office on Drugs and Crime, 2011). Therefore, opioid misuse is the use of opioids in a different way than it was prescribed, use of another person's medication and use for non-medical purposes.

The definition stated by ICD-11 and DSM V were not used in this study because their definition was that of 'opioid use disorder' and was not for 'opioid misuse' (WHO-FIC Foundation, 2024). Their definition was focused on the pattern and consequences of opioid misuse such as harm to the physical and mental state of the person who uses opioids, as well as physical harm inflicted on others by the person who uses opioids (Matone *et al.*, 2022). Their definition was also concerned with opioid intoxication, dependence and addiction (WHO-FIC Foundation, 2024). My focus in this thesis includes seeking ways of preventing the level of opioid use that could lead to the

patterns, consequences and outcomes that characterises opioid use disorder. This is why I used the definition of opioid misuse provided by the United Nations Office on Drugs and Crime, 2011 and National Institute on Drug Abuse, 2021. However, when describing the scale of the problem of prescription and OTC opioid misuse, definition by the ICD 11 was used to explain what drug misuse deaths means.

It is also important to state that though the terms drugs and medicines are often used interchangeably, they are not the same. Drugs are chemical substances that change the physiological process, and are used to prevent, diagnose, control, and treat diseases (European Medicines Agency, 2024). Drugs could also be described as active pharmaceutical ingredient (API). Medicines contain API which is the active component and excipients which are the non-active components (Reker *et al.*, 2019). While the API produces the desired pharmacological action, the excipients which include diluents, binders, colour, flavours and preservatives, enables the stability of the drug, improves compliance of the patient and enhances delivery of the drug (Kumar *et al.*, 2022). Medicines can also be defined as drugs that are in their formulated state and have specific dose and dosage forms which could be used to prevent, diagnose, control and treat diseases (Reker *et al.*, 2019).

1.2.2 Acknowledging the North American Opioid Epidemic

There is an opioid epidemic in the US and Canada (WHO-FIC Foundation, 2024). The main reason for this epidemic was the promotion of potent prescription opioids by pharmaceutical industries in the 1990s. These opioids were widely used for the treatment of chronic non-cancer pain and became widespread due to inadequate regulation of medicines at the time (Ciccarone, 2019). Its extensive use led to high rates of prescription opioid misuse, overdose, and addiction. In response to the high prescription opioid addiction rates, the heroine and synthetic opioids market was propelled, resulting in an epidemic characterised by higher rates of morbidity and mortality arising from prescription opioid misuse (Brown and Morgan, 2019). This implies that the indiscriminate use of prescription opioids could lead to chronic forms of opioid misuse such as opioid addiction in the long run. Poor management of opioid

addiction could result in overdose, drug poisoning, and death (World Health Organisation, 2023c). Harm reduction services are useful in preventing progression of opioid addiction and its deleterious effects (National Institute on Drug Abuse, 2022). This informed my decision to include harm reduction as an intervention in this study.

In the UK, the scale of opioid misuse is not as large as that of the USA and cannot be described to be an 'opioid epidemic', however, there are public health concerns regarding the increasing rates of morbidity and mortality due to opioid misuse (Roberts and Richards, 2023). There are also concerns regarding the increased rate at which opioids are prescribed and the rising number of people receiving treatment for opioid misuse (The Lancet Regional Health –, 2023).

1.2.3 Opioid misuse in the UK: Statistics

Globally, the number of people who use drugs for illegal reasons is about 296 million, estimated to be 5.8% of people aged 15-64 years (World Health Organisation, 2023b). Of this number, about 60 million use opioids (World Health Organisation, 2023b). There were approximately 600,000 deaths due to drug use worldwide in 2019. Around 80% of these mortalities are connected to opioid use with opioid overdose being the leading cause of death (World Health Organisation, 2023b).

The UK has the highest number of reported opioid users in Europe (Public Health England, 2021d). Drug misuse was implicated in two thirds of all registered drug poisoning deaths in the UK in 2020 (Office for National Statistics, 2021). Opioids were linked to approximately half of these deaths (Public Health England, 2021d).

1.2.4 Scale of the problem of prescription and OTC opioid misuse

Estimates of drug misuse in England and Wales published by the Office for National Statistics (ONS) are those of illicit drugs (Office for National Statistics, 2023c). Hence, no information relating to prescription and OTC opioid misuse which this thesis focuses on, was obtained from this publication. In addition, the proportion of deaths that result from prescription and OTC opioids use are not clearly stated by the

Office for National Statistics (ONS) (Office for National Statistics, 2021). This is because drug-related death rates reported by the ONS are joint percentages for deaths due to all opioids. There are no separate records for drugs obtained legally or illegally (Office for National Statistics, 2021). Information closely linked to prescription and OTC opioid misuse rates in the UK was obtained from the ONS publication titled 'Deaths related to drug poisoning in England and Wales: 2022 Registration' (Office for National Statistics, 2023b). In this publication, rates of drug misuse were estimated in terms of deaths that were associated with the use of drugs, otherwise known as drug related deaths, though statistics in this report is for both drugs obtained legally and illegally (Office for National Statistics, 2023b). The Faculty of Pain reiterates that though statistics on drug misuse deaths are published annually by the ONS, there are no separate statistics on whether the drug was obtained by prescription, OTC or illicitly (Faculty of Pain Medicine, n.d.). The Faculty of Pain also states that drug related death rates mirror their prescribing rates (Faculty of Pain Medicine, n.d.). Drug related deaths that were used in this thesis were drug poisoning deaths and drug misuse deaths as illustrated by the ONS (Office for National Statistics, 2023b)

According to the ONS, drug poisoning deaths must have a relevant International Classification of Diseases (ICD) code recorded as its underlying cause, based on conditions stated by the certifier and registered on the certificate (Office for National Statistics, 2023b). For drug misuse deaths, its underlying cause is drug abuse or dependence which is defined by the ICD11 as a mental and behavioural disorder that is due to the use of any substance that is controlled under the Misuse of Drug Act 1971 (Office for National Statistics, 2023b). Opioids are controlled under this Act and disorders due to the use of opioids are classified as 6C43 in the ICD11 (WHO-FIC Foundation, 2024).

In England and Wales, drug related deaths are on the rise and opioids are most frequently implicated in this mortality. Deaths due to drug poisoning in 2022 was 4,907 which corresponds to 84.4 deaths per million people. This rate is currently the highest when compared to other rates recorded since 1993 (Office for National Statistics, 2023b). Drug misuse accounted for 3,127 drug poisoning deaths which is

equivalent to 53.9 deaths per million people. Drug misuse also accounts for 63.7% of drug poisoning deaths. This rate increased to 85.3% when drug poisoning deaths that had no recorded drug information were excluded. Opioids were involved in about half, equivalent to 46.1% of all drug poisoning deaths in England and Wales (Office for National Statistics, 2023b). The region with the highest rates of drug misuse deaths in England and Wales is the North East with a rate of 133.9 deaths per million while the region with the lowest rate is the East of England with a rate of 37.2 deaths per million.

Based on data obtained from NHS England, opioid prescribing rates per patient in England are rising. The prescribing rates for high-dose opioids decreased by 4.8% in the period between 2017/2018 and 2018/2019, while there was a decrease of 7% between 2017/2018 and 2020/2021 (NHS England, 2023c). The number of patients that were prescribed high-dose opioids did not appear to have increased between 2017/2018 and 2020/2021. However, there was no decrease in the average number of high-dose opioid medicines prescribed per patient with records stating an increase of 35.6% and 37.5% in 2019/2020 and 2020/2021 respectively, when compared with high-dose opioid prescription rates per patient in 2017/2018 (NHS England, 2023c). On the other hand, the prescribing rate of low-dose opioids which are used by nearly all (99%) patients who use opioids seems to be increasing with a 3.5% and 4.3% rise recorded in 2018/2019 and 2020/2021 respectively (NHS England, 2023c). The average number of low-dose opioid medicines prescribed per patient also increased from 5.8 to 6.6 between 2016/2017 and 2019/2020. Despite the introduction of the most current clinical guideline for the treatment of chronic primary pain by the National Institute of Health and Care Excellence (NICE), which advises against the use of opioids, 47% of people with chronic pain still report that they were prescribed opioids (NHS England, 2023c).

There are also concerns pertaining to the supply of OTC opioids. Examples of such opioids are co-codamol which contains both codeine and paracetamol and is the second most frequently dispensed analgesic after paracetamol (Guirguis, 2023b). OTC opioids could be obtained from multiple community pharmacies without any

restriction. This could contribute to a rise in the number of persons who use and ultimately misuse opioids.

In terms of treatment of people that misuse prescription and OTC drugs, there was a 38% increase in treatment rates between 2009 and 2016. The proportion of persons receiving treatment for the misuse of opioids decreased from 65% in 2008 – 2009 to 54% in 2019 – 2020 (Burkinshaw *et al.*, 2017; Black, 2021). There was a slight decrease in the number of people in treatment for opioid use when comparison was done between the year 2020/2021 and 2021/2022. The number of people in treatment for opioid use in 2020/2021 was 140,863 while the number of people in treatment in 2021/2022 was 140,558 (Office for Health Improvement and Disparities, 2023). About half of all the adults in treatment for drug misuse were there due to opioid use problems. This group of persons, accounted for the largest group of drug users in treatment (Office for Health Improvement and Disparities, 2023). In addition, the number of persons who misuse opioids and complete treatment is fewer while an increased number of persons are dying while receiving treatment for opioid misuse (Burkinshaw *et al.*, 2017; Black, 2021). Furthermore, funding for addiction services has decreased, access to chronic pain treatment centres is inadequate and specialist pain services fell below the recommended standards on the most recent assessment in England and Wales between 2010 – 2014 (Price *et al.*, 2018).

Collectively, this evidence shows that the rate at which opioids are being misused remains high and that services focusing on opioid prevention are relevant to reduce the rates.

1.2.5 Populations affected by Opioid Misuse

Several factors have been associated with opioid misuse. Examples of such factors are age, gender, socioeconomic status, chronic illness or disabilities, and substance use and mental health (Faculty of Pain Medicine, n.d.).

The WHO states that people of younger age have higher rates of opioid misuse when compared with older persons (World Health Organisation, 2023a). In the UK, studies

have also shown that younger persons are more likely to develop opioid misuse than their older counterparts (Faculty of Pain Medicine, n.d.; Cragg *et al.*, 2019). Data from the Crime Survey for England and Wales showed that analgesic use was more common in younger persons than in older persons, which was equivalent to 7.2 % in persons aged 16 to 24 years when compared with 4.9% in persons aged 25 to 29 years (Faculty of Pain Medicine, n.d.). Similar findings were obtained in a systematic review of studies that reported risk factors to opioid misuse (Cragg *et al.*, 2019). In this study, it was reported that younger patients were twice as likely to misuse opioids when compared with older patients. It was also reported that the likelihood of young patients who were naïve about opioid use were five times higher than in older patients (Cragg *et al.*, 2019).

In terms of gender, males were more at risk of opioid misuse than females. In the UK, the rate of drug misuse in 2022 was 76.7 deaths per million while rates in females was 31.9 deaths per million (Office for National Statistics, 2023b).

There are varying findings regarding the relationship between opioid misuse and the use of substances. The Faculty of Pain reports that the misuse of prescription analgesic is less likely to be associated with the use of substances, specifically, alcohol. They observed that people who drank alcohol three or more days in a week and reported misuse of prescription analgesic were 4.6% when compared with 5.5% of people who reported less alcohol intake (Faculty of Pain Medicine, n.d.). They concluded that these rates were similar and hence there was no association between the use of prescription analgesics and the level of alcohol intake (Faculty of Pain Medicine, n.d.). Unlike these reports, an observational study carried out by Jani et al using UK primary care data stated that a history of substance abuse and alcohol abuse were associated with long term opioid use (Jani *et al.*, 2020c). Similar to the findings from Jani et al, a systematic review revealed that patients who had previously used or misused non opioid substances such as alcohol, tobacco and benzodiazepines were 2 to 4 times more likely to use or misuse prescription opioids when compared to persons who had not used or misused non opioid substances (Cragg *et al.*, 2019). Just as opioid misuse is most prevalent in the Northeast of England, alcohol misuse is also the

highest in the North East (Department of Health and Social Care, 2024). This could be an indicator that there is an association between opioid use and alcohol use.

It has also been reported that there is a relationship between having a mental health illness and the risk of misusing opioids. People with mental health illnesses have higher risk of misusing opioids when compared with patients who do not have mental health disorders. In countries like Canada, restrictive measures have been put in place to help limit prescribing opioids to patients with a history of mental illness or substance misuse while in the USA, extra monitoring of these group of patients should be carried out by health practitioners while using prescription opioids (Cragg *et al.*, 2019). Similarly, a 5-year prospective study of people who were prescribed opioids for chronic non cancer pain showed that opioid misuse was associated with history of mental health illnesses and substance use (Campbell *et al.*, 2020).

In addition, people with chronic illnesses or disabilities were more likely to have misused prescription analgesics compared to persons without chronic illnesses or disabilities. Among people with chronic illnesses or disabilities, 8.5% reported that they had used prescription analgesics while 4.8% of person without illnesses or disabilities reported that they had used prescription analgesics (Faculty of Pain Medicine, n.d.). Hence, persons with chronic illnesses could be more susceptible to misuse of prescription analgesics such as opioids.

It has also been established that Adverse Childhood Experience (ACE) were associated with opioid misuse. A survey carried out among persons seeking opioid detoxication in a treatment facility in the USA revealed that persons with ACE are more likely to initiate opioid use at an earlier age (Merrick *et al.*, 2020), inject drugs and have a lifetime overdose (Stein *et al.*, 2017). Regarding other forms of trauma, such as Post Traumatic Stress Disorder (PTSD), studies have shown that the prevalence of opioid misuse among persons with PTSD was higher than in persons without PTSD (Bilevicius *et al.*, 2018; Bernardy and Montaño, 2019). Intimate partner stress and sexual assaults are also forms of trauma that have been associated with opioid misuse (Williams *et al.*, 2020).

Regarding trends of opioid misuse in relation to socioeconomic status, it has been shown that there is a relationship between opioid misuse and the socioeconomic status of the population. In a quantitative study carried out by Chen et al, it was found that lower socioeconomic status such as household income, unemployment and education level was associated with higher opioid utilisation (Chen *et al.*, 2019). An econometric study carried out by Vandross et al, showed that there appears to be an association between persons who are unemployed and opioid prescribing data obtained from GP practices in England from 2011- 2017 (Vandoros, Gong and Kawachi, 2020). A retrospective observational study carried out with official government data from 2010 to 2014 showed that there were higher opioid prescribing rates in areas of high deprivation in the North of England (Jani *et al.*, 2020a). The WHO has also stated that people with low socioeconomic status have higher chances of misusing opioids (World Health Organisation, 2014).

The current care pathway for people who are dependent on prescription and OTC opioids have various requirements, necessitating a multidisciplinary, multi-agency approach to treatment. Access to a multidisciplinary team is advised for the medical, social, and psychological care necessary to manage opioid dependence. The person who misuses opioids undergoes an initial general examination in primary care with the aim of confirming opioid dependence, identifying and addressing related medical, mental health, or social issues (Phillips, Ford and Bonnie, 2017). The local safeguarding policy must be implemented if there is a risk of harm to a child, young person, or vulnerable or an at-risk adult. Referrals to specialised drug services are made when opioid dependence is detected; depending on local arrangements, some general practices may offer an integrated public health commissioned service for persons who misuse drugs (National Institute for Health and Care Excellence, 2024b). Guidance on overdose prevention, driving laws, harm reduction, and vaccinations are then put in place (National Institute for Health and Care Excellence, 2024a). Pharmacological and psychological therapies are used in specialist care of people who are dependent on opioids with the goal of enhancing the patient's general health, resilience, wellbeing and reduce chances of relapse (Department of Health, 2017b).

During the first evaluation, the goals of treatment, the person's motivation to change, availability of family and social support, psychosocial requirements, and treatment preferences of the individual are determined. These form the basis of person-centred therapy (National Institute for Health and Care Excellence, 2024b). The goal of psychosocial therapies, which are a crucial component of treatment for opioid misuse, is to foster resilience and encourage behavioural changes connected to opioid use (Department of Health and Social Care, 2021c).

A suitably qualified prescriber should supervise the initiation of treatment for opioid dependence. Options for drug treatment for opioid dependency include the first line treatment which is opioid agonist substitution therapy (OST), which includes methadone and buprenorphine (Public Health England, 2021c). Other treatment options are treatment for opioid-assisted withdrawal and maintenance therapy with opioid antagonists (National Institute for Health and Care Excellence, 2024b). Since the danger of death is highest during the commencement and titration of pharmacological treatment, the patient should see their specialist team every day. Subsequently, they should see them at least every two weeks, and if stable, at least once a month, or less frequently if the individual's conditions are very stable (Borders Addiction Service, 2021).

Buprenorphine and methadone hydrochloride are used as substitution treatments for opioid dependence. Commencement of opioid substitution therapy with a brief period of stabilisation, should precede either maintenance therapy or a withdrawal regimen (National Institute for Health and Care Excellence, 2024a). In addition to improving health and reducing drug use and criminal activity, maintenance treatment helps the individual to attain stability (Department of Health and Social Care, 2021c). Therapy should be evaluated frequently to make sure the patient is still benefiting. During initiation and titration of opioid substitution therapy, the patient should be informed of the warning signals of toxicity, and the physician should also monitor the individual to identify these signs (Public Health England, 2021a).

After stabilisation with buprenorphine or methadone hydrochloride, a withdrawal regimen should only be commenced after careful consideration. Enforced withdrawal increases the danger of relapse and eventual overdose due to loss of tolerance, and it is ineffective for long-term abstinence (East London NHS Foundation Trust, 2022). Complete opioid withdrawal often takes up to 12 weeks in community settings and up to 4 weeks in an inpatient or residential setting. The withdrawal regimen should be discontinued, and maintenance therapy should begin at the optimal dosage if abstinence is not attained, illegal drug use is resumed, or the patient is unable to cope with withdrawal. After a successful withdrawal treatment, at least six months of additional support and monitoring are necessary to sustain abstinence (Public Health England, 2021b).

It could be necessary to use adjunctive therapy to treat the symptoms of opioid withdrawal. Diarrhoea can be treated with loperamide hydrochloride, stomach cramps with mebeverine hydrochloride, headaches and muscle aches with paracetamol and non-steroidal anti-inflammatory medications, and nausea or vomiting with metoclopramide hydrochloride or prochlorperazine (Department of Health, 2017b). Muscle aches brought on by methadone hydrochloride withdrawal may be eased with topical rubefacients. Short-acting benzodiazepines or zopiclone may be administered to treat insomnia, however due to the possibility of addiction, these medications should only be used for a few days at a time. Specialist advice should be sought if agitation or anxiety experienced by the individual is severe (Tees Esk and Wear Valleys NHS Foundation Trust, 2018).

By reducing the rise in adrenergic neurotransmission that happens during opioid withdrawal, lofexidine hydrochloride may help reduce some of the physical symptoms of the withdrawal. As an adjunct to opioid substitution therapy, lofexidine hydrochloride may be taken concurrently with the opioid substitute or during its withdrawal (Lingford-Hughes *et al.*, 2012). As an alternative, patients with mild or uncertain dependence and those with a brief history of drug use may be prescribed lofexidine hydrochloride in place of an opioid substitute (Department of Health, 2017b).

Opioid-receptor antagonists like naloxone hydrochloride can be provided to patients who are opioid dependent in event of an accidental overdose. Those who are addicted to opioids have withdrawal symptoms after using an opioid receptor antagonist such as naltrexone hydrochloride. Naltrexone hydrochloride is prescribed to prevent relapse in people who were previously opioid-dependent. A suitably qualified prescriber should supervise the initiation of treatment for opioid dependence (National Institute for Health and Care Excellence, 2024a).

In the UK, general practitioners (GPs) and drug and alcohol services have separate roles intended to offer comprehensive care for individuals with drug misuse problems, but they function at different levels and focus on various areas. General practitioners have an important role in the initial detection and treatment of drug misuse, whereas drug and alcohol services offer specialised care and support for individuals experiencing addiction problems (Royal college of psychiatrists and Royal college of general practitioners, 2012).

GPs are often the first health care professional to be contacted by people who misuse drugs. They assess and screen the patients in order to identify whether the patient is misusing drugs and their extent of involvement. GPs develop care or treatment plans for patients who are identified to be misusing drugs, and these plans are reviewed regularly (Department of Health, 2017b). The risk that the patient poses to their family including children should be assessed to determine if child protection services or other safeguarding measures should be put in place (NHS England, 2024b). Patients that require more intensive treatment are referred to drug and alcohol services by GPs. GPs also offer comprehensive care to meet overall health needs of the patients, including co-morbid conditions, like mental health disorders (Royal college of psychiatrists and Royal college of general practitioners, 2012). In addition, GPs screen for infections and offer vaccination against or offer other preventive measures such as Hepatitis A, B, C and HIV. In addition, GPs offer support to patients who are undergoing treatment or recovery (Department of Health, 2017b).

Drug and alcohol services offer specialised treatment programmes such as counselling patients, provision of therapy and rehabilitation services. They also provide detoxification programmes that help people who are addicted to safely withdraw from the drug (Office for Health Improvement and Disparities, 2017). Educational services that are focused on drug misuse prevention in the local community are also offered. Depending on the individual's case, other departments such as social support, employment and housing could be invited in the management of the individual. They could also provide care after the individual has undergone treatment so as to prevent relapse and maintain recovery (Home Office, 2024).

Drug and alcohol services are commissioned by group of bodies comprising the ICBs, the UK Health Security Agency (UKHSA), and local authorities (Office for Health Improvement and Disparities, 2022a). Gaps in commissioning experienced by these bodies include a lack of clinical leadership and expertise in public health (British Medical Association, 2024). This signifies that members of the commissioning body might lack the necessary skills and expertise to carry out their commissioning roles (British Medical Association, 2024). Commissioning bodies such as ICBs also experience challenges with making effective decisions regarding the planning of services because of the difficulty they encounter while trying to access and share patient's information (NHS Confederation, 2023; Jager *et al.*, 2023). There are problems with allocating resources to meet diverse population needs, due to the challenges of balancing limited budgets (Bliss, Williamson and Alayo, 2024). Due to lack of sufficient engagement with local communities, ICBs could lack the capacity to commission services that meet the needs that the community actually requires (Charles, 2022; Integrated Care System, 2022). In addition, ICBs experience challenges with the monitoring and evaluation of already commissioned services which could impact adequate decision making (Lowe *et al.*, 2024). Furthermore, determining health inequalities within communities could also be cumbersome for the commissioning body (NHS Confederation, 2023).

1.3 General overview of opioid misuse prevention services that can be carried out in community pharmacies

The opioid misuse prevention services referred to in this research consist of services that are aimed at dissuading people from going into the practice of misusing opioids, such as offering education and information. These services also aim to promote the safe treatment of service users who are prescribed opioids, treating people who are already addicted to opioids, and preventing them from harm. Pharmacy services that will enable community pharmacists to achieve the above aims is the focus of this research. The pharmacy-based services will be classified into four categories: i) education or information provision; ii) screening, identification, and referral; iii) proper storage and disposal of prescription opioids; and iv) harm reduction services (Bach and Hartung, 2019; Kosobuski *et al.*, 2022). Each of these activities will be described sequentially below.

i. Education and information provision

This category includes all services that involve providing information or sharing knowledge about opioids (Bach and Hartung, 2019; Kosobuski *et al.*, 2022). These services are targeted at all people, especially those who are at risk of opioid misuse, such as young people, individuals who live in areas where opioid misuse rates are high, and people who would be using prescription opioids long-term. Education or information provision is part of the primary role of community pharmacists, which could be utilised to prevent people from misusing opioids.

The education could be targeted to the audience. For young people, education or information provision is often carried out through public health awareness programmes. Health care staff in the hospital, clinic, or pharmacy could provide advice, education, and counselling to individuals on long-term opioid prescriptions. Education and health awareness campaigns could also target people living in areas with high opioid misuse rates.

People who are on opioids need education about the dangers of using opioids differently from how they were prescribed by the general practitioners (GP) or

recommended by the pharmacist. An increased awareness is needed about the adverse effects of taking overdoses of opioids and taking them for a long period of time (Public Health England, 2015). Dispensing the medication to the service user gives pharmacist a valuable opportunity to offer advice and counselling regarding their medication.

ii. Screening, identification and referral of at-risk patients

Screening and identification of at-risk patients can be carried out by community pharmacists or other health care professionals (HCP) in primary care settings, such as the GP. These HCP can identify excessive use of opioids by: proactively carrying out Medicine Use Review (MUR) and estimating the risk of opioid misuse on at risk patients, and offer appropriate intervention (Royal College of Anaesthetists, no date). Screening and identification of people who are misusing drugs can be carried out by pharmacists with the aid of already established screening tools. For example, the prescription drug monitoring programmes (PDMP) enable community pharmacists to monitor people's opioid use and detect potential opioid misuse. This would allow community pharmacists to offer intervention early before opioid misuse occurs. If the community pharmacist is unable to offer any intervention, they can refer people to the GPs or health facilities that can treat opioid misuse (Bach and Hartung, 2019b).

iii. Storage and disposal of prescription opioids

Community pharmacists currently advise service users about the proper storage and disposal of prescription and OTC opioids. Informing service users on how to store or dispose of opioids in such a way that other individuals would not be able to access them will help to prevent opioid misuse (Thakur, Frey and Chewning, 2019). Community pharmacists play an important part in helping to promote the proper disposal of expired or unused opioids by requesting individuals to return such medications to the pharmacy. (Pharmaceutical Services Negotiating Committee, 2021).

iv. Harm reduction services

Harm reduction services aim to reduce the adverse effects of drug use on people as well as society through the use of evidence-based interventions that modify risks and risk behaviours (Hedrich and Hartnoll, 2021). Community pharmacists play well-established roles in halting the spread of infectious diseases like human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) by supplying clean needles and in preventing measles, polio and flu by administering vaccinations. Community pharmacists have the potential to deliver harm reduction treatments to mitigate the adverse consequences associated with negative behaviour among people who are addicted to opioids (Kosobuski et al., 2022). Harm reduction initiatives that can be carried out by community pharmacists include:

a. Needle and syringe exchange programme: clean needles and syringes are given to people who inject drugs (PWID) in exchange of used needles, to reduce transmission of HIV/AIDs and other blood borne diseases such as hepatitis B and hepatitis C which could be transmitted through shared needles (Avert, 2019a). This service is currently carried out by community pharmacies.

b. Opioid Substitution therapy: people who are dependent on injectable opioids are administered oral opioids such as, methadone and buprenorphine instead, to reduce the spread of infection that could arise from sharing injecting needles. Administration of oral opioids in place of injectable opioids will significantly reduce the transmission of HIV/AIDS and hepatitis B and C (Avert, 2019b; Bach and Hartung, 2019b). Community pharmacists dispense and supervise the consumption of methadone and buprenorphine.

c. Naloxone dispensing: naloxone is a drug that helps to reverse the effects of opioids overdose. Majority of opioid related deaths are due to opioid overdose (Office for National Statistics, 2023a). People who misuse opioids are given naloxone kits, so that they can use these kits if they are overdosed. The effect of naloxone lasts for 20-40 minutes. Hence, the HCP always advise that the overdosed person should be taken to the accident and emergency department immediately after naloxone administration

(Live, 2021). Naloxone dispensing are currently carried out by community pharmacists.

d. Hepatitis testing and hepatitis B and C vaccination: opioid misusers are at risk of developing hepatitis B & C from sharing infected syringe needles. Hence, HCP also carry out hepatitis tests on people who misuse opioids. Regular testing for hepatitis B & C can help people who have contracted the disease to be identified early and promptly treated. Administration of hepatitis B vaccine to drug misusers, who do not have hepatitis, will prevent them from developing the disease. Community pharmacists could potentially carry out this role to help prevent the spread of these infections.

e. HIV testing, treatment and pre-exposure prophylaxis: people who misuse opioids are prone to developing HIV because they may share unclean needles and indulge in risky sexual behaviour. These can hasten the spread of the infection. To detect and treat the infection early, HCP regularly test drug misusers for HIV (Pharmaceutical Services Negotiating Committee, 2021a). HCP also provide pre-exposure prophylaxis to people who misuse opioids to prevent HIV infection. Community pharmacists could adapt these roles to inhibit the spread of infections among people who are addicted.

Having gone through the opioid misuse prevention services that can be carried out by HCP like the community pharmacists, a description of community pharmacy practice in the UK, who their stakeholders are, and the opioid misuse prevention services that the Royal Pharmaceutical Society suggests they can carry out will be described in the following subheadings.

1.4 Community pharmacy practice in the UK

Community pharmacy is the branch of pharmacy that is sometimes known as retail pharmacy or chemists (Smith, 2023; Community Pharmacy England, 2023a). They are generally perceived as dispensers of prescription medicines (Lindsey *et al.*, 2017). However, this role has evolved also to include clinical services to better suit their

integration with other health care services in the NHS (Baird and Beech, 2020). Community pharmacy is considered to be one of the four pillars of primary care, alongside general practice, dentistry and optical services (Baird and Beech, 2020).

There are different types of community pharmacies, and this classification is based on the size of the pharmacy. There are the large high street chain pharmacies and small, individually owned pharmacies (Community Pharmacy England, 2023a). Chain pharmacies could be located in the high street or in supermarkets while the individually owned pharmacies are usually located in small areas, in suburban communities or rural settings (Community Pharmacy England, 2023a). Although the definitions of community pharmacies are discrete, in reality some chain pharmacies operate in rural settings, and some independent pharmacies will operate in busy urban high streets.

In terms of accessibility, about 90% of people in England live within a 20-minute walking distance from a community pharmacy while 99% of those who live in areas of greater deprivation live within a 20-minute walking distance from a community pharmacy (Todd *et al.*, 2014). This shows that community pharmacy is very accessible, especially to people who live in areas of deprivation and might therefore be instrumental in reducing health inequalities (Murray, 2016).

In the UK, the services that community pharmacists carry out are stipulated by the Community Pharmacy Contractual Framework (CPCF) which indicates the services that could be provided by community pharmacies, how the quality of these services could be assured, their safety and other requirements (Baird and Beech, 2020). This framework is negotiated between NHS England and NHS Improvement, the Department of Health and Social Care and the Pharmaceutical Services Negotiating Committee (PSNC). The PSNC is the representative of the pharmacy sector in this negotiation (NHS England, 2024a). Community pharmacy services are classified into three main groups (Anderson and Sharma, 2020). These services are:

i. Essential services and clinical governance: these are services that have been set nationally and are mandatory for community pharmacies to carry out as part of their

contract with the NHS (Baird and Beech, 2020). There are six services in this group: dispensing of medicines and medical appliances, repeat dispensing, disposal of spare or unwanted medicines, giving advice about healthy living, promotion of healthy lifestyle (public health) and providing medicines support after patients' discharge from hospital (Community Pharmacy England, 2022a).

ii. Advanced services: these services are optional and are nationally set. Any community pharmacy can provide these services if they meet specified minimum requirements that are stated in the Secretary of State Directions (Baird and Beech, 2020; Community Pharmacy Hertfordshire, 2022). Eight advanced services are currently commissioned by NHS England: the flu vaccination service, the New Medicine Service (NMS), and the Community Pharmacist Consultation Service (CPCS), pharmacy contraception service, hypertension case-finding service, smoking cessation service, Appliance Use Review (AUR) and Stoma Appliance Customisation (SAC) (Community Pharmacy England, 2023b).

iii. Enhanced services: these services are commissioned nationally by NHS England or locally by public bodies such as the newly established Integrated Care Boards (ICB), formerly known as CCGs (Clinical Commissioning Groups), or local authorities (Baird and Beech, 2020). Nationally commissioned enhanced services were previously commissioned by primary care trusts but following their abolishment, are now commissioned by NHS England in consultation with Community Pharmacy England (Community pharmacy England, 2022b). An example is the Corona virus disease 2019 (COVID-19) Vaccination Service (Community Pharmacy South Central, 2023).

Locally commissioned enhanced services enable community pharmacists to provide services that are mostly needed by a locality. Examples of locally commissioned enhanced services include services such as inhaler check-up service, needle and syringe exchange, and weight management service (Community Pharmacy West Yorkshire, 2023).

Furthermore, there are also services that are privately carried out and are not commissioned by the NHS. An example is the travel health advice service (Balogun, 2023).

1.5 NHS long term plan and the community pharmacy

The NHS long term plan states the priorities for the healthcare services for the next five years. It is drawn up by healthcare staff who are in the frontline, patients, their parents and other professionals (NHS England, no date-a). This plan is aimed at ensuring that everybody gets a better life, provide first class care for chronic conditions and support people to age healthily (NHS, 2019).

In the 2019-2024 framework, community pharmacies are expected to carry out more efficient dispensing by increasing their utilisation of technology and automation. Community pharmacies are also expected to partner with primary care networks (PCN) in order to meet patients' needs in the local area (NHS, 2019; Baird and Beech, 2020). A PCN consists of several GP practices working collaboratively with each other, alongside other health and social care institutions to provide comprehensive services to their local community (NHS England, 2023e). The PCN is the potential medium through which primary care would have stronger representation in the integrated care systems (ICS). By bringing together all the clinical directors from the different networks, a connection between the GP and the rest of the system is formed which might help to facilitate collaboration between community pharmacies and PCN (Baird and Beech, 2020; Fisher, Thorlby and Alderwick, 2019). Benefits expected to arise from this collaboration include reduction of workload of the GPs, thereby freeing up time across all practices in the NHS. It will also help to prevent the duplication of efforts and promote the provision of complementary services by GPs and community pharmacies (Royal Pharmaceutical Society, 2019).

Currently, clinical pharmacists work with PCNs to provide structured medication reviews (SMR) to manage patients with polypharmacy. They also provide expert advice on medicines use which ultimately helps in promoting self-care and reducing medicine waste. It is expected that clinical pharmacists will further enhance efforts

targeted at integrating primary care with other healthcare practitioners such as community and hospital pharmacists in order to better meet the needs of the local population (Royal College of General Practitioners, 2019).

1.6 Community pharmacy stakeholders

Having described the type of services that can be carried out in community pharmacy, it is necessary to give details of community pharmacy staff and other community pharmacy stakeholders such as national and local commissioning bodies that will be referred to in this research. In this study, the stakeholders referred to are the pharmacy staff and the commissioners. These stakeholders will be individually described below.

1.6.1 Community pharmacy staff

Community pharmacy staff consist of registered pharmacists and their support staff such as registered pharmacy technicians, pharmacy assistants, accredited checking technicians (ACT), dispenser/dispensing assistant, and medicines counter assistant (MCA). (Community Pharmacy England, 2023d).

Registered pharmacists are qualified pharmacists that are registered with the General Pharmaceutical Council (GPhC) that regulates pharmacy professionals, premises and practice in Great Britain (General Pharmaceutical Council, 2023). They are responsible for ensuring that the medicines supplied to patients are of good quality, within the law, are suitable and that the patient is given relevant information, including dosage and side effects (General Pharmaceutical Council, 2023). To operate, every community pharmacy must have a registered pharmacist known as the responsible pharmacist (Baird and Beech, 2020). The responsible pharmacist is appointed by the owner of the pharmacy to oversee the sale and supply of medicines and to ensure the safe and effective running of the pharmacy. They must be responsible for only one pharmacy at a time (Baird and Beech, 2020; Royal Pharmaceutical Society, 2023b).

Pharmacy Technicians mainly dispense and supply medicines to patients. Though their work is supervised by the pharmacist, pharmacy technicians are usually held accountable for carrying out services safely and accurately. They are also licensed by the GPhC and their professional leadership body is known as The Association of Pharmacy Technicians UK (APTUK) (Community Pharmacy England, 2023d).

Accredited Checking Technicians (ACT) have completed accredited training that enables them to undertake the final accuracy check of medicines that are dispensed under the authority of a pharmacist before they are supplied to the patient. Pharmacists carry out clinical checks in addition to the final accuracy check of the prescription during dispensing but when an ACT is present in the pharmacy, in most cases, pharmacists will not carry out the final accuracy check. This role wis given to an ACT (Community Pharmacy England, 2023d).

Dispensers/ Dispensing Assistants help the pharmacist to dispense prescriptions and manage stock of medicines or medical appliances in the dispensary. Dispensers will also carry out the roles of Medicines Counter Assistants (MCAs) when needed. To ensure that they are professionally competent, dispensers are required to have attained or should be training to acquire a minimum standard that is equivalent to the Pharmacy Services Scottish/National Vocational Qualification (S/NVQ) level 2 qualification (Community Pharmacy England, 2023d).

MCAs are often the first staff that patients meet in the pharmacy. They receive the prescriptions, advise on the treatment of minor illnesses, and provide healthy lifestyle support, following a protocol while being supervised by a pharmacist. Trained and accredited MCAs can carry out some NHS commissioned services like the NHS Health Checks. MCAs who have undergone or are undergoing a relevant course are authorised to sell medicines under an agreement (Community Pharmacy England, 2023d).

1.6.2 Pharmacy commissioners

According to the NHS England, commissioners are responsible for assessing needs of health services (Department of health and social care, 2021b). Commissioners are also

involved in planning, prioritising and monitoring these services in order to achieve the best outcomes. The ICBs supervised by NHS England are responsible for the commissioning of NHS services. As discussed previously, community pharmacy services are commissioned both nationally by NHS England and locally by the ICB or local authorities (Baird and Beech, 2020).

The ICBs are the potential commissioners that would be involved in the local commissioning of opioid misuse services. ICBs are part of Integrated Care Systems (ICSs). ICSs are partnerships of bodies that combine efforts to deliver healthcare services to improve the lives of people in an area (Community Pharmacy England, 2023c). Following the health and care Act 2022, 42 ICSs were formed across England on the first of July 2022. ICSs are made up of ICBs, local authorities, Integrated Care Partnerships (ICPs), place-based partnerships, and provider collaboratives (Community Pharmacy England, 2023c; NHS Digital, 2023). There are also 42 ICBs in England because each ICS contains an ICB (NHS England, 2023a).

The ICB is in charge of planning NHS services to meet the health needs of the area. It is also responsible for NHS budget management and organising service provision in the ICS area. As mentioned earlier, the ICB was set up following the dissolution of the CCG. The ICB has a chief executive and a chair who are accountable to NHS England for NHS expenditure and activities within the population (Community Pharmacy England, 2023c). ICBs took up control of the primary medical services which were previously delegated to the CCGs in July 2022. Nine early adopter ICBs took responsibility for the commissioning of Pharmaceutical Services in their population. (Community Pharmacy England, 2023c). These were North West region: Cheshire and Merseyside; Lancashire and South Cumbria; Greater Manchester and South East region: Buckinghamshire, Oxfordshire and Berkshire West; Frimley; Kent and Medway; Hampshire and the Isle of Wight; Surrey Heartlands; Sussex (Community Pharmacy England, 2023c). All other ICBs including North East and North Cumbria ICB, took up this responsibility from the first of April 2023 (NHS, 2022; Community Pharmacy England, 2023c).

1.7 The RPS recommendation for pharmacists' role in the prevention of opioid misuse

The following recommendations have been put forth by the RPS with the aim of mitigating difficulties that may arise from the misuse of drugs, particularly in the context of opioids. The recommendations are classified into five categories which are: harm reduction; improved multidisciplinary working; prescribing, treatment and review; education and training and future developments (Royal Pharmaceutical Society, 2023a). These groups will be described individually:

1.7.1 Harm Reduction:

There are five recommendations in this group. Namely, i) availability of naloxone, ii) tools for prevention and identification of people who might be misusing opioids, iii) shared records, a shared system of recording OTC opioid medication sales, iv) inclusion of opioids in new medication/high risk medication service, and v) public health campaigns. Each of these will be explained in the following paragraph.

The RPS recommends that naloxone could be available in all community pharmacies and could be supplied to people who use opioids, their family, carers and health personnel. Naloxone could be stored in first aid boxes in all clinical settings for emergency use. Community pharmacy staff could also be trained on how to use naloxone in any setting where people who use opioids attend. This is important since a study showed that the rate at which people have and carry naloxone were both low (Burton *et al.*, 2021). The RPS further states that in addition to supplying naloxone to people who use opioids, their family, carers and health personnel, it is also important to inform them about the importance of naloxone. Informing them about the importance of naloxone will also motivate them to use naloxone when there is a case of overdose.

Community pharmacy staff are in an ideal position to make this important intervention. It is therefore important, that all community pharmacy staff are capable of offering naloxone to any person who is at risk of opioid misuse or anyone who is likely to witness one (Royal Pharmaceutical Society, 2023a). These could be offered

as a collection of services which promotes the benefits of carrying naloxone, its accessibility and safe use. Pharmacists who work in other care settings, such as GP practices, and specialist services could also educate people who use opioids about harm reduction, especially the benefits of naloxone. Pharmacists could also ensure that people who use opioids have a good supply of naloxone (Scottish drug deaths taskforce, 2021).

Community pharmacy staff could also be able to administer 'opportunistic interventions' such as hepatitis interventions, injecting equipment, and training on how to recognise an overdose and how to use naloxone. The RPS recommends that this is of high importance given that community pharmacists are the most accessible healthcare professionals that can enable the applicability of these interventions when required, which could be daily. This service should not only be restricted to people who use opioids, but also to their family, friends and the community at large (Royal Pharmaceutical Society, 2023a).

The RPS further suggests that people who are at risk of overdose like patients who are just beginning treatment with opioids, and people who used to take opioids but stopped using it for a long period of time, such as, prisoners who have just been released from prison and patients who have just recently been discharged from hospitals could also be offered this intervention (Morrison *et al.*, 2018).

Pharmacy staff could also have tools to prevent and identify people who are possibly misusing prescription or OTC opioids. They could also be trained to administer brief interventions that are person centred. These brief interventions could be given in a non-confrontational manner and should be aimed at helping patients to think about their drug use and recognise when a change of medication is necessary so as to reduce harm. This recommendation also includes signposting to appropriate services where additional needs are identified (Statista, 2021). These brief interventions are proposed to be an important tool for preventing and identifying likely opioid misuse in young people, and at initial assessment of opioid misuse. It is also important in the treatment of older people who are being treated with opioids, and often have coexisting health

conditions (Department of Health, 2017a). The use of brief interventions also ensures that every communication between community pharmacy staff and the patient is beneficial. This could be achieved by the use of tools that are particularly developed to deliver clear and specific messages that will help to educate patients meaningfully and effectively. Pharmacy staff could also be trained to deliver messages consistently and professionally. The use of aide memoirs is also encouraged to further help to deliver messages effectively. Community pharmacies are strategically placed to offer this service because an appointment is not required to receive this service and they are not time consuming (Royal Pharmaceutical Society, 2023a).

RPS recommends that community pharmacy teams could have a shared system of recording OTC opioids purchased from their pharmacies. Since OTC opioids could be purchased from multiple pharmacies without any record or control, a shared record will enable opioid misuse to be recognised promptly so that intervention can be quickly offered. This could also be facilitated by registering patients to one pharmacy for the purchase of all their OTC medications (Chiappini *et al.*, 2020).

Medicines that can lead to dependence, such as opioids could be included in the new medication and high-risk medication services offered by community pharmacists. In this service, pharmacy staff could adopt current tools that are used for other high-risk medication to identify harm in patients who are taking opioids. Adopting tools that are currently used for other high risk medication, will promote prevention, early detection and intervention to harm (Public health England, 2020). This service will also enable community pharmacy staff to offer education when opioids are being dispensed or prescribed, if the community pharmacist is a prescriber. This discussion will enhance person centred treatment that will enable feasible targets to be set and agreed upon. This communication will also improve the patient's knowledge about the side effects and risks associated with using opioids and gives room to enlighten the patient about non-pharmacological therapies that might be beneficial to the patient (Royal Pharmaceutical Society, 2023a). Community pharmacists are best suited to offer this service because they are the health professionals that dispense the

medication and could conveniently offer this service while dispensing opioids to patients.

Community pharmacy staff can carry out public health campaigns to raise awareness about opioid misuse and its effects. Education should also focus on the different treatment options that are available as this would help to limit stigma associated with seeking treatment. To ensure the effectiveness of campaigns, all pharmacy staff could be trained and involved in the campaign. Visual aids, posters and leaflets could also be used to reinforce the key message and this could be linked to an event taking place outside the pharmacy (Matheson *et al.*, 2014). Education should also be targeted at people who purchase OTC opioids. Pharmacy staff should aim to raise awareness about the effects of opioid misuse while making sure that patients do not discontinue their medication suddenly. They could also consider educating the public about options of drug treatment as a means of reducing stigma around seeking treatment with opioids. They could educate patients about the benefits of adhering to dosage regimens, drug interactions, self-management and how to seek help when the need arises. Due to the accessibility of community pharmacies, they are well suited to deliver the key message of a campaign through education of patients (Scottish Government, 2017).

1.7.2 Improved multidisciplinary collaboration

The RPS recommends that improved multidisciplinary collaboration relates to the combination of efforts by different professionals to prevent opioid misuse. There are two recommendations in this group, and they are: i) shared patient records and clear communication between pharmacist and other professionals, and ii) pharmacies could serve as centres where people who use drugs can receive services from other organisations.

According to RPS recommendations, all pharmacists could be able to access the shared records of patients and have distinct pathways for communicating with other healthcare professionals who are involved in caring for people who misuse opioids. A computerised setup that will enable pharmacists and other healthcare teams to

improve their clinical role through shared patient records and improved communication has been proposed across Great Britain. This would allow the provision of a variety of care services that people who are addicted to opioids would benefit from (Scottish Government, 2017). Shared patient records mean that independent prescribing could be provided from different healthcare settings and thus increases the patients' opportunity to choose where they would like to receive treatment. Long-acting opioids such as buprenorphine and methadone could be offered in clinics set up in community pharmacies. For this clinic to run effectively, pharmacists need to have the ability to prescribe against an NHS budget. This will enhance the recording and monitoring of the prescribing and sales of medicines that are prone to being abused such as opioids (Royal Pharmaceutical Society, 2023a; Scottish government, 2021).

Shared patient records will also increase the ability to share important and lifesaving information with other healthcare professionals faster and easily, thereby reducing the rate of drug deaths (NHS England, no date-b). For example, the attendance of patients who receive buprenorphine or methadone with other medications could be improved if shared data indicates that this patient has issues with attending the community pharmacy to collect buprenorphine or methadone. This could be resolved by aligning the collection times of buprenorphine or methadone with their other medications. In addition, shared records could also help community pharmacy staff to identify when patients are at high risk, for example, when the patient has lost a loved one or when the patient has just been recently involved with an overdose (Welsh Government, 2018).

Shared patient records will facilitate holistic care of people who are addicted to opioids since all agencies involved in the care of the patient would have access to patient's records (NHS England, 2023b). Examples of such agencies are social care, housing, the police, ambulance services, GP, community pharmacies, and other care providers (Royal Pharmaceutical Society, 2023a).

Conclusively, shared patient records will facilitate interprofessional collaboration between community pharmacists, GPs, and other health providers which will further help to improve the health outcomes of people who misuse opioids (NHS England, 2023b).

Community pharmacies could operate as hubs where primary care, public health, and holistic services are offered, if provided with the required resources. These community pharmacy hubs could enhance access and referral to other relevant NHS and community services. The availability of these community pharmacies would be based on the needs of the area where they would be located. Consultation rooms and private areas in the pharmacy could be developed to enable people who are homeless or who have not registered with any health care service to access other health professionals or other agencies that are involved in their care, for example, housing (Royal Pharmaceutical Society, 2023a; Office for health improvement and disparities, 2024a). This could help people who are homeless or are not registered with any health service to receive professional support from the community pharmacy staff, thereby contributing towards preventing inequalities of access to healthcare. Community pharmacies could also serve as centres from which outreach services are offered either by pharmacy staff or voluntary providers. This will help pharmacy staff to provide the service that patients in that area really need while maintaining relationship with these patients (Royal Pharmaceutical Society, 2023a). The location of pharmacies within communities and their accessibility makes them most suitable for people who misuse opioids and are not able to access professional services.

1.7.3 Prescribing, treatment and review

This refers to pharmacists' intervention through prescribing, treatment and review. Three types of interventions have been identified here and these are polypharmacy reviews and health checks, treatment, and referral. These will be explained below.

i. Polypharmacy reviews and health checks: Community pharmacists can carry out polypharmacy reviews and health checks as part of a multidisciplinary team when required. This is important, especially for the older people who misuse opioids since

they often experience comorbidities or who have complex health needs that often result in polypharmacy (Gov.UK, 2019). Community pharmacists can contribute towards preventing patients from encountering further harm by carrying out polypharmacy reviews (Royal Pharmaceutical Society, 2023a).

Community pharmacies could also operate such that patients who are elderly or have complex health needs and cannot access health services at the recommended times could receive polypharmacy review services at times that are convenient for the patient (Lowrie *et al.*, 2019). This service could be carried out in collaboration with other members of the multidisciplinary team and a digitalised record of the patients' data could be in place (Royal Pharmaceutical Society, 2023a; Lowrie *et al.*, 2019). This will enable all members of the team to be aware of any intervention that will be offered by the pharmacy staff and also allows pharmacy staff to refer these patients to other health services when required, for example, patients who are suspected of having mental health issues could be referred to receive mental health assessment from a mental health specialist. Community pharmacy staff could also carry out basic medical checks in order to identify health issues that could be quickly treated (Royal Pharmaceutical Society, 2023a).

ii. Treatment: Community pharmacies could also serve as clinics where long-acting buprenorphine injection, independent prescribing, and deprescribing services are provided. This will broaden patients' treatment options in the pharmacy and will contribute to improving patients' ability to access treatment. When pharmacists have been trained and can access adequate support and infrastructure, they could offer oral opioid substitution therapy and long-acting buprenorphine prescribing (Scottish government, 2021). This service would be very beneficial, especially to patients who reside in rural settings with limited access to treatment. It also provides the opportunity for pharmacy staff to inform and guide the patient on treatment options that are available while allowing the patient to make informed decisions about their therapy (Fenning, Smith and Calderwood, 2019). They could also provide opioid deprescribing services. Community pharmacists are well suited to offer these services

because they are drug experts and they are highly accessible (Royal Pharmaceutical Society, 2023a).

iii. Referral: A pathway that will allow people who misuse opioids to be referred from prisons and hospitals to a community pharmacy, where they can receive treatment, could be developed. These community pharmacies could also have adequate resources that will enable people who are at risk to access the necessary care during periods when they cannot access care from addiction services, such as during weekends or during festive periods when emergency opioid supply pathways might be interrupted (Scottish Government, 2017).

In addition, this is important because people who misuse opioids might be discharged from the hospital or released from prison abruptly. This could lead to a disruption in the normal referral pathway and will put the patient at more risk. To meet requirements of national policies in England which requires that a high quality and seamless care could be offered to all patients across all parts of the healthcare system, it is important that an alternative route of care is developed to meet up with demands during weekends, holidays or emergency discharge from hospitals and release from prison (Gov.UK, 2017).

The community pharmacy would be in an ideal position to offer such services if equipped with the right infrastructure that will enable information-sharing and control. Community pharmacies are also open during weekends and are open for long hours when other services must have closed. However, to ensure consistent service delivery, addiction services could consider extending their work hours (Royal Pharmaceutical Society, 2023a).

1.7.4 Education and training

Education and training recommendation by the RPS refers to the type of knowledge and information that could be given to pharmacists that will enable them to communicate effectively and offer appropriate services to people who are addicted to

opioids. Education and training comprise of psychologically informed care, addiction and harm reduction, and training at undergraduate level. (Scottish government, 2021).

Pharmacy staff could be trained in such a way that they are psychologically informed as this will help reduce the stigma felt by people who misuse opioids (Scottish Government, 2018b). Pharmacy staff could receive additional training that will enable them to interview people who misuse opioids in such a way that a non-judgemental relationship is built between pharmacists and people who misuse opioids. Depending on the need of the area where the community pharmacy is located, pharmacists could undergo enhanced training in order to offer a more structured intervention (Royal Pharmaceutical Society, 2023a; Scottish drugs forum, 2020). Community pharmacy staff could also offer services remotely, such as, the online Cognitive Behavioural Therapy (CBT) but for this service a pharmacist must be on site to guide the process (Scottish drugs forum, 2020). Pharmacy teams could consider ways of service improvement that will help reduce the level of stigma felt by people who misuse opioids, for example, extending opening hours, and improving communication skills. This will ensure that people who use opioids are treated consistently, fairly, and in a dignifying manner (National Institute on Drug Abuse, 2021c). Community pharmacy staff could undergo compulsory training on addiction and harm reduction (Royal Pharmaceutical Society, 2023a).

Community pharmacists could be equipped to offer opioid substitution therapy and harm reduction services. They could be trained to offer naloxone, opioid substitution therapy, suicide awareness, mental health first aid, child protection, domestic abuse/violence and safer injection techniques (Matheson *et al.*, 2016; Walters *et al.*, 2012). This training will improve community pharmacists' knowledge, skills, attitude and confidence towards providing these services. It will also improve their knowledge and skill about mental health first aid and suicide awareness which will be very useful because of the strong relationship between opioid misuse and mental health. This will enable community pharmacists to offer holistic care to people who misuse opioids (Public health Scotland, 2021).

Enhanced training on topics such as handling challenging discussions, trauma training and psychologically informed environments training could also be undergone (Scottish Government, 2018b). Trauma training will help the pharmacy staff to recognise when a person who uses opioids is affected by trauma. This will enable the community pharmacists to respond appropriately and reduce harm (NHS education for Scotland, 2024).

Community pharmacists are accessible to people who misuse opioids. If community pharmacists are trained to offer these support services, it will contribute towards reducing harm that results from misusing opioids, for example, drug death rates.

Undergraduate pharmacy programmes could include topics on addiction, harm reduction, and in-depth training on pharmacological and non-pharmacological therapy. Teaching and learning at this level could be at par with other clinical topics taught, such as, diabetes or cardiovascular disease where extensive detail or information is provided (Royal Pharmaceutical Society, 2023a). This could be achieved by integrating strategies that will enable teaching and learning within the requirements of the GPhC standards for the initial education and training of pharmacists. Course teams could decide on how best to deliver this teaching since universities have individual modular formats and different geographical areas have varying levels of opioid misuse. Irrespective of how teaching is structured to be delivered, details of the key competencies that students must acquire in this course could be stated (General Pharmaceutical Council, 2024).

The RPS also recommends that the topics could also cover other aspects of addiction such as why certain people become addicted and others do not, and deeper issues facing people that misuse opioids, such as, trauma, co-morbidities, stigma and inequalities. Teaching could be delivered in a variety of ways: through workshops, experiential learning delivered through visits to treatment sites, and through the lived experiences of people who misuse opioids (Royal Pharmaceutical Society, 2023a). Emphasis could also be placed on reducing inequalities associated with accessing treatment services, and students could be encouraged to share this information with

people that have a stigmatising attitude. To further help reduce stigma experienced by people who misuse opioids, the first aid course offered during the foundation training year could include the emergency administration of naloxone (Royal Pharmaceutical Society, 2023a).

Hearing the lived experiences of people who misuse opioids will highlight areas of inequalities and stigma. It will also help to reveal areas of good practice. People who can share their experiences could be selected from different backgrounds so that students are informed about the peculiarities of these people and the best way to care for them (Scottish Government, 2018a). This will prevent students from seeing all people who misuse opioids from the same perspective, thereby motivating them to adopt a person centred approach in their practice (Public health England).

Due to community pharmacists' accessibility, the chances that pharmacy undergraduates will encounter people who misuse opioids once they graduate is high. Hence, this training will help prepare them to offer appropriate services to people who misuse opioids (Royal Pharmaceutical Society, 2023a; Welsh Government, 2018).

1.7.5 Future developments

The RPS recommends the set-up of Regulated Supervised Drug Consumption Rooms (SDCRs) and expansion of treatment options to include Heroin Assisted Treatment (HAT). From the start of these programmes, pharmacists' input needs to be acknowledged. These services have been used successfully with proven evidence of 30 years effectiveness at reducing drug death rates. Globally, there are 100 SDCRs and majority of them are located in Europe (Royal Pharmaceutical Society, 2023a).

Establishing SDCRs is important because it provides a safe, clean site for people who inject opioids and also gives them access to treatment and support services available in the SDCRs. Pharmacists are well placed and knowledgeable to offer advice regarding the legal, ethical and practical implications of dealing with controlled drugs (CD) on how the SDCRs can be run safely and effectively. They could also advise on

procurement, destruction, governance, compliance checks, reconstitution and dose preparation of CD (Royal Pharmaceutical Society, 2023a).

1.8 Summary

This chapter described the background to the study, definitions of opioid misuse, and the increasing death rates due to opioid misuse. It highlights opioid misuse prevention services that can be carried out in community pharmacies, and gives a detailed description of community pharmacy practice in the UK; the NHS long term plan and how it affects community pharmacy services; community pharmacy stakeholders; and the RPS recommendations regarding pharmacists' role in the prevention of opioid misuse which focus on how community pharmacists could contribute towards preventing opioid misuse in the UK.

1.9 Structure of the thesis

This thesis consists of eight chapters including this introduction chapter. Chapter 2 is the literature review chapter in which literature regarding community pharmacists' role in opioid misuse in the UK, and in other countries are reviewed. The aim of carrying out the literature review was to determine the gaps in the literature to help in the development of the research aim, research question and objectives of this study.

Chapter 3 is the methods and methodology chapter which explains my philosophical stance and study design, and describes the methods adopted to answer my research questions. It also details my reflexivity and positionality throughout this research and states my ethical considerations.

Chapter 4 details the systematic review which was conducted to synthesise qualitative evidence on the role of community pharmacists in the prevention of prescription and OTC opioid misuse. This chapter describes the processes of data selection, data extraction and quality assessment, thematic analysis, and mapping of findings to the capability, opportunity, motivation and behaviour (COM-B) model of behaviour.

Chapter 5 describes findings from the data collected from the pharmacy staff. These were obtained by mapping themes from the interviews of community pharmacy staff to the COM-B model of behaviour.

Chapter 6 details the themes from interviews with commissioners while chapter 7 is the intervention development chapter. Interventions were developed based on findings of the systematic review, the pharmacy staff interviews, and the commissioners' interviews. These findings were then mapped to the behaviour change wheel (BCW) model to develop interventions.

Chapter 8 is the discussion chapter where all the findings are summarised and how these findings can contribute to knowledge is detailed. Comparison between findings from this study and existing literature are carried out. The strengths and limitations of the study, recommendations, implication to policy, practice and research. and concluding remarks are also presented in this chapter.

Chapter 2 Literature Review

2.1 Introduction

The previous chapter presented the background to the study- it stated relevant definitions, and statistics and describes the current and potential roles of community pharmacists in the prevention of prescription and OTC opioid misuse in the UK. This chapter reviews existing literature regarding community pharmacists' roles in the prevention of prescription and OTC opioid misuse in the UK, factors that influence community pharmacists' roles in the prevention of prescription and OTC opioid misuse, and suggestions for improving community pharmacists' roles in opioid misuse. The chapter will finish with identified gaps in the literature, significance of the study, aim of the study, research questions and objectives.

The type of review that was undertaken in this chapter was the narrative literature review. This review was carried out without following a systematic methodology. Searches were carried out using 'Google' and 'Google scholar' search engines. This literature review was carried out to identify trends, patterns and themes in identified literature which enabled me to determine gaps in the literature. The research questions and the focus of this research were then developed based on the identified gaps in the literature. Articles were searched by typing a combination of key words that were related to the research title in 'google' or 'google scholar'. Examples of these combinations or phrases are 'opioid misuse prevention and community pharmacist's role' or 'opioid misuse prevention and community pharmacy roles'. The abstract of articles that were retrieved from the search were read to determine its relevance to the study. Abstracts that had important information pertaining to the study were read in full and suitable themes were obtained. Similar themes were grouped together, and a coherent narrative was then written. The search for articles was stopped when the same articles that were previously identified reappeared.

The type of studies that were included in this literature review were qualitative studies, quantitative studies, cross-sectional studies, scoping reviews, narrative reviews, commentary, pilot studies, systematic reviews, an algorithm development study,

descriptive studies, feasibility studies, implementation studies, delphi studies, mixed methods studies, and online surveys.

2.2 Community pharmacists' roles in the prevention of prescription and OTC opioid misuse

Community pharmacists carry out a wide range of roles that help prevent prescription and OTC opioid misuse. The roles include education and information provision; screening, identification, and referral of patients who are at risk of opioid misuse; proper storage and disposal of prescription opioids; and harm reduction services.

2.2.1 Education and/or information provision

Community pharmacists' role involves educating or informing people about the critical risks of opioid misuse and to discourage them from misusing opioids. In the UK, community pharmacists recognised their role in providing educational services to people who use opioids (Alenezi, Paudyal and Yahyouche, 2021). A study carried out in the North West of England showed that it was feasible for community pharmacists to carry out signposting and information-related roles (Mackridge *et al.*, 2010). In a study carried out in the South-West of England to determine the perception of pharmacists regarding the management of OTC co-codamol misuse, pharmacists informed service users of safe and appropriate ways of using OTC opioids which they considered not only as an ethical service but as a professional means of safeguarding service users and the general public (Barrett and Costa, 2018). Educational services have also been identified as one of the factors that positively influence a patient's decision to attend a pharmacy. Education might help improve people's knowledge about drug misuse and administration (Laird *et al.*, 2016; Agomo, 2012). On the other hand, studies have also reported the poor ability of community pharmacists to carry out educational services among people who are addicted to opioids (Hill *et al.*, 2021), cancer patients, or their families and caregivers in the UK (Savage *et al.*, 2013). Thus, there is a need for upskilling and reskilling of community pharmacists to provide quality education or information provision in the UK.

In the USA, several studies have recorded community pharmacists' involvement in overdose prevention education, counselling services, education in areas such as pain management, non-drug therapy, and risks of opioid misuse (Chisholm-Burns *et al.*, 2019; Vadiei *et al.*, 2022; Riley and Alemagno, 2019; Thakur, Frey and Chewning, 2019). A community pharmacy-led Brief Motivational Intervention-Medication Therapy Management (BMI-MTM) which consisted of counselling the service user about the use of opioids was acceptable, feasible and effective at preventing opioid misuse when carried out by community pharmacists in the USA (Cochran *et al.*, 2019).

2.2.2 Screening, identification, and referral of service users who are at risk of opioid misuse

This role relates to the screening of opioid prescriptions by the community pharmacist to enable them to identify people who might be misusing prescription opioids. Identified persons are then referred to the appropriate health professional for treatment and counselling. Community pharmacists recognise that they have a role in the monitoring of patients' opioid use through screening of their prescriptions (Vadiei *et al.*, 2022). Several screening tools have been developed and evaluated for use in community pharmacies.

In the UK, few studies have been carried out on the screening of opioid misuse. These studies include two research projects that were carried out in Belfast, Northern Ireland in which the harm-minimisation model was used to identify people who were abusing or misusing OTC drugs such as opioids, and refer identified persons to GPs (Fleming, McElnay and Hughes, 2004; Wazaify, Hughes and McElnay, 2006). Another study was a pilot study of the first Home- Office-Licensed Pharmacist-led drug checking service and showed that pharmacists were able to carry out drug testing services in their pharmacies (Guirguis, Gittins and Schifano, 2020).

In the USA, the Opioid Misuse Risk Prevention Toolkit was used to identify patients who were misusing prescription opioids (Strand, Eukel and Burck, 2019). Other studies carried out in the USA have also used prescription opioid misuse screening toolkits to identify substance misuse behaviours in patients (Cochran *et al.*, 2017; Lindley, Cox and Cochran, 2019; Salwan *et al.*, 2020; Cochran *et al.*, 2015; Rickles

et al., 2019). In the USA, a novel screening tool in community pharmacies, known as the Screening, Brief Intervention and Referral to Treatment (SBIRT) model has been used not only for the identification of persons who misuse prescription opioids but to refer them to appropriate treatment services (Bach and Hartung, 2019a; Shonesy *et al.*, 2019).

Twelve screening tools that could help community pharmacists to identify service users who are at risk of opioid misuse were highlighted in a review (Lindley, Cox and Cochran, 2019). To improve the ability of community pharmacists to provide patient centred care, it is recommended that these tools are used with other tools like the Prescription Drug Monitoring Programmes (PDMP) (Picco *et al.*, 2023; Lindley, Cox and Cochran, 2019). This recommendation was made because when the PDMP which is objective in nature and based on the pharmacists' record is used together with any of the other screening tools stated above such as the Opioid Misuse Risk Prevention Toolkit, and the SBIRT, more complete and accurate information about the patient's opioid use is obtained (Picco *et al.*, 2023; Lindley, Cox and Cochran, 2019). As a result, the combined use of objective screening tools which are based on pharmacy records, and subjective screening tools that are formed from report provided by the service user will improve the pharmacists' ability to screen, identify and refer persons who misuse opioids for appropriate treatment (Picco *et al.*, 2023). Though studies have shown that it is feasible to use subjective screening tools, especially the SBIRT in community pharmacies, researchers suggest that further studies are needed to improve the validity of its use in community pharmacies (Fatani *et al.*, 2022; Shonesy *et al.*, 2019). Besides, these tools might not be suitable for all pharmacy settings and hence future research should assess the most effective tool to use in a particular circumstance and/or setting (Lindley, Cox and Cochran, 2019). Therefore, there is need for advancement of these tools to enable community pharmacists carry out their role in screening, identification and referral of service users effectively and efficiently.

In other countries, the feasibility of using screening tools in community pharmacies has also been tested. A study carried out in France showed that community pharmacists could identify persons who misuse prescription opioids by using the

screening tool known as the Prescribed Opioid Misuse Index (POMI) (Philip *et al.*, 2022). In Australia, the feasibility of using the Routine Opioid Outcome Monitoring (ROOM) in detecting prescription opioid misuse has been proven as effective (Nielsen *et al.*, 2019).

The lack of UK research on the role of community pharmacists in screening, identification and referral might be due to pharmacists feeling they were not well equipped and that it was not their responsibility to carry out screening, identification and referral services (Alenezi, Yahyouche and Paudyal, 2022). Therefore, further research is needed to understand why community pharmacists' use of opioid misuse screening tools is poor and to identify ways through which community pharmacists' role in screening, identification and referral of people who misuse opioids could be improved.

2.2.3 Proper storage and disposal of opioids

The importance of installing and maintaining effective and efficient storage and disposal system is key to effective prevention of opioid misuse. Community pharmacist's role involves informing service users about how to store or dispose opioids safely without other persons accessing them. When opioids are not stored or disposed safely, other persons could have access to the medication which might potentially result in fatal opioid misuse. No research on community pharmacists' role in proper storage and disposal of medication in the UK was found. Three studies showed that community pharmacists were involved in educating service users about proper storage and disposal of prescription opioids; all of these studies were carried out in the USA (Kennedy-Hendricks *et al.*, 2016; Thakur, Frey and Chewning, 2019; Vadiei *et al.*, 2022). Hence, it is important to facilitate research on community pharmacists' role in proper storage and disposal of opioids as this will provide research evidence and expertise towards appropriate storage, disposal and prevention of opioid misuse.

2.2.4 Harm reduction services

Harm reduction services are aimed at reducing the harmful effects of drug use among people who misuse drugs by providing person-centred care that is free from stigma (Centers for Disease Control and Prevention, 2022). Harm reduction services include needle and syringe exchange programme, opioid substitution therapy (methadone and buprenorphine dispensing), naloxone dispensing, hepatitis testing and vaccination, and HIV testing, treatment and pre-exposure prophylaxis (Substance Abuse and Mental Health Services Administration, 2023).

In the UK, studies have shown that community pharmacists carry out opioid substitution services, and needle exchange services (Matheson, Bond and Tinelli, 2007; Britton and Scott, 2010; Sheridan *et al.*, 2007). The level of involvement of community pharmacists in opioid substitution services (specifically methadone dispensing and supervised consumption) and needle exchange services were stated to have increased when measured over 10 years. (Matheson, Bond and Tinelli, 2007; Sheridan *et al.*, 2007). A follow up study carried out by Matheson et al in 2016 which was a repeat of the study they carried out in 2007, revealed that there was an increase in community pharmacists' involvement in harm reduction services over 20 years (Matheson *et al.*, 2016). In all these studies, it was recommended that community pharmacists' role in harm reduction services need to be enhanced. More recent research studies on the involvement of community pharmacists in carrying out opioid substitution services and needle exchange services in the UK were not identified. Similarly, no study on the involvement of community pharmacists in naloxone dispensing in the UK was found. There is a need for more research to be carried out in this area.

Studies have shown that community pharmacists are involved in harm reduction services, though their level of involvement varies with the type of harm reduction service. A review revealed that the harm reduction services that community pharmacists were most frequently involved include the needle supply or exchange programmes (Watson and Hughes, 2012; Samitca *et al.*, 2006; Parry, Van Hout and

Norman, 2017; McMillan, Chan and Hattingh, 2021). In addition to needle supply or exchange, community pharmacists in Switzerland and Australia were also highly involved in opioid substitution therapy while community pharmacists in the USA were involved in naloxone dispensing (Parry *et al.*, 2021; Samitca *et al.*, 2006; McMillan, Chan and Hattingh, 2021). High levels of involvement of community pharmacists in naloxone dispensing was also observed in three studies conducted in the USA (Morton *et al.*, 2017; Bachyrycz *et al.*, 2017; Bakhireva *et al.*, 2018). The roles were carried out more in the urban areas than in the rural areas while pharmacists were less involved in HIV and HCV screening (Parry *et al.*, 2021). Despite community pharmacists' having a good level of involvement in needle supply or exchange, opioid substitution therapy and naloxone dispensing, pharmacists felt unrecognised as part of the drug management team and lacked sufficient support that would enable them expand on their role in harm reduction (McMillan, Chan and Hattingh, 2021; Samitca *et al.*, 2006; Watson and Hughes, 2012; Parry, Van Hout and Norman, 2017). Hence, there is a need for improvement in community pharmacists' roles in harm reduction services.

2.3 Opioid stewardship Intervention and pharmacists' role

Opioid stewardship is a set of practices that focuses on maximising the benefits of opioids while reducing their risks. It ensures that opioids are appropriately prescribed, correctly used for pain management and used only when necessary (Shrestha *et al.*, 2023). It is an intervention that has been developed and tested for opioid misuse prevention in different settings (Simpson, Levy and Mariano, 2023).

Pharmacists have varying roles in opioid stewardship. A scoping review carried out by Gondora et al showed that pharmacists can carry out opioid stewardship interventions especially education, risk assessment, medication therapy adjustments, and setting of policy and guidelines (Gondora *et al.*, 2022). Majority (82%) of the studies included in this review were carried out in the USA. Pharmacy settings that were studied in this review were hospitals, primary care clinics, medical centers, community pharmacies, academic settings, and other settings like the dental clinics. The community pharmacy setting accounted for 17% of all settings, while majority (74%) of the studies were carried out in hospitals, primary care clinics and medical

centers. Most of the included studies (58%) were pharmacist-led while the other studies were multidisciplinary (35%), and student-led (6%). In this review, education was the most reported intervention, followed by medication therapy adjustment or naloxone supply. Education had to do with pharmacists educating patients, health care professionals and members of the public. Education produced significant improvement when intervention outcomes were accessed. Pharmacists offered medication therapy adjustment or naloxone supply, using their prescribing or dispensing authority, or as part of an interdisciplinary team (Gondora *et al.*, 2022). However, majority of the interventions were carried out when pharmacists worked in interdisciplinary teams. In these teams, pharmacists could easily communicate prescription issues with doctors. Thus, emphasising the effectiveness of pharmacists' roles in opioid stewardship while working in an interdisciplinary team. To further expatiate on the importance of interdisciplinary collaboration in opioid stewardship, two pharmacist-led studies included in the review did not show any improvement in the outcomes measured (Gondora *et al.*, 2022). It has also been reported in other studies that working in collaboration with other health care professionals as part of an interdisciplinary team could improve working relationship (Jové *et al.*, 2014), enhance communication between health professionals (Hinata *et al.*, 2019b) and improve patients' outcomes (Jové *et al.*, 2014). These findings imply that interdisciplinary collaboration could contribute towards the successful delivery of opioid stewardship roles by community pharmacists.

Nielsen et al has also developed some intervention practices that could be carried out by pharmacists to help prevent opioid misuse and promote opioid stewardship. They developed best practices statement that can support the safe use of prescription opioids (Nielsen *et al.*, 2024). These best practices involve opioid stewardship roles such as education and communication, risk identification which includes the use of PDMP, deprescribing and pain management, overdose prevention with naloxone supply, offering OAT treatment for persons that have developed opioid misuse and support the training and education of staff, stigma reduction, interprofessional collaboration and patient centred care (Nielsen *et al.*, 2024). In previous studies, community pharmacists' role in educating patients has been identified as an opioid stewardship

role that could help to prevent opioid misuse effectively (Kosobuski *et al.*, 2022; Riley and Alemagno, 2019). Pharmacists' contribution towards deprescribing opioids, which is another effective opioid stewardship role, has also been detailed in other studies (Niznik *et al.*, 2022; Shoemaker-Hunt and Wyant, 2020). In the study by Niznik et al, patient and provider education and medication chart reviews were strategies that propelled successful deprescribing. Similarly, the study by Shoemaker-Hunt and Wyant reported that carrying out strategies such as provider and staff education, including audit and feedback facilitated the implementation of deprescribing.

2.4 Factors that influence community pharmacists' roles in the prevention of prescription and OTC opioid misuse

Factors that influence community pharmacists' roles in the prevention of prescription and OTC opioid misuse are presented as limiting factors such as barriers, challenges, and motivating factors such as facilitators. Barriers and facilitators that were focused on preventing prescription and OTC opioid misuse, and factors that limited community pharmacists' role in harm reduction were identified from literature. Barriers and facilitators were classified as pharmacist related, physical environment or work process related, and social environment related and will be described individually in the subsequent paragraphs.

Pharmacist related barriers included insufficient education and training and other pharmacists' characteristics that could affect community pharmacists' role in opioid misuse. A scoping review reported that pharmacists' education and training regarding prescription and OTC opioid misuse to be poor (Hoppe, Ristevski and Khalil, 2020). Areas lacking adequate education and training were identification of medication misuse and diverting features, and counselling service users who were addicted to opioids (Fendrich, Bryan and Hooyer, 2018; Leong *et al.*, 2016; Lafferty, Hunter and Marsh, 2006). One study did report that community pharmacists have sufficient training that will enable them identify inappropriately prescribed analgesia (Meaadi, Obara and Nazar, 2023). Community pharmacists experienced some difficulties handling patients who deceptively obtained medications from prescribers in order to

sell them or to achieve euphoria. They feared physical or verbal abuse, losing customers, and potential litigation (Cochran, Field and Lawson, 2015; Fleming, Bapat and Varisco, 2019; Butler and Sheridan, 2010; Hagemeier *et al.*, 2016a; Wright *et al.*, 2016a). Moreover, community pharmacists did not view themselves as having adequate authority to control prescription opioid misuse with pharmacists ascribing authority on prescribers and the regulatory bodies (Rao *et al.*, 2021a).

Barriers related to the physical environment and work process have been identified in studies carried out in the USA (Vadiei *et al.*, 2022; Fleming, Bapat and Varisco, 2019; Lafferty, Hunter and Marsh, 2006). These barriers consisted of insufficient space in consultation area (Vadiei *et al.*, 2022), lack of privacy (Vadiei *et al.*, 2022; Fleming, Bapat and Varisco, 2019), perceived lack of clarity of pain management guidelines (Vadiei *et al.*, 2022; Fleming, Bapat and Varisco, 2019; Lafferty, Hunter and Marsh, 2006), limited scope of role (Vadiei *et al.*, 2022), work pressure (Fleming, Bapat and Varisco, 2019), lack of time (Fleming, Bapat and Varisco, 2019), and no reimbursement for patient-centred roles (Vadiei *et al.*, 2022).

Challenges that were related to the social environment had to do with how community pharmacists interacted with other health professionals, and service users. Community pharmacists stated that they had issues with referring service users who use prescription opioids to other treatment providers because they had insufficient knowledge about addiction services, lacked confidence in informing and referring service users to addiction services, and perceived the referral process to be cumbersome and prolonged (Hagemeier, Gray and Pack, 2013; Hagemeier *et al.*, 2016b; Butler and Sheridan, 2010; Sheridan and Butler, 2011). There is a relationship between this social environment related barrier and the pharmacist related barrier discussed earlier, in that, this social environment related barrier resulted from a lack of knowledge of the pharmacist regarding the referral pathway for people who were addicted to opioids.

Another social environment related barrier that limited pharmacists' role in the prevention of prescription and OTC opioid misuse was the lack of prescriber and

service users' understanding of pharmacists' roles. This could result in poor communication, which might negatively impact community pharmacists' ability to share information with the prescriber and patients (Vadiei *et al.*, 2022; Hartung *et al.*, 2018; Hagemeier, Gray and Pack, 2013). Inability of pharmacists to access patient's medical record which would enable them to intervene when presented with high-risk opioid prescriptions was another barrier (Hartung *et al.*, 2018; Rao *et al.*, 2021a).

When looking at across the three different factor categories, challenges that limited community pharmacists from carrying out roles that were focused on preventing OTC opioid misuse specifically are pharmacist related barriers such as: difficulty associated with determining the therapeutic need of the service user, uncertainty of where people who were addicted to OTC opioids should be referred, social environment related roles like supply of OTC opioids from multiple pharmacies, and negative attitude of service users (Hamer *et al.*, 2014). Facilitators to OTC opioid misuse prevention roles of the pharmacist are social environment related factors like up scheduling of OTC opioids to prescription opioids (Hamer *et al.*, 2014). Thus, providing a logical reason for pharmacists to refuse the sale of OTC opioids and improving pharmacists' confidence towards educating and advising service users about opioid misuse (Hamer *et al.*, 2014).

Facilitators to naloxone dispensing services include: patient related factors like improved awareness of the importance of intranasal naloxone among patients that use opioids and their families, increased education of the general public, and physical environment and work process related factors such as improved access to programmes and tools for opioid misuse screening (Bakhireva *et al.*, 2018). Barriers to naloxone dispensing services include physical environment related factors such as poor remuneration of community pharmacists, pharmacists' limited time, and poor coverage. Barriers to naloxone dispensing in the USA consists of patient related factors which affect the demand for this service. Examples of these factors are out-of-pocket payments by service users, stigma experienced by people who use opioids, and unaffordability of naloxone, especially for households with low income. In addition, barriers include a pharmacist related factor, which is the stigmatising attitude of the

pharmacists (Rao *et al.*, 2020; Muzyk *et al.*, 2019; Bakhireva *et al.*, 2018; Cid *et al.*, 2021).

Factors that limited community pharmacists' role in methadone service delivery are theft and risk to property/staff, which are physical environment related factors, and stigmatising attitude of pharmacy managers which is a pharmacist related barrier (Mackie *et al.*, 2004; Luty, Kumar and Stagias, 2010). Other barriers that can limit community pharmacists from offering methadone and buprenorphine dispensing were poor knowledge exhibited by some pharmacists which is a pharmacist related factor and lack of support which is related to the social environment (Yadav *et al.*, 2019). The motivating factors to methadone service delivery were better security measures which is related to the physical environment and improved demand for methadone services which is related to the social environment (Mackie *et al.*, 2004; Luty, Kumar and Stagias, 2010).For the needle exchange programmes, physical environment related factors such as the cost effectiveness and efficacy of the service determine the level at which service users will utilise them (Roberts and Hunter, 2004).

Overall, recognising the factors that influence the role of community pharmacists in the prevention of prescription and OTC opioid misuse could contribute towards the development of strategies that could help improve community pharmacists' role in the prevention of prescription and OTC opioid misuse. Strategies that were identified during this literature search are discussed below.

2.5 Strategies for the improvement of community pharmacists' roles in the prevention of prescription and OTC opioid misuse

Intervention Strategies that will enhance community pharmacists' roles in the prevention of prescription and OTC opioid misuse will target the factors that influence community pharmacists' role in the prevention of prescription and OTC opioid misuse. The strategies aim at overcoming the barriers and/or challenges that limit community pharmacists' role in prescription and OTC opioid misuse. Since barriers affect multiple areas of community pharmacists' role in the prevention of opioid misuse, it is important that intervention strategies are not only pharmacist focused but should target other areas that challenges have been identified, which could be at the

societal and the system level (Bakhireva *et al.*, 2018). The strategies are broadly classified into three based on their target. The strategies are pharmacist level strategies, system level strategies and societal level strategies. Pharmacist level strategies aim at mitigating pharmacist level barriers such as insufficient education and training of pharmacists. System level strategies will target physical and social environment related barriers that inhibits manager support, and limits reimbursement while societal level strategies will target social barriers that will limit service users from accessing community pharmacy based opioid misuse services like stigma experienced by people who are addicted to opioids.

In the UK, system level strategies that aim at barriers related to the social environment such as GP and pharmacists' collaborative relationships are required for community pharmacists to effectively screen, identify and refer persons who are misusing opioids for treatment (Fleming, McElnay and Hughes, 2004; Wazaify, Hughes and McElnay, 2006). In the USA, a collaboration between community pharmacists and physicians who prescribe buprenorphine improved patients' accessibility to treatment (Wu *et al.*, 2021a). Collaboration between community pharmacists and GPs has also been stated to be key in preventing prescription and OTC opioid misuse in Australia, New Zealand and Canada (Hoppe, Ristevski and Khalil, 2020; Sheridan and Butler, 2011; Leong *et al.*, 2016; Hamer *et al.*, 2014; Dubé *et al.*, 2018). However, for collaborative practices to be effective, community pharmacists and GPs would require education to improve their communication skills, recognise their roles in collaborative practice and eliminate bias (Makdessi, Day and Chaar, 2019). Collaboration among community pharmacists to facilitate information sharing has also been recommended for the prevention of OTC opioid misuse. This would better inform community pharmacists about service users who might be potentially misusing OTC opioids, and will enable experienced pharmacists to transfer ideas that will help improve pharmacists' roles in OTC opioid prevention (MacFadyen, Eadie and McGowan, 2001).

A system level strategy that was focused on limiting barriers related to the physical environment was reported in studies carried out in the USA is the electronic databases such as the real time prescription monitoring (RTPM) system (Hagemeier *et al.*, 2014;

Wright *et al.*, 2016b).This system enables pharmacists to screen and identify persons who misuse opioids, and then refer them to the GP. The RTPM has been used in the USA and has been reported to be beneficial for effectively monitoring prescription and OTC opioid use, in order to identify persons who might be misusing opioids thereby preventing misuse (Cochran, Field and Lawson, 2015; Hagemeier *et al.*, 2014; Hagemeier *et al.*, 2016b; Wright *et al.*, 2016b). The Prescription Drug Monitoring Programme (PDMP) is another electronic database that is used for monitoring prescription opioid use, thus helping pharmacists to prevent its misuse (Makdessi, Day and Chaar, 2019). Two other models for identifying OTC opioid misuse have been developed and shown to be feasible to carry out in community pharmacies in the UK (Fleming, McElnay and Hughes, 2004; Wazaify, Hughes and McElnay, 2006). Other system strategies targeted at barriers related to physical and social environment are referral to GPs, reduction of medication pack size, preventing early supply of opioids to patients, prohibiting multiple pharmacy opioid dispensing to the same service user, and accessibility to both patients' records and prescribers (Leong *et al.*, 2016; Hamer *et al.*, 2014).

Pharmacist level strategies such as education and training target the pharmacists' related barriers. Studies carried out in the USA (Muzyk *et al.*, 2019; Bakhireva *et al.*, 2018; Bach and Hartung, 2019a; Cochran *et al.*, 2020; Bachyrycz *et al.*, 2017; Chisholm-Burns *et al.*, 2019; Skoy *et al.*, 2020), and one study conducted in Canada (Cid *et al.*, 2021) have recognised that education and training are essential for effective delivery of opioid related services. Education and training have also been shown to improve community pharmacists' attitude towards carrying out opioid misuse prevention roles (McCormick *et al.*, 2006). Education enhances pharmacists' attitude towards people who are addicted to opioids (Eukel *et al.*, 2019). Interventions that are required for the delivery of an effective needle exchange programme by community pharmacists include: training of pharmacists and improving clients' awareness (McVeigh *et al.*, 2017). Training will also improve pharmacists' willingness to expand their services to include harm reduction services (Crawford *et al.*, 2013).

A study carried out in Scotland indicated that increased training of community pharmacists might have resulted in the improvement of community pharmacists' role in methadone dispensing and supervised methadone consumption in the previous five years, 1995 - 2000. (Matheson, Bond and Pitcairn, 2002). Similarly, pharmacists' training, improved their involvement in needle exchange programmes, methadone and buprenorphine dispensing services within a 20-year period, from 1995 to 2014 (Matheson *et al.*, 2016). In addition, education and training increases pharmacists' familiarity with administrative elements such as, standing orders and billing procedures, and clinical tasks, such as starting up a conversation with a patient and identifying eligible patients (Cid *et al.*, 2021). Potential concerns that the pharmacists might have about medications used in treating persons who are addicted to opioids were reported to be clarified through education (Bakhireva *et al.*, 2018). The reported concerns include the possibility that the dispensing of intranasal naloxone would promote opioid abuse or attract 'undesirable clientele' (Bakhireva *et al.*, 2018). Pharmacists could be educated either through the undergraduate pharmacy programme or through continuing professional development (CPD) programmes (Rao *et al.*, 2020; Chisholm-Burns *et al.*, 2019). Concerning training community pharmacists about the prevention of OTC opioid misuse, a distance learning training programme was identified to be most suitable and convenient because of pharmacists' busy schedules (MacFadyen, Eadie and McGowan, 2001). The distance learning programme will minimise barriers to pharmacists' training such as the exemption of non-regular staff and workers who are not involved in medicine sales from training, and the cost incurred from training staff (McBride *et al.*, 2003).

It is also important to note that other pharmacy staff might also need to be trained in order for pharmacists to carry out their role effectively (Scott and Mackridge, 2009). A study carried out in the UK identified training needs of pharmacy support staff such as pharmacy assistants, dispensers and technicians to enable them support community pharmacists' role in harm reduction services. These training needs include advising service users, availability of treatment centres, outcomes of treatment, and clinical and legal features (Mackridge and Scott, 2009). Another study recommended that for effective delivery of community pharmacy-based harm reduction services like the

needle exchange programme, security personnel also needs to be trained (Hall and Matheson, 2010). This will help reduce stigma and discrimination experienced by the service users, and improve their confidence in the pharmacist (Radley *et al.*, 2017).

System level strategies that target the social and physical environment related barriers, such as renumeration and provision of support systems to aid community pharmacists' interaction with people who are addicted to opioids, could improve community pharmacists' role in carrying out harm reduction services such as methadone dispensing and needle exchange services (Fleming *et al.*, 2001). Community pharmacists' role in harm reduction could also be enhanced by supporting pharmacists to recognise appropriate referral centres for persons who are addicted to opioids (Bates *et al.*, 2015). The introduction of a pharmacy service which provided information and support to community pharmacists was beneficial in enhancing Irish community pharmacists role in methadone dispensing (O'Connor, Sheridan and Corrigan, 2001).

2.6 Gaps in the literature

Majority of studies on the prevention of prescription and OTC opioid misuse were carried out in the USA. There is a dearth of literature with a specific focus on community pharmacists' role in opioid prevention and misuse in the UK despite the relative high prevalence of opioid misuse especially in the Northeast of England. In the UK, a study has been carried out to investigate community pharmacists' perception about inappropriately prescribed analgesia (Meaadi, Obara and Nazar, 2023). The study did not focus on opioids specifically but examined prescription analgesics. Also, the study only focused on pharmacists and did not include other pharmacy stakeholders like pharmacy support staff and pharmacy commissioners.

Furthermore, the study carried out by Meaadi et al (2023) interviewed pharmacists from different regions of UK but was not focused on pharmacists in the Northeast region. The North East region of UK has relative high levels of drug misuse, highest number of drug related deaths, high opioid prescription rates, socioeconomic deprivation and health inequalities when compared with other regions in England

(Marmot, 2020) (Office for National Statistics, 2020; Jani *et al.*, 2020b; Curtis *et al.*, 2019).

This study will address the gaps observed in the previous paragraph. In this study, the views of other stakeholders were sought to get a comprehensive view of factors that influence community pharmacists' behaviours in relation to the prevention of prescription and OTC opioid misuse. The use of a varied group of participants will also enable the development of more comprehensive strategies that will target and mitigate all identified factors and barriers. This research will also be carried out in the Northeast of England that has high levels of opioid misuse. As highlighted in overall study aim, the study is planned to intervene and contribute to knowledge of prevention of prescription and OTC opioid misuse studies in England and trigger further studies in the opioid and prescription prevention misuse, upskill the competencies of community pharmacists in dealing opioid related problems and intervene in the socioeconomic problems prevalent in the northeast of England and with a view to proffer strategic and well-informed solutions targeting challenges to the prevention of opioid misuse in the UK.

2.7 Significance of the study

The findings of this study will potentially help local policy makers and commissioners to make informed decision about the types and extent of support and training that would improve community pharmacists' involvement in drug misuse prevention and management activities. In addition, the findings could also be beneficial to community pharmacists, as it would help them to offer effective drug misuse prevention and management services in Northeast England. In the long term, it is hoped that the implementation and policy changes triggered by the findings of the studies would lead to a reduction in hospitalization and death rates that arise from drug misuse in the region, as well as significant reduction in health inequalities between the Northeast and other regions. Furthermore, from available data and knowledge, this is the first study that developed intervention strategies targeted specifically on opioid misuse based on interview of multiple groups of pharmacy stakeholders in Northeast England. Its contribution to and advancement in knowledge would help in building

local evidence and practice data bank that will link to existing body of knowledge and/or literature nationally and globally in opioid misuse prevention studies. Overall, the study is significant to greater understanding of the important roles of community pharmacists to regional and national development of UK especially as it relates to pharmacy education, and control of opioid use.

2.8 Aim of the study

This research aims to develop intervention strategies that will help to enhance community pharmacists' roles in the prevention of prescription and OTC opioid misuse in the UK.

2.9 Research Questions

i. What factors influence community pharmacists' role in the prevention of prescription and OTC opioid misuse can be obtained from literature?
ii. What are community pharmacy staff's views about factors that influence community pharmacists' roles in the prevention of prescription and OTC opioid misuse in the UK?
iii. What are commissioners' views about community pharmacists' roles in the prevention of prescription and OTC opioid misuse in the UK?
iv. What intervention strategies could enhance community pharmacists' roles in the prevention of prescription and OTC opioid misuse?

2.10 Research objectives

i. To identify, collate, and appraise existing evidence of the factors that influence community pharmacists' role in the prevention of prescription and OTC opioid misuse;
ii. To identify pharmacy staff views regarding factors that influence community pharmacists' roles in the prevention of prescription and OTC opioid misuse in the UK;
iii. To identify commissioners' views about community pharmacists' roles in the prevention of prescription and OTC opioid misuse in the UK

iv. To develop intervention strategies that could enhance community pharmacists' roles in the prevention of prescription and OTC opioid misuse.

2.11 Summary

This chapter discussed existing literature on the role of community pharmacists in the prevention of prescription and OTC opioid misuse. Research gaps were then identified based on the outcome of the reviewed literature. The research gaps enabled the identification of study aim, research questions and objectives of the study. The next chapter will describe the methods and methodology adopted in this study.

Chapter 3. Methods and Methodology

3.1 Introduction

The preceding chapters provide a background to this research, the importance of carrying out further research on the role of community pharmacy in the prevention of prescription and OTC opioid misuse in the UK, and the study aims, questions, and objectives. This chapter describes the methodological approaches that were used to meet these aims and objectives, including the underpinning research philosophy, methods of data collection and analysis, and ethical considerations.

3.2 Choice of Methodology

3.2.1 Ontological and Epistemological Assumptions

The philosophical position that was taken while carrying out this research is the critical realist position. Philosophy is a system of the researcher's thought which produces new knowledge about the concept studied (Pranas, Jolita and Regina, 2018). The philosophical perspective that a researcher takes reveals the assumptions that were made about their research and how those assumptions affect decisions that relate to its objectives, design, methods, data analysis, and interpretation of data (Moon and Blackman, 2014; Crotty, 1998). The philosophical stance that a researcher takes is based on ontology and epistemology. Ontology is the study of reality and it raises fundamental questions about human existence and the nature of its being (Crotty, 1998). In ontology, there is the assumption that there is a reality to be studied and the other assumption which states that there is no reality to be studied outside the human mind (Moon and Blackman, 2014).

Epistemology is the study of knowledge, which has to do with comprehending how a person knows what they know, and relates to the relationship between knowledge and the human (Crotty, 1998; Denzin, 2005) . Epistemology consists of objectivism and subjectivism(Crotty, 1998). Objectivism posits that knowledge about truth or reality is gained by observation while subjectivism is based on the assumption that

knowledge and reality are based on individual experiences (Crotty, 1998; Denzin, 2005).

These ontological and epistemological assumptions form the basis of all philosophical frameworks. There are three basic philosophical positions that could be taken in research (Fryer, 2020; Crotty, 1998) . These positions which could also be called frameworks consist of: the positivist framework, the constructionist framework, and the critical realistic framework (Fryer, 2020; Crotty, 1998). The positivist framework assumes that there is a reality to be studied outside of the human mind but that knowledge about this reality could only be gained through observation of physical processes (Ryan, 2018; Pranas, Jolita and Regina, 2018). The constructionist framework states that there is no individual reality but that knowledge about our reality is gained through interactions in society or social constructs (Ryan, 2018; Burr and Dick, 2017). The critical realist framework which was adopted in this study lies between the realist framework and the constructionist framework (Ryan, 2018; Bhaskar, 2016).

The critical realist framework was developed by an Indo-British philosopher, Roy Bhaskar, and other theorists (Taylor, 2021).The critical realist framework also assumes that there is a reality to be studied but that the interpretation of this reality depends on how the researcher views it and is influenced by the researcher's experiences (Fletcher, 2016; Blandthorn *et al.*, 2018). Critical realism also challenges the positivist framework in that critical realism proposes that not all reality can be observed. In critical realism, there are underlying mechanisms that generate concepts that could be observed (Fletcher, 2016; Leung and Chung, 2019). Critical realism proposes that there are three strata of reality: empirical, actual, and real. These strata could also be described as experiences, events and causal mechanisms respectively (Bhaskar, 2016). The empirical strata have to do with experiences or that which could be observed, the actual strata have to do with events that take place but may or may not be observed by the researcher, while the causal mechanisms are the invisible forces that generate the actual and empirical strata (Figure 3.1) (Raduescu and Vessey, 2009). In critical realism, the researcher attempts to understand the depth of reality

rather than just its surface (Fletcher, 2016). Critical realism also proposes that these generative mechanisms could be layered as physical, biological, social, psychosocial and organizational strata, and that complex interaction between these layers could influence the resultant events that are produced (Danermark, Ekström and Karlsson, 2019; Oltmann and Boughey, 2012).

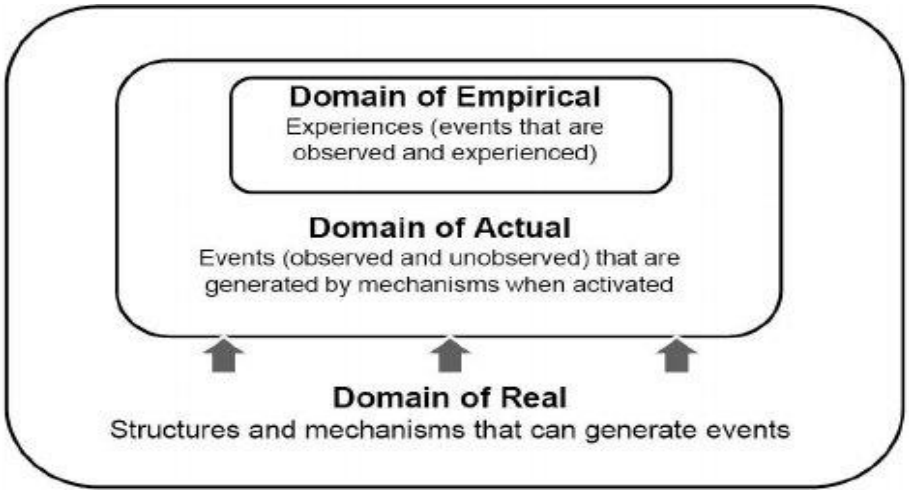


Figure 3.1 Domains of Reality in the Critical Realist Ontology
Figure was obtained from Raduescu & Vessey (2009)

Generally, in the natural sciences, experiments are carried out in a controlled environment in which independent variables are manipulated in order to measure their effect on dependent variables (Oltmann and Boughey, 2012). In these experiments, other independent variables that could influence the dependent variable are held constant (Bhandari, 2022). This allows the researcher to study the variable of interest objectively to ascertain whether that independent variable affects the dependent variable (Oltmann and Boughey, 2012). Controlled experiments do not allow for the subjective interpretation of research data. This is typical of the positivist approach that posits that there is a reality that exists outside of the human mind (Bhaskar, 2016; Mingers and Standing, 2017). However, in social research, where human interactions are involved, it is difficult to control human actions and movements. In addition, human activities could be active or inactive. Hence, it will be challenging to apply controls that will enable the researcher to carry out objective observations (Oltmann and Boughey, 2012; Yeung and Mohammed, 2019). Thus, in social research, it is ideal

to use the critical realistic framework which allows the researcher to seek to understand a variety of experiences at the surface, that is, the empirical level, and also attempts to explore the underlying mechanisms that give rise to these observable experiences (Mingers and Standing, 2017; Dalkin *et al.*, 2015).

The critical realist stance was assumed in this research because it enabled me to effectively explore the experiences of community pharmacy stakeholders regarding community pharmacists' role in prescription and OTC opioid misuse (Bhaskar, 2013). In this study, community pharmacists' role in prescription and OTC opioid misuse was considered to be the behaviour of concern or the reality. Critical realism enabled me to explore this reality in-depth, that is, the empirical layer which represents the experiences of the stakeholders and also helped me to understand the underlying mechanisms which could be physical, social, psychological, or organisational that might contribute to stakeholders' experiences (Benton and Craib, 2023; Archer *et al.*, 2013). These underlying mechanisms also include interactions among community pharmacists and social structures such as policy, funding, training etc. that influence community pharmacists' behaviour (Elder-Vass, 2010; Cruickshank, 2012). These underlying mechanisms which are known as factors in this study were revealed by asking research questions that begin with the words 'how', and 'why' (Leung and Chung, 2019; Sayer, 1992). Furthermore, critical realism enabled the exploration of a variety of experiences from different stakeholders simultaneously while delving deep to try to assess underlying mechanisms that gave rise to the behaviour of concern (Oltmann and Boughey, 2012; Danermark, Ekström and Karlsson, 2019). Therefore, this approach would enable me to explore the underlying mechanisms that might have influenced community pharmacists' role in the prevention of prescription and OTC opioid misuse (Pawson and Tilley, 1997).

Another reason for using the critical realist approach is that community pharmacists' interactions in this study cannot be controlled like is done in an experimental study (Bhandari, 2022; Williams, Rycroft-Malone and Burton, 2017). Hence, using the positivist approach which observes outcomes objectively, would not have been possible. In addition, the constructionist approach could not be used for this study

because the reality of community pharmacists' roles in the prevention of prescription and OTC opioid misuse could be observed and is independent of the human mind (Ratner, 2006; Taylor, 2018).

3.2.2 Methodology

Having clarified my ontological and epistemological perspective, it was decided that a qualitative method would be the best approach to use to explore community pharmacist stakeholders' experiences. This decision was taken because the qualitative method has been described as one of the most widely used method that could be used to explore human experience as it facilitates understanding of human experience (Wu and Volker, 2009; Harper and Thompson, 2011).

A qualitative research approach was also adopted because it helped me to understand the respective views of the different groups of stakeholders, and was also ideal for answering the 'how' and 'why' questions that enabled participants to speak extensively about the questions asked (Oltmann, 2016). This helped me to obtain the views of participants and also understand the underlying factors that could influence community pharmacists' role in prescription and OTC opioid misuse (Hammarberg, Kirkman and de Lacey, 2016). Qualitative methods are also useful in achieving research objectives that begin with words like 'to identify' as stated in my research objectives (Oltmann, 2016). This is because research objectives that begin with such words cannot be assessed using a quantitative method (Busetto, Wick and Gumbinger, 2020).

Other methods that were considered were quantitative and mixed methods. Quantitative methods were not used in this study because community pharmacists' experiences will not be effectively explored by carrying out objective assessments that are used in quantitative methods (Barnham, 2015). They would not enable me to answer my 'why' and 'how' questions (Lakshman *et al.*, 2000). The mixed method was not also used because this study was focused on obtaining the views of participants regarding the role of community pharmacists in the prevention of prescription and OTC opioid misuse. This objective will be better achieved by using

the qualitative method. The mixed method was not also used because the quantitative aspect of the mixed method study would not be useful for exploring stakeholders' experiences because of the reason stated in the previous paragraph and thus will not contribute any additional findings to the qualitative aspect of the mixed method study.

i. Data collection

The data collection method that was appropriate to be used in this qualitative research was the semi-structured interview method. The semi-structured interview is the most common data collection method used in qualitative research (Kallio *et al.*, 2016). This method allowed me to obtain detailed and rich data from stakeholders (Smith, 1995; Horton, Macve and Struyven, 2004) me to ask open-ended questions aimed at answering my research questions and to gain deep insight into the data (Pessoa *et al.*, 2019). The semi-structured interviews were carried out using topic guides that consisted of key topics to be covered in the interview, along with prompts that helped elicit responses from the stakeholders (Baumbusch, 2010). These topic guides enabled me to engage in conversation with the stakeholders while maintaining focus on the topics to be covered (DiCicco-Bloom and Crabtree, 2006). The semi-structured approach also allowed me to make clarifications about the interview where required without strictly following the topic guides (Qu and Dumay, 2011).

Other methods like structured and unstructured interviews were also considered. The structured interview was not used because it is carried out in such a manner that shorter responses are elicited from research participants. This is because the interview questions are specific and are predetermined in a fixed order with a small number of response groups which will not allow detailed and rich responses to be elicited from the stakeholders (Stuckey, 2013). The unstructured interview was not used because it has no predetermined plan on how the interview will progress, which sometimes makes it difficult for the interviewer to capture the key topics that must be covered in each interview (Mathers, Fox and Hunn, 1998; Fox, 2009). Consequently, key themes might not be captured in some interviews which makes comparison across all interview data difficult to carry out by the researcher (Mueller and Segal, 2014).

Another data collection method that was considered to be used was the observation method. In this method, the researcher uses their five senses (sight, hearing, touching and smelling) to provide a description of the event under study (Kawulich, 2005; Paradis *et al.*, 2016). It could also be described as watching a phenomenon of interest until insight is gotten regarding that situation (Kumar, 2022). This method was not adopted because the views and experiences of participants cannot be obtained by watching community pharmacists carry out their roles (Jamshed, 2014).

One-to-one interviewing was used in this research because it helped to ensure that confidentiality was observed and that each participant was comfortable to respond to questions without interference from other participants as is the case in focus groups (Noon, 2018; Prevue, 2021). Observation of non-verbal cues such as body language, eye contact and facial expression facilitated researcher's understanding of the participants' narratives (Ryan, Coughlan and Cronin, 2009). One-to-one interviews also helped the researcher to probe the interviewee when clarity was needed (Stofer, 2019; Ryan, Coughlan and Cronin, 2009). These interviews were carried out via zoom because it helped to facilitate scheduling of meeting times that were suitable for both the interviewee and interviewer (Gray *et al.*, 2020). Zoom was also convenient to use since it could be accessed either through a phone or computer. In addition, recordings and transcriptions of interviews were produced by zoom at no extra cost to the researcher (Gray *et al.*, 2020).

ii. Data analysis

The qualitative method that I chose to use in the analysis of the interview data was the thematic analysis (TA) method. TA is normally used to summarise important patterns across data and to interpret the data in line with the research question (Braun and Clarke, 2014). TA was useful in summarising relevant themes across my study participants' account and also helped me to write a rich, detailed and interpretative narrative about participants' data (Boyatzis, 1998). In addition, the reflexive TA method is flexible and not tied to a particular epistemology or theoretical position (Braun and Clarke, 2006).

Other qualitative methods such as the Interpretative Phenomenological Analysis (IPA), which was also considered to be used in this study, is tied to the phenomenological epistemological framework which focuses on understanding a phenomenon based on participants' experiences (Smith, Jarman and Osborn, 1999; Braun and Clarke, 2006). In addition, my study was not focused only on determining in-depth knowledge about individual participants' subjective experiences (perceptions, on obtaining feelings, thoughts etc) as is obtainable in IPA, but was also aimed at determining participants' experiences with a view to identifying factors that could influence pharmacists' behaviour, and to develop interventions that could modify behaviour (Smith and Osborn, 2015; Bhaskar, 2016). Hence, some level of interpretation of data was needed in this study which the TA enabled me to achieve. The constant comparative method associated with Grounded Theory was also considered; this is aimed at developing a theory of a phenomenon that is based on the data (Glaser and Strauss, 2017; McLeod, 2001). Since my study was not focused on developing theories, this method was not used (Holloway and Todres, 2006). In addition, TA is more suitable for studies that are aimed at identifying, summarising and interpreting relevant patterns across data (Braun and Clarke, 2021; Charmaz, 2006). Reflexive TA with the critical realist framework has also been used successfully in other studies that were aimed at determining factors that influence health professionals' roles in offering substance or drug misuse services (Kersey, Hutton and Lyons, 2023; Waples, Carlisle and Maynard, 2023; Selbekk, Sagvaag and Fauske, 2015).

3.3 Use of theoretical models to map research findings

Two inter-related behavioural models were used to explain research findings from this study: the capability, opportunity, motivation and behaviour (COM-B) model and the behaviour change wheel (BCW). These models helped me understand community pharmacists' behaviour with respect to opioid misuse, and to identify strategies that might contribute towards improving community pharmacists' behaviour respectively. The COM-B model is used to identify aspects of a behaviour that needs to be changed for an intervention to be effective (West and Michie, 2020) which is an important step

in understanding behaviour. The COM-B model is related to the BCW model because it forms the core of the BCW model. The BCW model helped me to develop intervention strategies aimed at identified aspects of behaviour that require change (Michie, van Stralen and West, 2011a).

The COM-B/BCW model were used in this research because it will enable me to achieve my research aim, which is to develop intervention strategies that will help to enhance community pharmacists' roles in the prevention of prescription and OTC opioid misuse in the UK (Michie, van Stralen and West, 2011c). I decided to use these models when I recognised that the COM-B model could help me identify factors (including social, environmental and motivational factors) that could influence community pharmacists' behaviour and that strategies that are targeted at improving each factor identified could be developed by the BCW model (Timlin, McCormack and Simpson, 2021). Furthermore, the COM-B model comprises part of the BCW model and is the core of the BCW model. Therefore, the BCW model provided a comprehensive tool that helped me to obtain my research aims and objectives. The BCW model was also chosen because it was designed based on findings of a systematic review of 19 behaviour change models (Michie, Atkins and West, 2014b). This implies that the BCW model is a robust tool for understanding behaviour, as well as for designing intervention strategies that will help improve the behaviour (Michie, van Stralen and West, 2011c). This further explains my decision to use this model for this research.

Other research models that were considered for this research were the Health Belief Model (HBM), the Theory of Planned Behaviour (TPB) and the Transtheoretical model (stages of change) (Hossain *et al.*, 2021). The HBM was not used in this study because it mainly focuses on a person's belief and does not recognise other factors that could influence human behaviour such as social and environmental factors (Orji, Vassileva and Mandryk, 2012).

The TPB was not also chosen for use in this research because it is largely centred on an individual's intention. It considers this intention to be the factor that predicts the

individual's behaviour (Sniehotta, Presseau and Araújo-Soares, 2014). It does not consider the fact that an individual might have an intention and may not act on it. It does not also take into cognisance environmental factors that could influence an individual's intention to carry out the behaviour (Ho *et al.*, 2024).

The Transtheoretical model (stages of change) classifies behaviour change into different stages- precontemplation, contemplation, preparation, action and maintenance (Hashemzadeh *et al.*, 2019). This could over oversimplify the behaviour change process, which is often a complex activity. This model recognises a person's ability to make decisions and their motivation, but does not capture social and environmental influences on the person's behaviour (Deng *et al.*, 2022). As a result, this model was not use in this research.

These COM-B model and the BCW model will be discussed in detail below.

3.3.1 COM-B model

The COM-B model was developed by Susan Michie and colleagues in 2011 (Mayne, 2017; Michie, van Stralen and West, 2011a). An illustration of the COM-B model is displayed in Figure 3.2.

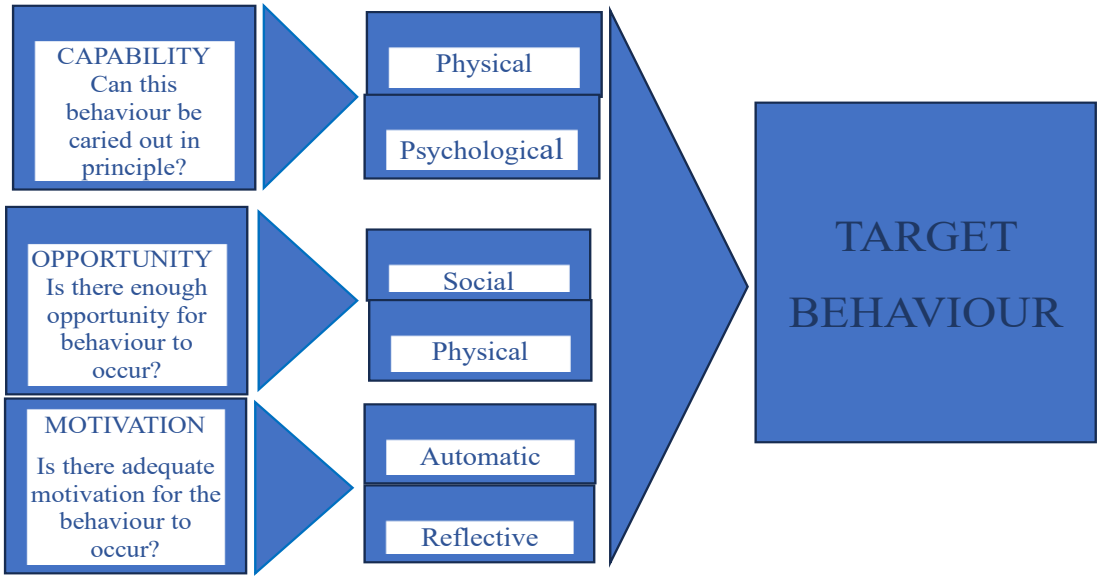


Figure 3.2 The COM-B Model
The figure was adapted from the decision lab 2024.

The COM-B model helped me to understand community pharmacists' behaviour, that is, identify factors that influence behaviour, thereby contributing towards developing an intervention that will cause behavioural change (West and Michie, 2020). The COM-B model states that three factors must be present in order for behaviour change to be effected: capability, opportunity and motivation. A person who has the capability and opportunity to carry out a particular behaviour, will be motivated to carry out that behaviour (Michie, van Stralen and West, 2011a). Capabilities are the abilities inherent in a person that enable them to change behaviour, provided opportunities are present. There are two groups of capability: psychological capability and physical capability. Examples of psychological capability include knowledge, decision making skills, psychological skills, and memory while physical capability include strength, stamina, and physical skill. Opportunities are environmental factors that facilitate individuals to change behaviour, provided that capability is present (West and Michie, 2020). Opportunities consist of two parts: physical opportunities and social opportunities. Examples of physical opportunities are time, location, money, resources etc while social opportunities include policies, laws, cultural or societal norms, etc. Motivation refers to a combination of mental processes that enable behaviour change in an individual (West and Michie, 2020; Michie, van Stralen and West, 2011a). There are also two groups of motivation: reflective and automatic. Reflective motivation relates to high cognitive processes such as goals, values, beliefs etc while automatic motivation include emotional responses, impulses, habits and inhibitions. In addition, an individual's motivation for behaviours for which change is sought should be higher than their motivation for other activities (West and Michie, 2020). The behaviour under study in this research is community pharmacists' role in prescription and OTC opioid misuse prevention.

Hence, capability, opportunity and motivation could either act as a barrier or facilitator to behaviour change. Identifying the factors that act as barriers or facilitators helped me to develop feasible strategies that could destroy barriers and enhance the facilitators. Thus, improving behaviour of the community pharmacist.

3.3.2 Behaviour Change Wheel (BCW) model

The BCW model was used to identify interventions that might contribute towards improving community pharmacists' role in prescription and OTC opioid misuse. The BCW model was also developed by Susan Michie and colleagues in 2014 as an improvement of the COM-B model (Michie, van Stralen and West, 2011a). This is why the COM-B model forms part of the BCW model and is located at the centre of the BCW model (Figure 3.3). The BCW model was developed by systematically searching for behavioral science frameworks of interventions from a wide range of sectors and disciplines and compiling the most useful components of these frameworks (West and Michie, 2020). In addition to the COM-B component, the BCW model also consists of nine intervention functions and seven policy categories components, which are useful for developing interventions for behaviour change (Michie, van Stralen and West, 2011a).

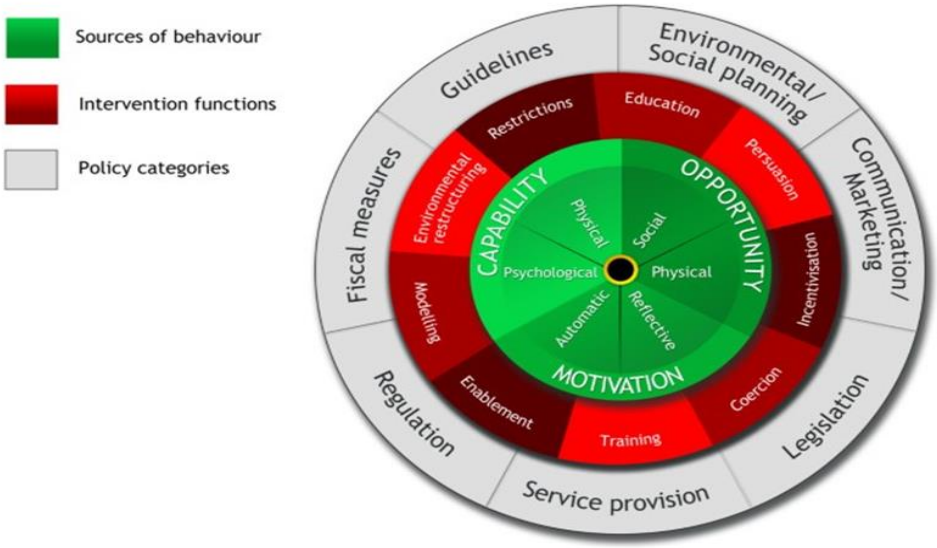


Figure 3.3 BCW model
This figure was obtained from Michie et al (2011)

The BCW model has been previously used in developing interventions for improving: the use of primary care clinical guidelines; the use of hearing aids; everyday discussion about physical activity in the health sector; physical activity in women with

gestational diabetes; and the delivery of mental health support in the audiology department (Kredo *et al.*, 2018; Barker, Atkins and de Lusignan, 2016; Reid *et al.*, 2022; Smith *et al.*, 2022; Bennett *et al.*, 2023). A description of the intervention and policy functions propounded by the BCW model are displayed in Table 3.1.

Table 3.1 Description of the intervention and policy functions of the BCW

Intervention function	**Definition**	**COM-B target**
i. Education	It helps to improve a person's knowledge and understanding	Capability, Motivation
ii. Persuasion	This function relates to the use of communication to produce negative or positive feelings, and to stimulate action	Motivation
iii. Incentivisation	Incentivisation produces an expectation of benefit which could help to improve reflective and automatic motivation	Motivation
iv. Coercion	It produces an expectation of cost or punishment which could improve reflective and automatic motivation	Motivation
v. Training	This function improves an individual's skill	Capability Opportunity Motivation
vi. Enablement	This function helps to improve capabilities or minimize barriers to capabilities	Capability Opportunity Motivation
vii. Modeling	Modeling involves the provision of a model for people to imitate.	Motivation Opportunity
viii. Environmental restructuring	This relates to modifying the physical or social environment.	Opportunity Motivation
ix. Restrictions	Restrictions are rules that minimize an individual's ability to be involved in the target behaviour or rules that improve the individual's ability to be involved in the target behaviour.	Opportunity
Policy category	**Definition**	
i. Communication/ Marketing	This consists of the use of mass or social media, telephone, print etc	
ii. Guidelines	This involves the creation of documents that stipulate or recommend practice, and this includes modification to service provision.	
iii. Fiscal Measures	These are measures that increase or decrease financial costs through the tax system.	
iv. Regulation	This involves setting up rules that guide behaviour or practice.	
v. Legislation	This involves the making or modification of laws that relate to a behaviour or practice.	
vi. Environmental/ Social Planning:	This involves designing and/or controlling the physical and social environment.	
vii. Service Provision:	This policy category has to do with delivering a service	

Table was adapted from Peiris et al (2015)

To enable the development of 'active components' that are necessary for the development of intervention strategies that will change behaviour, the BCW model also consists of identifying content and implementation options. Ultimately, the BCW model consists of three stages as displayed in Figure 3.4. Namely, understanding the behaviour, identifying intervention options, and identifying content and implementation options. Understanding the behaviour is achieved by mapping community pharmacy staff findings to the COM-B model, which is the core of the BCW model. This helped to determine factors that influence community pharmacists' roles in the prevention of prescription and OTC opioid misuse and identify the aspects of the target behaviour that need to change or improve.

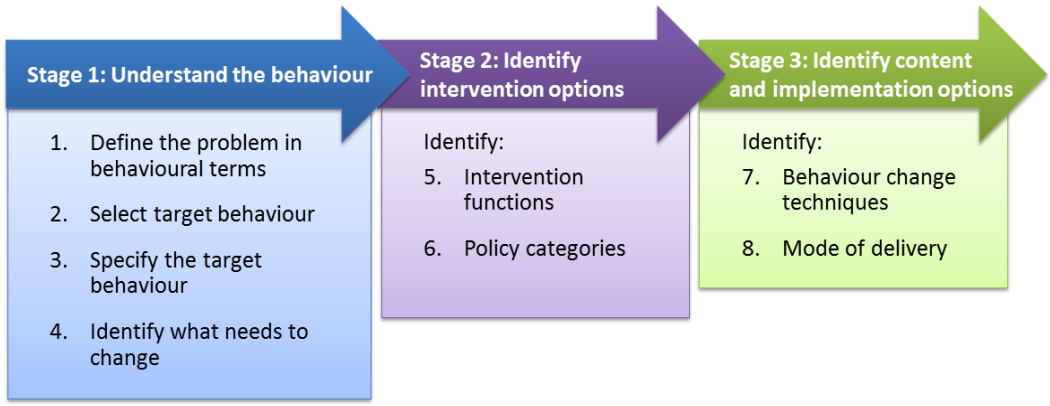


Figure 3.4 Stages in the development of strategies
This figure was obtained from Michie et al (2014)

3.3.3 Stages in the development of intervention strategies developed using the BCW

Identifying intervention options involves mapping of the aspects of behaviour that need to change to the appropriate intervention function that will help to change or improve the target behaviour. Identifying intervention options also relates to the mapping of appropriate intervention functions to relevant policy categories that will help to deliver these functions. There are nine intervention functions in the BCW model as displayed in Table 3.1. This table also provides the definitions of each of these intervention functions and the seven policy categories from the BCW that could help in the delivery of these functions.

Identifying content and implementation options has to do with identifying the Behaviour Change Techniques (BCT) that are relevant to deliver the selected intervention functions and the most appropriate mode of delivery. BCTs were identified based on evidence of targets for intervention that were identified from research data, that is the systematic review, pharmacy staff and commissioner findings and were named in line with the Behaviour Change Technique Taxonomy Version 1 (BCTTv1) (See Appendix A: Behaviour Change Technique Taxonomy Version 1) (Michie *et al.*, 2013). The BCTTv1 was developed to provide standardised and uniform terms that could be assigned to behaviour change interventions or techniques. The BCTs are also referred to as the active ingredients in intervention development which cannot be reduced or divided (Michie *et al.*, 2013). There are 93 BCTs in the BCTTv1, classified into 16 groups. These BCTs help in identifying strategies that could change behaviour. The appropriate mode of delivery for the strategies were then identified at this stage (Michie, Atkins and West, 2014a).

3.4 Methods

Prior to carrying out the qualitative research, a systematic review was carried out. Hence, this research involved three studies: i) a systematic review of published qualitative studies; ii) an interview study involving 28 community pharmacy staff; and iii) a second interview study involving eight commissioners of community pharmacy services. The systematic review helped me to obtain baseline understanding and insight into the experiences of stakeholders regarding community pharmacists' role in prescription and OTC opioid misuse globally. Findings from this systematic review also provided a framework for developing the topic guides that were used to carry out the qualitative studies. These approaches are described in detail below:

3.4.1. Systematic Review

The systematic review aimed to identify, collate and appraise findings of all published research on the views and perceptions of stakeholders regarding barriers and facilitators to community pharmacists' role in the prevention of licit opioid misuse. The stakeholders referred to in this systematic review were community pharmacists,

pharmacy staff, physicians, other health professionals and patients. This systematic review was carried out to determine gaps in the literature which helped to inform the focus of the qualitative study.

Literature on the barriers and facilitators to community pharmacists' role in prescription and OTC opioid misuse was reviewed. The PRISMA (Preferred Reporting Item for Systematic Reviews and Meta-Analysis) guideline (See Appendix B: PRISMA 2020 Checklist) (Page *et al.*, 2021) was used in carrying out this review and the protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) (registration number CRD42021260590 (Offu, Visram and Lindsley, 2021).

The steps carried out in this systematic review are detailed below.

Information sources

The following electronic databases were used to identify evidence: MEDLINE, EMBASE, Scopus, Web of Science, CINAHL, and PsycINFO. Search was carried out in January 2022. No country restriction was placed. Searches were also carried out on Google and Google Scholar. The reference lists of included articles were searched and forward traced for articles that met the inclusion criteria.

Study selection

To be included, studies had to meet the following criteria:

i. Qualitative studies that reported findings of barriers and facilitators of community pharmacists' role in prescription and OTC opioid misuse.

ii. Other types of studies in which data were analysed qualitatively such as mixed methods studies, surveys.

iii. Studies that were reported in English language.

iv. Research that focused either on OTC opioids only, prescription opioids only or a combination of any of the opioid types.

vi. Studies in which community pharmacists collaborated with other groups of pharmacists, such as hospital pharmacists and academic pharmacists.

vii. Studies in which community pharmacists collaborated with other health care practitioners, such as physicians and nurses.

Studies were excluded if they were:

i. carried out on hospitalised patients.

ii. not reported in English language.

iii. studies or conference papers that have only abstracts, that is, the full text articles could not be located.

Search strategy

Free text, keywords and Medical Subject heading (MESH) terms were developed and used to carry out the database searches. The main keywords that were used to carry out the search were community pharmacy, opioid misuse intervention and opioid misuse. Other search terms used in this review are displayed in Table 3.2.

Table 3.2 Search terms used in database searches

Keywords	Search terms
Community pharmacy	Community pharmacy, retail pharmacy
Opioid misuse intervention	education, information, screening, harm reduction, needle and syringe exchange, opioid substitution therapy, buprenorphine, methadone
Opioid misuse	opioid addiction, opioid abuse, opioid related disorder, opioid epidemic, prescription opioid misuse, codeine misuse, tramadol misuse, cough syrup misuse, fentanyl misuse, pentazocine misuse, pethidine misuse, oxycodone misuse, morphine misuse, hydrocodone misuse, co-codamol misuse

Boolean operators (AND, OR) were used to combine selected terms for the search. Truncation (*) was also used in searching words that could have different endings. Filters and limits were not used in this search.

Selection process

Titles and abstracts were screened for eligibility. Full text screening of eligible articles was then carried out. Each stage of screening was carried out independently by the researcher and the supervisory team. When consensus was not reached on the eligibility of included articles, the supervisor not involved in the screening, assessed eligibility of the selected articles.

Data extraction and quality assessment

A modified Joanna Briggs Institute (JBI) data extraction form was used to extract relevant characteristics of each included study. Quality assessment was carried out with the JBI critical appraisal checklist. Extraction of data and quality assessment were carried out by the researcher and overseen by the supervisors.

Analysis

Narrative synthesis was used in analysing data from included articles. This method was used to synthesise the findings from several studies and it depends mainly on the use of texts or words to explain or summarise findings (Popay *et al.*, 2006). Narrative synthesis is also known as story-telling and is suitable for the synthesis of qualitative studies because of their reliance on narratives (Popay *et al.*, 2006). It is important to note that different forms of narrative synthesis are used in analysing data, since consensus on the method of narrative synthesis to be adopted by researchers has not been reached. However, the elements of narrative synthesis proposed by Popay et al was adopted here because their guidance provides a systematic and transparent method of analysing and reporting systematic reviews (Popay *et al.*, 2006). This narrative synthesis consisted of preliminary synthesis and mapping of themes to the COM-B model of behaviour.

Preliminary synthesis was conducted using the thematic analysis method proposed by Thomas and Harden for analysis of data obtained from primary qualitative studies (Thomas and Harden, 2008). These stages are: coding of text (stage 1), identification of descriptive themes (stage 2), and identification of analytical themes (stage 3). In the context of this systematic review, line-by-line coding of findings from included studies was carried out in stage 1, description of these findings were then carried out in stage 2 while stage 3 consisted of the identification of new findings (from outside individual studies). Stage 1 and 2 often overlap each other. On completion of stage 2 analysis, the descriptive themes were mapped to the COM-B model of behaviour. This resulted in the development of analytical themes.

The descriptive themes that were identified in stage 2 were mapped to the COM-B model of behaviour by classifying them into the 'capability, 'opportunity' and 'motivation' groups. Themes that were classified as 'capability' were those that were related to knowledge and skill, themes that were classified as 'opportunity' were associated with environmental and system level factors while themes that were classified as 'motivation' were related to attitude. This process was carried out by the researcher, but guidance was given by a member of the supervisory team who is a psychologist with expertise in this area.

3.4.2 Primary Qualitative Studies

Having described the first approach that was used in this study, the second and third approaches which were qualitative analysis are described in detail here. As stated earlier, the systematic review helped in the development of topic guides that were used to obtain data from the qualitative studies. The qualitative studies will be described here.

Setting for qualitative studies 1 and 2

This qualitative study was carried out in the North East of England, which consists of 12 local authorities: County Durham, Darlington, Gateshead, Hartlepool, Middlesbrough, Newcastle-upon-Tyne, Northumberland, North Tyneside, Redcar and Cleveland, South Tyneside, Stockton and Sunderland. The region has the highest

prevalence of deaths due to opioid misuse in England (Office for National Statistics (ONS), 2023) some of the most deprived areas (Corris *et al.*, 2020).

The number of community pharmacies in North East and Yorkshire was 1,928 in 2022 (NHS Business Service Authority, 2022). The North East and Yorkshire is also the region with the second highest number of community pharmacists in England (Powell, Harker and Kulakiewicz, 2022). The statistic for the North East and Yorkshire was stated here because statistic for only the North East was not found.

Sampling of participants

The participants in the qualitative study consisted of 36 pharmacy stakeholders. The first qualitative study involved 28 community pharmacy staff (16 pharmacists, 10 dispensers, one pharmacy assistant and one pharmacy technician) while the second qualitative study involved eight commissioners (four members of the ICB, three members of both the ICB and the PCN and one member of the PCN). Community pharmacy staff were sampled into the first qualitative study because they delivered opioid misuse services to clients or patients. Interviewing them provided information that will enable the interviewer to understand community pharmacists' experiences and identify factors that influence community pharmacists' roles in opioid misuse prevention. The commissioners were the focus of the second qualitative research in order to understand their views and perceptions about community pharmacists' role in opioid misuse, and how community pharmacists could be supported to improve their role in the prevention of opioid misuse. In addition, focusing this study on community pharmacists and commissioners in the Northeast will help to fill a gap in opioid misuse prevention research.

Recruitment of participants for qualitative studies 1 and 2

The recruitment of the different groups of participants was carried out across a period of eight months, from August 2022 to March 2023.

i. Community pharmacy staff (qualitative study 1)

Community pharmacy staff were recruited from County Durham, Gateshead, Middlesbrough, Newcastle-upon-Tyne, North Tyneside, Northumberland, South

Tyneside, Stockton, and Sunderland. Convenience and snowball sampling methods were used to recruit pharmacy staff into the study. These methods were used because of the challenges the researcher faced while trying to recruit participants from community pharmacies that were located outside the local authority that the researcher was based in. In addition, time and budget restraints also informed my decision to use the convenience and snowball sampling methods. The decision on which community pharmacy to visit, was based on proximity.

The choice of use of the convenience and snowball sampling methods were informed by the difficulty the researcher encountered when attempting to put calls through to community pharmacy premises that were located further afield. Almost all staff of pharmacies that were contacted through phone calls declined participating in the study. The researcher then decided to visit pharmacies that were located within 5 miles from her residence in Newcastle where she informed the pharmacy staff about the study and pleaded with them to inform their colleagues working in other pharmacies. This strategy enabled the researcher to recruit participants from different areas, with wider coverage within the NENC region. Areas that were covered in the qualitative study of pharmacy staff were County Durham, Gateshead, Middlesbrough, Newcastle-upon-Tyne, North Tyneside, Northumberland, South Tyneside, Stockton, and Sunderland.

The researcher initially visited 12 community pharmacies that were within proximity, about five miles from where the researcher resided, and spoke with the pharmacist or the pharmacy manager about the study. They were given copies of the participant information sheets (See Appendix C: Participant information sheet for community pharmacy teams and Appendix D: Participant information sheet for commissioners) and consent forms (See Appendix E: Consent form for community pharmacy teams and commissioners) and were asked to share information about the study with other staff. They were also asked to cascade the information to other pharmacies and pharmacists who they thought would be interested in the study.

For pharmacies further afield, emails and phone numbers of community pharmacies were obtained from NHS England's online 'Find a Pharmacy' search tool and Google maps. Eighteen pharmacies were contacted via telephone and details about the study shared with the pharmacy staff who answered the call. The researcher sent emails to eight pharmacy staff who requested a copy of the participant information sheet and consent form. The recruitment process is illustrated in Figure 3.5.

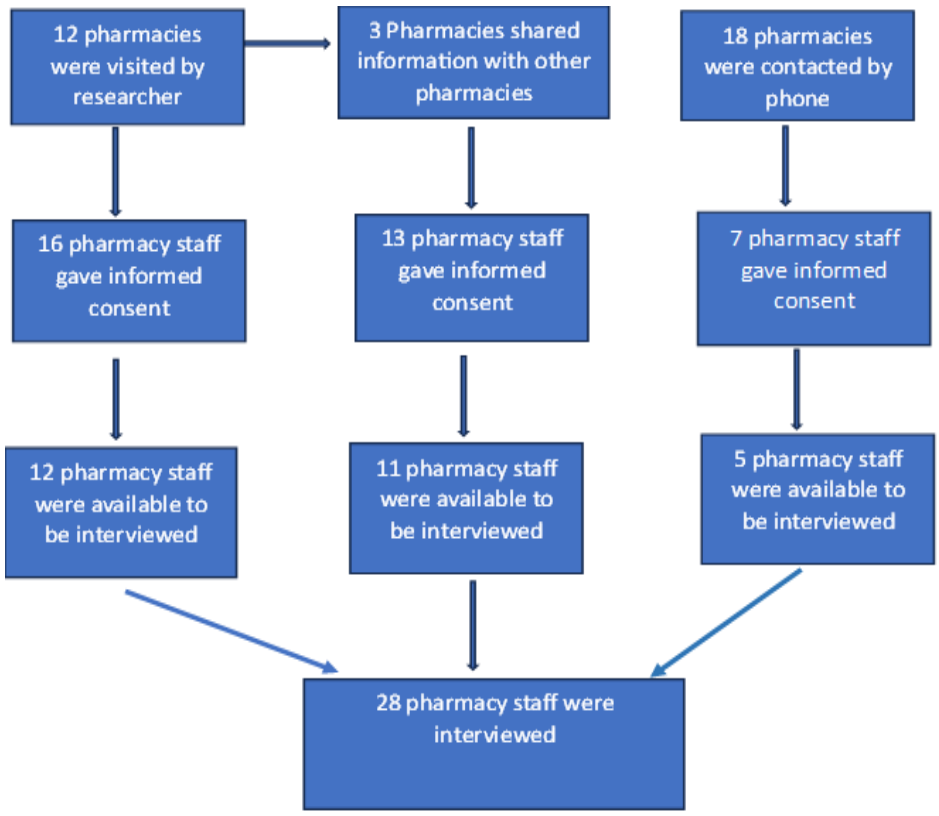


Figure 3.5 Recruitment of community pharmacy staff

ii. Commissioners (qualitative study 2)

Convenience and snowball sampling methods were used to recruit commissioners into the study. Recruitment of commissioners was carried out by sending emails containing the participant information sheet and consent form to contact addresses found in NHS England, North East and North Cumbria Integrated Care Boards (NENC ICB), and Local Pharmaceutical Committee (LPC) Newcastle websites. Phone calls were made when there were no responses to emails sent.

A policy maker from another region in England was approached at a pharmaceutical conference and asked to help share information about the study with commissioners in the Northeast. The first three participants who expressed interest in this study were also asked to inform other commissioners. Five other participants expressed interest in this study. These eight participants gave informed consent and interviews were arranged.

The recruitment of commissioners stopped at eight participants because of pragmatic reasons. Given the tight work schedule of commissioners, it was cumbersome for the researcher to recruit commissioners into the study. It was also time consuming given the limited time to conduct this research. In addition, the ICBs were just recently set up at about the time that recruitment of commissioners commenced. Hence, relevant bodies that were contacted during the recruitment period were unsure of how commissioners of the ICBs could be reached, due to changes in offices and designations. This further contributed to the difficulty that was encountered with recruiting commissioners into this study. This was why eight members of the NENC ICB were interviewed in the research.

Public health commissioners for drug and alcohol services comprises of a group of health organisations such as the ICB, Public Health England (PHE) now referred to as the UK Health Security Agency (UKHSA), and local authorities. The ICBs/PCNs were used in this study because they work together with the local authorities to commission substance misuse services, of which drug and alcohol services fall under. The ICBs were also used in this research because they are involved in commissioning some substance misuse services that are carried out in community pharmacies, such as, harm reduction services like needle exchange programmes and supervised consumption of methadone and buprenorphine. The experience gained by members of the ICBs while commissioning harm reduction services in community pharmacies could enable the ICBs to make pragmatic suggestions that might help in developing relevant intervention strategies that could contribute towards improving community pharmacy staff roles in the prevention of opioid misuse. The recruitment process for the NENC ICB members is displayed in Figure 3.6.

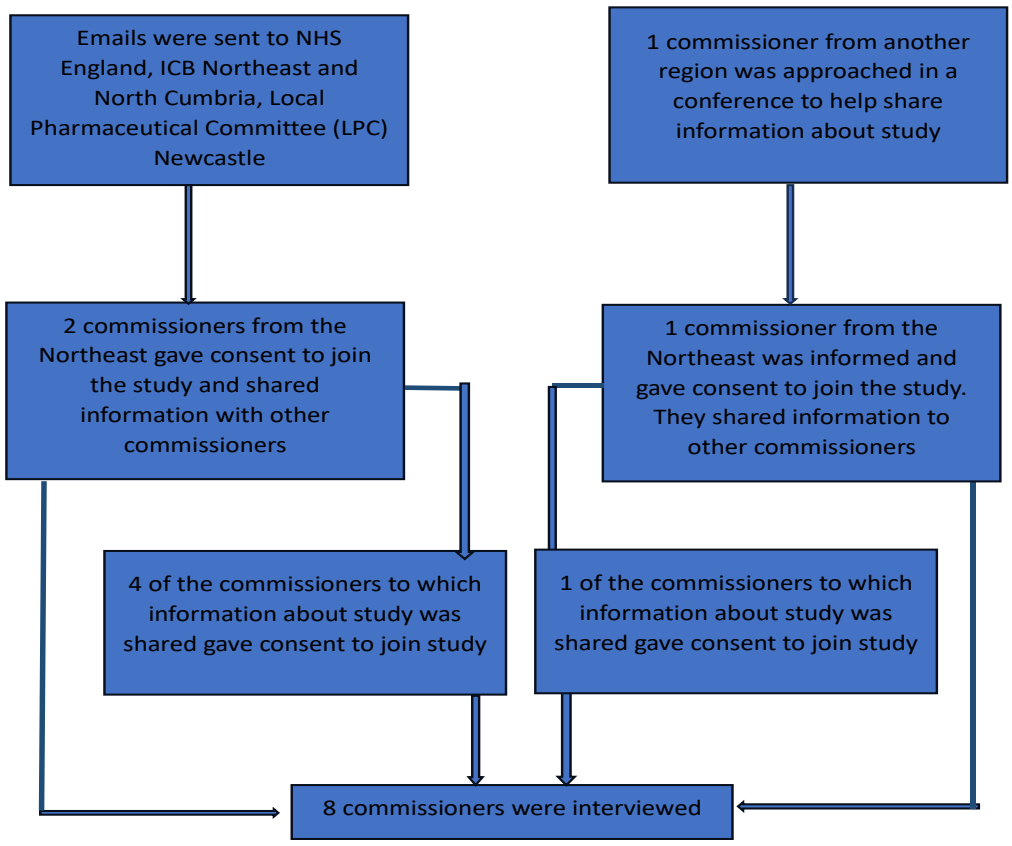


Figure 3.6 Recruitment of commissioners

Data collection for qualitative studies 1 and 2

The data collection method was the semi-structured one-to-one interview method.

i. Data collection instruments

Two topic guides were developed for carrying out the interviews with community pharmacists and commissioners (See Appendix F: Topic guide for community pharmacy teams and Appendix G: Topic guide for commissioners). The topic guides consisted of series of open-ended questions relating to the topic under study.

The topics that were discussed were informed by findings of the systematic review and were based on the research questions. The topic guides were reviewed by the supervisory team to ensure that questions that were relevant to the research questions were asked (Noon, 2018). The topic guides were piloted with three community pharmacists to make sure that the topic guide was fit for purpose. The topic guides

consisted of open-ended questions and prompts that were used to obtain specific information, where needed (Noon, 2018).

The topic guide for the commissioners was more focused and was not as broad as the topic guide used for the pharmacy staff because the topic guide developed for the pharmacy staff interviews were aimed at understanding the factors that influenced all aspects of community pharmacists' role in the prevention of opioid misuse (including education and information provision, screening, identification and referral, proper storage and disposal, and harm reduction). On the other hand, the topic guide for the commissioners was primarily developed to obtain suggestions on how the factors identified from the community pharmacists' interviews could be improved. As a result, the topic guide for the commissioners was more focused and targeted at obtaining recommendations or suggestions.

These topic guides were administered to three lecturers who were also pharmacists, at the School of Pharmacy in Newcastle University to assess whether the topic guides were fit for purpose. This is the extent to which Patient and Public Involvement and Engagement (PPIE) was engaged with in this research.

Before interviews, participants were required to fill in an online demographic form (See Appendix H: Demographic form for pharmacy teams and Appendix I: Demographic form for commissioners), which was sent as a link to the participants' emails or phones. Participants were then invited to a one-to-one interview via Zoom. Participants who could not access the link before attending the interview were sent the link by zoom chat before the interview commenced. Each interview lasted between approximately 30 minutes and 1 hour 30 minutes, with an average duration of 34 minutes. The interviews were carried out at a time that was convenient for the participants.

ii. Interview process

The interview began with the researcher making an introduction and briefing the participants on: the aims of the research, how long the interview was expected to last,

that information revealed would be kept anonymized and confidential, that the interview was going to be recorded and that they could withdraw at any time. The researcher asked open-ended questions that enabled the participant to talk more broadly about the concept being discussed. Probes were also used when further detail about a question was required, and prompts were used when the interviewee seemed not to have understood the question asked. At the end of each interview, the participants were debriefed by thanking them for their time and asking if they could be contacted if the researcher needed clarification about any of the questions. Each participant received a £35 Amazon voucher as compensation for participation.

Preparing the transcript for qualitative studies 1 and 2

.After each interview session held via Zoom, the transcripts of the audio recordings were downloaded, and saved securely in the Newcastle University network. The researcher read through the transcript in order to identify words that were not correctly transcribed. The researcher then listened to the audio recording again to identify the accurate words that were incorrectly transcribed, and the transcripts were edited accordingly.

All personal information, work information or other information that could be linked to an individual or organization were deleted. This process was carried out immediately after each interview was concluded.

Data saturation

Saturation was reached when no new information with respect to the research question emanated from the data (Bryant and Charmaz, 2007). However, four more interviews were carried out in the community pharmacy staff group to check that saturation had actually occurred (Hennink and Kaiser, 2022).

Data Analysis

Braune and Clarke's approach to reflexive TA was adopted in this research. This process was carried out with the aid of NVivo 11 Pro: QSR International Pty Ltd, 2015,

a qualitative data analysis computer software. The steps that were carried out are described in detail below (Braun and Clarke, 2006).

i. Familiarisation with data

Part of this process was carried out while preparing the transcripts. The process of re-reading the transcripts and listening to the audio recordings helped the researcher to familiarise with the data. The transcripts were read three times to gain ideas regarding meaning or patterns in the data. These ideas were taken note of and were referred to during the coding process.

ii. Generating initial codes

A hybrid method of identifying patterns in data was adopted, which involves both inductive and deductive analysis (Swain, 2018; Ligurgo *et al.*, 2018). Deductive analysis, also known as the top-down approach, was used to establish categories based on the research questions (Crabtree and Miller, 1992). These categories were: barriers, facilitators, community pharmacists' services and views and perceptions about services. Inductive analysis, also known as the bottom-up approach, was then used to identify codes from participants' accounts, which enabled themes that were closely linked to the interview data to be generated (Braun and Clarke, 2006). Open coding was used to carry out this process and helped to minimize the influence of the researcher's preconceptions on the coding process (Braun and Clarke, 2006; Maguire and Delahunt, 2017). Coding was carried out with an open mind so that the true meaning in the data was identified (Gibbs, 2007). Identified codes were then grouped under the deductive category that best described them. This process is also known as 'abduction matching' because the systemic features of my theoretical base were combined with the systemic features that were obtained from the collected data (Ligurgo *et al.*, 2018).

iii. Developing themes

In this stage, the researcher assessed the codes and codes that were related to a particular concept were combined to form a theme.

iv. Reviewing themes

The extracts that formed each theme were read at this stage to confirm that they explained the theme coherently and distinctively. Themes developed from extracts that did not form a coherent story were broken down into a number of themes. In addition, codes were moved to other themes where they were better fitted. This was an iterative process and was stopped when the researcher was satisfied that the themes were telling a coherent story and that each theme was distinct.

v. Defining and naming themes

Each theme is defined in this stage, that is, what each theme represented with respect to the research question was stated. The codes that formed these themes and the relationship between the codes and the themes were stated. Descriptive names were then assigned to the themes (Braun and Clarke, 2006).

vi. Writing up

A logical story of how these themes answer the research question was written and this was evidenced by quotes that were obtained from the data. This write up was not merely descriptive but was also interpretative (Braun and Clarke, 2006).

3.5 Reflexivity

Because I took an active role in directing the flow of the conversation between me and the stakeholders, and in also interpreting the data, it was important for me to reflect on how my motives, experiences, perspective, and beliefs might have affected the research (Holmes, 2020).

Reflexivity is a continuous, multi-dimensional activity that is carried out throughout the research process in order to neutralise the influence of the researchers' subjectivity on the research (Qin, 2016). This will help ensure that the interpretation of the researcher represents the lived experiences that are expressed by the participants (Bourke, 2014). Though being a pharmacist myself helped me to ask insightful questions, and to understand, describe and interpret interviewee's narrative more

'truthfully', I deliberately practiced 'bracketing' throughout the research process (Berkovic *et al.*, 2020; Holmes, 2020). This means that I approached every aspect of the research with an open mind, taking care that my knowledge and experience of pharmacy did not influence the meaning in the data (Berkovic *et al.*, 2020).

Reflexivity was observed during the interview stage by acknowledging that power dynamics might be evident during the interview. These power dynamics are due to perceived imbalances that exist between the interviewer and the interviewee and arise from the interview process itself. In research, the researcher asks the questions while the participant answers the questions. This can make the interviewee assume a position of lower control over the content and extent of discussion when compared to the interviewer (Karnieli-Miller, Strier and Pessach, 2008) preventing them from expressing lived experiences clearly and completely. This power imbalance was neutralised by introducing myself to the interviewee prior to starting the interview, informing them of the reason for carrying out the research, reminding them that all personal information would be anonymised, that only audio recordings would be downloaded, and that recordings would be saved securely in the university network. This was very helpful because I noticed that while interviewing some of the pharmacy staff, they were responding with very brief answers. Once this was observed, I quickly reminded them that I was a PhD student and that I was asking the questions solely for academic and research purposes, and that all personal information would be anonymised, confidential and protected as ethically required. This enabled the interviewee to be relaxed and fully express themselves when asked questions.

I also made effort to ensure that the research was carried out at the interviewee's most convenient time. All interviewees said they were comfortable holding the interview on zoom. Allowing the interviewee to decide on time and location also helped to balance the power dynamics between the researcher and the researched. During the interview, I allowed the participants to express their experiences fully without interrupting them, avoiding the use of words such as 'I agree' or 'I disagree', and avoiding body languages that are judgmental (DeJonckheere and Vaughn, 2019; Wood, Daley-Moore and Powell, 2019). Lastly, I showed respect to the participant

throughout the research process by listening actively and by saying ‘thank you’ after each response was given. The participants felt appreciated when they were told ‘thank you’, which also encouraged them to speak more. Listening actively made participants feel that the researcher valued the discussion, and this motivated the participant to speak more (Boyce and Neale, 2006). Since English was not my first language, active listening also enabled me to notice when a participant did not understand my question, thus, helping me to quickly modify the way the questions are presented to the participant in order to facilitate understanding. Where I did not understand the dialect of the interviewee, I politely asked them to repeat (DeJonckheere and Vaughn, 2019).

In addition, during the data interpretation stage, I was careful not to allow my personal knowledge, beliefs, experiences and preconceptions about opioid misuse prevention interfere with my interpretation of the data (Muthanna and Alduais, 2023).

3.6 Positionality statement

I am an international student who had completed all previous studies outside the UK and had not resided in the UK before starting this PhD programme. I am also a pharmacist who was trained and had practiced pharmacy outside the UK. I acknowledge that my personal beliefs, conception, knowledge and experiences of community pharmacy might be different from what it is in the UK, and I deliberately made attempts to avoid viewing and interpreting data based on prior perceptions and professional experience.

3.7 Ethics

Ethical clearance was obtained from Newcastle University Faculty of Medical Sciences Research Ethics Committee (See Appendix J: Ethical approval letter). Informed consent was obtained from participants. Audio recordings, notes and transcripts were anonymised and securely saved in the Newcastle University network where only the researchers could access. The recordings were deleted after the research was completed.

3.8 Summary

This chapter described the methodology that was used to obtain the study's findings. First, my ontological and epistemological position was detailed. Second, the theoretical models to which the findings of the study were linked were described. Third, the two approaches that made up the research design- the systematic review and the qualitative interview studies were described. The findings of the systematic review and the qualitative analysis are presented in the subsequent chapters.

Chapter 4 Systematic Review results

4.1 Introduction

The preceding chapter described the methodological approaches that were used to carry out this research, which involved a systematic review of published qualitative studies, an interview study involving community pharmacy staff, and a second interview study involving commissioners of community pharmacy services. This chapter[1] sets out the results of the systematic review, including the study selection process, the results of the data extraction and quality assessment processes, and the thematic analysis findings (Offu *et al.*, 2022). This review enabled me to get a baseline understanding and insight into the experiences of stakeholders regarding community pharmacists' role in prescription and OTC opioid misuse globally. It also provided a framework for developing the topic guide that was used to carry out the qualitative studies.

4.2 Study selection

Electronic database searches produced 1,234 hits. After removing duplicates, 717 articles remained. The titles and abstracts of these articles were screened for eligibility, resulting in 603 articles being excluded. Full text screening was carried out on the remaining 114 articles and 10 of these were deemed eligible to be included in the review (Figure 4.1). Reasons for exclusion of articles after full text screening were: i) wrong methods, i.e. not qualitative or mixed methods study, ii) wrong topic, i.e. not prescription or OTC opioids, iii) wrong study population, i.e. not focusing on the role of community pharmacists and iv) wrong publication type, i.e. not peer reviewed primary research articles.

4.3 Data extraction and quality assessment

All of the included studies were qualitative studies (n=10). Studies were carried out in the USA (n=5) (Fleming, Bapat and Varisco, 2019; Hagemeier *et al.*, 2018; Kang *et al.*, 2019; Rao *et al.*, 2021b; Curran *et al.*, 2019), UK (n=2) (Alenezi, Yahyouche

[1] This systematic review has been published in the International Journal of Pharmacy Practice.

and Paudyal, 2021; Savage *et al.*, 2013), Australia (n=2) (Makdessi, Day and Chaar, 2019; Nielsen, Cameron and Pahoki, 2013) and multi-country settings (South Africa, Ireland and UK; n=1) (Carney *et al.*, 2016).

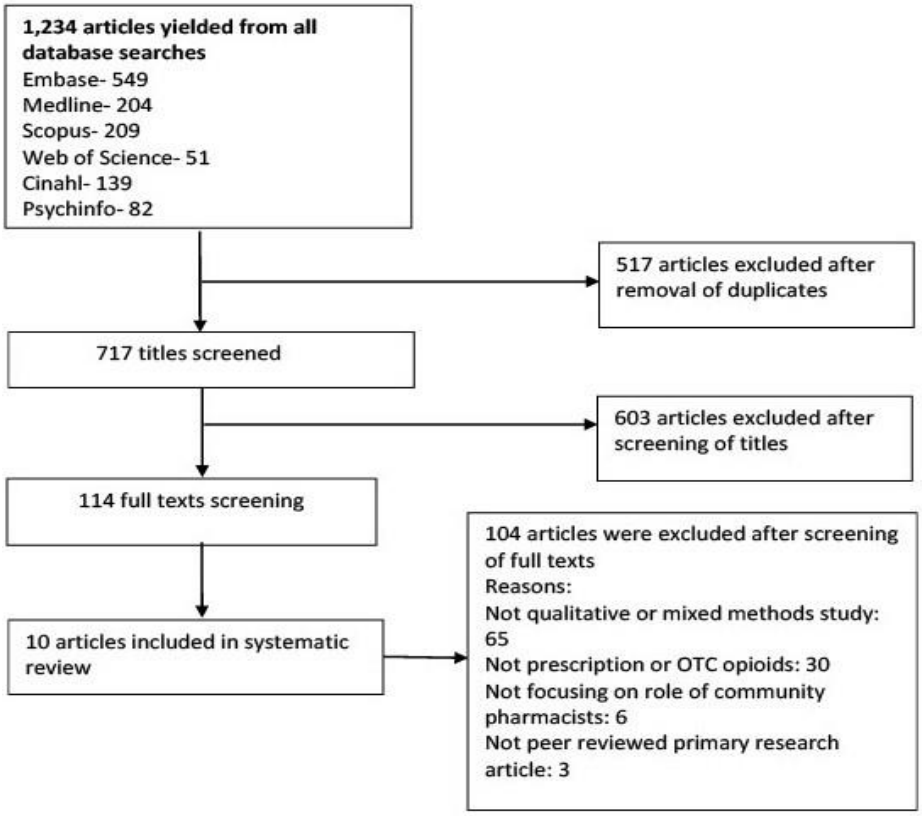


Figure 4.1 Prisma flow diagram for systematic review

Studies were carried out among community pharmacists only (n=6) (Alenezi, Yahyouche and Paudyal, 2021; Carney *et al.*, 2016; Fleming, Bapat and Varisco, 2019; Rao *et al.*, 2021b; Savage *et al.*, 2013; Makdessi, Day and Chaar, 2019), community pharmacists and physicians (n=2) (Kang *et al.*, 2019; Curran *et al.*, 2019), community pharmacists and nurse prescribers (n=1) (Hagemeier *et al.*, 2018) and service users (n=1) (Nielsen, Cameron and Pahoki, 2013). Eight studies focused on prescription opioids (n=8) (Alenezi, Yahyouche and Paudyal, 2021; Fleming, Bapat and Varisco, 2019; Hagemeier *et al.*, 2018; Kang *et al.*, 2019; Rao *et al.*, 2021b; Savage *et al.*, 2013; Curran *et al.*, 2019; Makdessi, Day and Chaar, 2019) and two on OTC opioids (n=2) (Carney *et al.*, 2016; Nielsen, Cameron and Pahoki, 2013). The data collection methods included interviews (n=6) (Alenezi, Yahyouche and Paudyal, 2021; Kang *et al.*, 2019; Savage *et al.*, 2013; Makdessi, Day and Chaar, 2019; Curran *et al.*, 2019;

Nielsen, Cameron and Pahoki, 2013), focus groups (n=3) (Carney *et al.*, 2016; Fleming, Bapat and Varisco, 2019; Hagemeier *et al.*, 2018) and open ended questions that were stated in a questionnaire (n=1) (Rao *et al.*, 2021b). Study characteristics and key findings are presented in Table 4.1.

Table 4.1: Characteristics of included studies

Article number	Author/ year	Country/ setting	Participants	Type of opioid	Data collection method	Key findings
1	Alenezi , 2022	UK	20 community pharmacists	Prescription opioids	Semi-structured interviews	Poor knowledge and skill were identified; training was needed.
2	Carney, 2016	UK, Ireland, South Africa	45 community pharmacists, 6 focus groups	OTC opioids	Focus groups	Improved surveillance, integration of pharmacist-prescriber data are important to prevent patients from accessing multiple pharmacies.
3	Curran, 2019	USA	60 community pharmacists, 48 physicians	Prescription opioids	Semi-structured interviews	Co-location of community pharmacists and prescribers will enhance teamwork
4	Fleming, 2019	USA	31 community pharmacists	Prescription opioids	Focus group	Workflow support (e.g., technicians) enables pharmacists to counsel patients for longer periods.
5	Hagemeier 2018	USA	Six nurses, 13 physicians & 16 community pharmacists	Prescription opioids	Focus group	Identifying methods of improving prescription monitoring programmes is necessary for enhanced physician-pharmacist communication
6	Kang, 2019	USA	15 physicians & 25 pharmacists	Prescription opioids	Semi-structured interviews	Collaborative efforts between pharmacists and prescribers were inhibited by lack of payment
7	Makdessi 2019	Australia	25 community pharmacists	Prescription opioids	Interview	Education is key to improving community pharmacists' confidence and perception of their role
8	Nielsen, 2013	Australia	20 OTC codeine users	OTC opioids	Interviews	Increasing pharmacists' involvement in OTC opioids sale will create more opportunity for opioid users to be counselled
9	Rao, 2021	USA	134 community pharmacists	Prescription opioids	Open ended questions (part of a questionnaire)	Strategies that aim at improving community pharmacists' attitude towards opioid users might help to reduce opioid misuse rates.

10	Savage, 2013	UK	25 community pharmacists	Prescription opioids	Interview	Pharmacists' training on how to communicate effectively with chronic pain patients, who were being treated with opioids was limited

All included articles met the majority (≥ 6 out of 10 criteria) of the criteria on the JBI checklist. Less than three articles met the criteria that relate to positionality of the researcher. These are: 'Is there a statement locating the researcher culturally or theoretically?' (n=1) and 'Is the influence of the researcher on the research, and vice-versa, addressed?' (n=2). The results of the quality assessment are presented in Table 4.2.

Table 4.2: Quality analysis of included studies

	Article number									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Is there congruity between the stated philosophical perspective and the research methodology?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Is there congruity between the stated philosophical perspective and the research methodology?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Is there congruity between the research methodology and the methods used to collect data?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Is there congruity between the research methodology and the representation and analysis of data?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Is there congruity between the research methodology and the interpretation of results?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Is there a statement locating the researcher culturally or theoretically?	x	x	x	x	x	x	x	x	x	✓
Is the influence of the researcher on the research, and vice- versa, addressed?	x	x	x	x	x	✓	x	x	x	✓
Are participants, and their voices, adequately represented?	✓	✓	✓	✓	✓	✓	✓	✓	x	✓
Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	✓	✓	x	x	x	✓	✓	✓	x	✓
Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Score (out of 10)	8	8	7	7	7	9	8	8	6	10

4.4 Thematic analysis

On completion of line-by-line coding of the included studies, descriptive themes identified were: i) individual factors relating to pharmacists' knowledge, skills and attitude, ii) environmental factors relating to pharmacists relationships with prescribers, available time, numbers of support staff, and the availability of a private counselling room and iii) system level factors relating to remuneration of services, up-scheduling of OTC opioids, corporate pharmacy support, and electronic programmes.

4.4.1 Environmental factors

These factors related to the overall physical and social environment of community pharmacies where pharmacists worked.

Physical environment

The physical environment consists of the physical resources and structures in the premises where the community pharmacist worked. Physical environment related factors that were identified from this study were resources and private counselling rooms. These factors will each be explained below.

Resources

Community pharmacists reported that reviewing patients' prescriptions and counselling opioid users about their drugs is time consuming (Rao *et al.*, 2021b; Kang *et al.*, 2019; Fleming, Bapat and Varisco, 2019; Carney *et al.*, 2016; Alenezi, Yahyouche and Paudyal, 2021; Curran *et al.*, 2019). Community pharmacists that work in pharmacies with few support staff have reported that they do not offer opioid misuse interventions because it takes up the time that would have been used to attend to other clients that visit the pharmacy.

> *"Staffing. If you're the only pharmacist, then that goes with time, too. When there's nobody else keeping up." (Fleming, 2019, p.996)*

Pharmacists also reported that the presence of adequate support staff in the community pharmacy will give them enough time to review patients' prescriptions and counsel them about their opioid use (Fleming, Bapat and Varisco, 2019; Rao *et al.*, 2021b). In addition, experienced support staff could recognise suspicious patients' behaviours and report them to the community pharmacists for further investigation and intervention.

> *"I have a tech that likes doing detective work like that… she's been there for years, and so she knows most of the customers. So, if something's off, she's the one that goes in and looks."(Fleming, 2019, p.996)*

Private counselling room

One study reported patients preferred to receive opioid misuse prevention services from community pharmacies with a private consultation area. Community pharmacists also reported that a private consultation room will enable the patient to interact freely with the community pharmacist (Fleming, Bapat and Varisco, 2019).

> *"Where I work, we actually have a private area. It is sensitive information. If you have a private area, where you can pull them into, you can actually talk to them, and they can interact with you." (Fleming, 2019, p.997)*

Other community pharmacists expressed worry about the safety of community pharmacists when alone in a private room with the opioid user and advocated for a semi-private counselling room instead (Fleming, Bapat and Varisco, 2019).

> *"Well, the room, like she was saying, poses another risk, because you're alone with them in a room.' 'Private, but not too private." (Fleming,2019, p.997)*

Social environment

The social environment consists of how the community pharmacists interact with health care professionals that are involved in prescribing opioids. A social environment related factor that was identified in this study was relationship with prescribers which will be discussed below.

Relationships with prescribers

Community pharmacists' roles in opioid misuse prevention was influenced by their relationship with prescribers. This was reported as a barrier in the majority of the included studies (Alenezi, Yahyouche and Paudyal, 2021; Carney *et al.*, 2016; Fleming, Bapat and Varisco, 2019; Hagemeier *et al.*, 2018; Kang *et al.*, 2019; Rao *et al.*, 2021b; Savage *et al.*, 2013; Curran *et al.*, 2019; Makdessi, Day and Chaar, 2019). Most community pharmacists reported that physicians were unfriendly whenever they were contacted to discuss a patient's opioid prescription (Savage *et al.*, 2013; Curran *et al.*, 2019; Makdessi, Day and Chaar, 2019) while some reported that they had poor perceptions about certain physicians because they consistently received prescriptions that needed dosage adjustment from them (Hagemeier *et al.*, 2018). Pharmacists also reported that it was difficult to communicate directly with the physicians, (Hagemeier *et al.*, 2018; Alenezi, Yahyouche and Paudyal, 2021; Savage *et al.*, 2013; Curran *et al.*, 2019; Makdessi, Day and Chaar, 2019) which made them adopt indirect means of communication, such as leaving voice messages, passing messages through the physician's secretary and sending the patient back to the physician. Community pharmacists believed physicians felt that it was not the duty of the community pharmacist to question the accuracy of a prescription they had written (Fleming, Bapat and Varisco, 2019; Curran *et al.*, 2019; Makdessi, Day and Chaar, 2019).

> *"…when you ask them, 'What is the diagnosis for this? Why are you prescribing all these pain meds?' And they're just taken aback, 'In my 25 years of practice, nobody's ever asked me, what the ICD-9 code for this OxyContin is. I mean, I'm just writing it – fill it."*
>
> *(Fleming, 2019, p.996)*

However, community pharmacists and nurse prescribers were reported to enjoy a good professional relationship (Savage *et al.*, 2013).

> *"If a nurse prescribed, then the nature of professional communication developed, with nurses asking the pharmacist for prescribing advice on dose equivalents or asking them to monitor a patient." (Savage, 2013, p.154)*

Some community pharmacists reported that the implementation of collaborative care models improved the relationship between community pharmacists and prescribers (Carney *et al.*, 2016; Hagemeier *et al.*, 2018; Savage *et al.*, 2013; Curran *et al.*, 2019). This model comprises a practice whereby community pharmacists collaborate with other health professionals (physicians, nurses, physiotherapists and others), in the same health system to offer care to prescription and OTC opioid misuse patients. This results in improved familiarity and enhances professional relationship between community pharmacists and other health professionals.

> *"In a small town, you know, pharmacist X here, or pharmacist Y can call me up and say, 'I am really worried about this.' That's a big difference from some random pharmacist on the phone calling me up." (Hagemeier, 2018, p.92)*

4.4.2 Individual factors

These factors related to the individual professional delivering services to opioid users.

Knowledge and skills

The level of community pharmacists' knowledge and skills influences their involvement in opioid misuse prevention activities. Many of the community pharmacists reported that they had poor knowledge and skills for counselling patients about opioids (Alenezi, Yahyouche and Paudyal, 2021; Carney *et al.*, 2016; Fleming, Bapat and Varisco, 2019; Hagemeier *et al.*, 2018; Rao *et al.*, 2021b; Savage *et al.*, 2013; Makdessi, Day and Chaar, 2019; Nielsen, Cameron and Pahoki, 2013). Those

who had been qualified for a while felt they would benefit from up-to-date training (Alenezi, Yahyouche and Paudyal, 2021).

> *"……little or no formal training on how to review opioid prescriptions and identify misuse; only "one lecture or something" (Alenezi,, 2022, p.187)*

In addition, community pharmacists reported that they had no routine training on how to communicate effectively with opioid users, especially when the discussion becomes emotional. Hence, they try to avoid interacting with these patients (Savage *et al.*, 2013).

> *". . , they (opioid users) want to discuss the patient, they want to discuss how they are doing, and the prognosis, so yes, sometimes it is difficult, because I do get people who really get emotional about it." (Savage, 2013, p.156)*

Poor understanding about dose titration and opioid conversions was identified as an issue by some community pharmacists (Savage *et al.*, 2013). Furthermore, in a study that assessed the opinion of opioid users, it was reported that community pharmacists lacked objectivity in identifying inappropriate supply of opioids (Carney *et al.*, 2016). Community pharmacists' judgement of who was misusing opioids was based on patient's appearance, whereby patients who 'looked responsible' could obtain opioids more readily than those who did not.

> *"I would always dress in my suit or tie to make sure that I looked professional, . . . and I looked responsible so they would sell me 48 tablets at a time, I was able to get my day's supply . . . When I wasn't in my business suit…[pharmacists] wanted to know my name, and wanted to write it down." (Nielsen, 2013, p.164)*

In some studies, pharmacists acknowledged that they required education that will equip them to offer opioid misuse prevention services such as, counselling and

referral (Alenezi, Yahyouche and Paudyal, 2021; Carney *et al.*, 2016; Fleming, Bapat and Varisco, 2019; Savage *et al.*, 2013).

> *"Formal training. Like we have an MTM (Medication Therapy Management) certificate, we would need one for controlled substance. "(Fleming, 2019, p.995)*

Pharmacists' attitudes

Attitude is a determining factor in pharmacists' role in opioid misuse prevention. Community pharmacists in some of the included studies reported poor attitude to providing opioid misuse prevention services (Alenezi, Yahyouche and Paudyal, 2021; Fleming, Bapat and Varisco, 2019; Rao *et al.*, 2021b; Makdessi, Day and Chaar, 2019). This was partly because they felt questioning prescribing decisions was not their role (Fleming, Bapat and Varisco, 2019). Part of the hesitancy was linked to the perception that the use of methadone and buprenorphine in the treatment of opioid misuse will keep patients dependent on opioids for life. Community pharmacists also felt that dosage regimens were not reviewed regularly and that it was not safe to dispense methadone and buprenorphine regardless of standing orders (Rao *et al.*, 2021b).

> *"In my opinion, opioid antagonists appear to be a failed attempt to fix a problem but isn't effective at getting patients to be opioid free since they end up becoming depend [dependent] on that therapy." (Rao, 2021, p.2101)*

In addition, opioid users felt that community pharmacists exhibited stigmatising attitudes towards them. This inhibits effective communication between the opioid user and the community pharmacist.

> *"If the pharmacist starts to think that [the patient is] abusing their opioids, it's very easy to treat them almost like a criminal and as a*

result of that, patients become very defensive and almost standoffish" (Makdessi, 2018, p.969)

However, other community pharmacists reported that they felt that they were responsible for ensuring that clients opioid use is safe. They also reported that they felt motivated to report opioid misuse to doctors whenever they notice one (Alenezi, Yahyouche and Paudyal, 2021).

"…. As a pharmacist, you would intervene by highlighting it to the doctor because the doctor is going to take the decision at the end of the day" (Alenezi, 2022, p.185)

4.4.3 System level factors

These factors related to the system within which pharmacists practiced.

Remuneration of services

Remunerating community pharmacists for offering opioid misuse prevention services was reported to be an important factor in this role. In some of the included studies, community pharmacists reported receiving no payment for offering prescription and OTC opioid misuse services, which limited their involvement (Alenezi, Yahyouche and Paudyal, 2021; Kang *et al.*, 2019). In the UK, there was no funding for the review of prescriptions containing opioids (Alenezi, Yahyouche and Paudyal, 2021).

"Cost is the biggest issue. Who will pay for things? Insurance? Will there be a co-pay? It's hard to get our patients to see the costs versus benefits" (Kang, 2019, p.1029)

Some community pharmacists also reported that they often dispense opioids without offering any intervention because they were afraid that they might lose patronage of their clients and that they also needed the money to pay bills (Carney *et al.*, 2016).

"Poverty walks through the front door and ethics usually goes out the back door!! I should not really sell to the patient but you need to pay the rent at the month." (Carney, 2016)

Regulation of opioids

Community pharmacists reported that opioids that are available as OTC medications are easily purchased by patients because they do not require a prescription to obtain them. Decisions to supply OTC opioids requires pharmacists' assessment of the patients' responses to questions, however literature suggests patients are aware of how to respond to pharmacists' questioning and checks (Carney *et al.*, 2016). In addition, where patients may not have been suitable for opioids but had requested them, community pharmacists were wary of losing customers if they did not supply OTC opioids (Carney *et al.*, 2016).

"It can be difficult though at this stage because people have gone through the questions so many times. They know that if you say have you tried something else?^ they know to say yes. And if you say what are you using it for? they immediately jump to I was in a car crash/ I was on morphine^ They immediately go for something really extreme because the more dramatic it is you know…" (Carney, 2016)

However, community pharmacists also reported that up-scheduling of opioids (from OTC category to the prescription-only category) will prevent disagreements about the suitability of the product between pharmacists and the patients. It will also dissuade the patients from patronising multiple pharmacies (Carney *et al.*, 2016).

"[One they become prescription only] then at least you've, sort of, a blame mechanism saying I'm not allowed to sell anymore^. Then it's not your fault, it's removed from you." (Carney, 2016)

Government and corporate pharmacy support

Government and corporate pharmacy support relates to the provision of resources by the government and pharmacy managers that enabled pharmacists to provide opioid misuse prevention activities, such as- providing materials to support referral of patients and provision of support staff (Fleming, Bapat and Varisco, 2019; Rao *et al.*, 2021b). Community pharmacists reported that they need to be empowered to refer patients to appropriate opioid misuse specialists (Fleming, Bapat and Varisco, 2019).

> *"I put having resources for referrals, because we are not trained mental health professionals……we would need to know who to turn them to with that expert care in that field. A company approved resource…Yeah, a pamphlet.'" (Fleming, 2019, p.997)*

Community pharmacists also stated that they need supporting policy that will enable them to carry out counselling, educational activities and rehabilitative services that are effective against opioid misuse (Rao *et al.*, 2021b).

> *"I think that we need support from our government to invest in effective youth education programs and effective rehabilitation services and counselling." (Rao, 2021, p.2100)*

This theme also related to national digital programmes to monitor the quantity of opioids dispensed or supplied OTC to support appropriate therapeutic decision making (Kang *et al.*, 2019; Hagemeier *et al.*, 2018; Fleming, Bapat and Varisco, 2019; Alenezi, Yahyouche and Paudyal, 2021; Makdessi, Day and Chaar, 2019),

> *"…….. an electronic prescription drug monitoring program such as the Prescription Drug Monitoring Programs (PDMPs) would be useful in the detection of opioid abuse/misuse." (Alenezi, 2022, p.188)*

They also reported that implementation of these programmes is limited by cost (Kang *et al.*, 2019) while their effectiveness is minimized by time (Alenezi, Yahyouche and Paudyal, 2021) and patients' patronage of multiple pharmacies (Hagemeier *et al.*, 2018).

> *"I get there would be an electronic program, it would be good if it's regular patients, but what if someone goes from another pharmacy or place?" (Alenezi, 2022, p.188).*

4.4.4 Analytical themes

The descriptive themes formed part of the analytical themes- capabilities, opportunities and motivation (based on the COM-B model). Capabilities were mapped to knowledge and skills (Individual factors); the opportunities were mapped to relationship with prescribers, resources, remuneration of services, scheduling of OTC opioids, corporate pharmacy support, private counselling room and electronic programmes (Environmental and System factors); while motivation was mapped to pharmacists' attitude (Individual factor). These results are displayed in Table 4.3.

Table 4.3: Factors that influence community pharmacists' role in the prevention of prescription and OTC opioid misuse

Analytical themes	Descriptive themes		Article number
Capabilities	Individual factors	Knowledge and skill	1, 2, 4, 5, 7, 8, 9, 10
Motivation	Individual factors	Pharmacists' attitude	1, 4, 7, 9
Opportunities	Environmental factors:		
	i. Physical environment	Resources	1, 2, 3, 4, 6, 7, 9
		Private counselling room	4
	ii. Social environment	Relationship with prescribers	1, 2, 3, 4, 5, 6, 7, 9,10
	System level factors	Remuneration of services	1, 2, 6
		Regulation of OTC opioids	2
		Government and corporate pharmacy support	4, 9
		Electronic programmes	1, 4, 5, 6, 7

Figure 4.2 illustrates how identified facilitators improve community pharmacists' involvement in opioid misuse roles, based on the COM-B model.

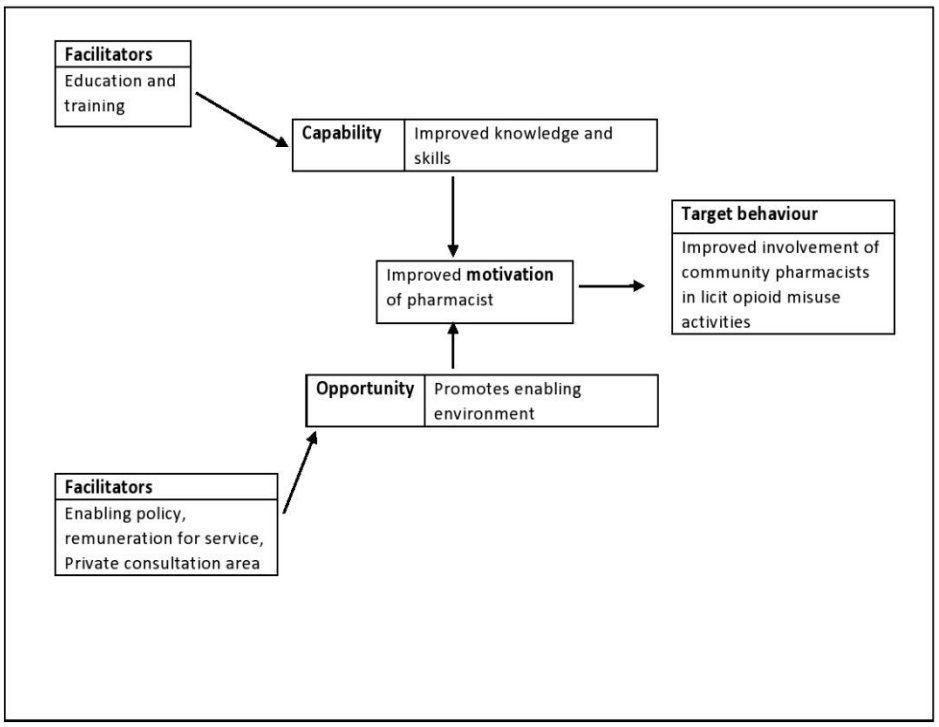


Figure 4.2: COM-B model showing the factors that influence community pharmacists' role in the prevention of opioid misuse

4.5 Summary

The findings of this research enabled me to determine the factors that influence community pharmacists' role in the prevention of opioid misuse as obtained from existing literature. Factors such as education and training could influence the capabilities- knowledge, and skills of community pharmacists regarding the prevention of opioid misuse. Opportunities such as community pharmacists' relationship with the physicians, number of staff, funding, and the consultation area could be improved by the implementation of enabling policy to support community pharmacists carry out opioid misuse prevention roles, increased remuneration and number of staff, and improving the safety of the consultation room. An improved capability and opportunity could enhance the community pharmacists' motivation to carry out opioid misuse prevention roles.

These research findings provided a basis for me to understand the experiences of stakeholders regarding community pharmacists' roles in the prevention of opioid misuse and helped to inform the topic guide that was developed for the qualitative

studies. The research highlights a gap in qualitative research aimed at exploring the views of pharmacy stakeholders regarding community pharmacists' role in the prevention of opioid misuse in the North East region of the UK. Hence, there is a need for more research to be carried out in this area.

Chapter 5 Pharmacy staff findings

5.1 Introduction

In the previous chapter, the methodology adopted to carry out this study was described in-depth. Here, the results of the thematic analysis of transcripts from the interviews with 28 community pharmacy staff are presented and mapped to the COM-B model of behaviour. In addition, interventions that will help improve community pharmacists' role in the prevention of prescription and OTC opioid misuse will be identified using the BCW.

5.2 Participants' information

Table 5.1 displays community pharmacy staff demographics. Demographic data demonstrates a varied sample.

Table 5.2: Community pharmacy staff characteristics

Participants characteristics		Number	Percentage
Gender	Female	21	75.00
	Male	7	25.00
Age group (in years)	18-30	16	57.14
	31-40	4	14.29
	41-50	6	21.43
	51-60	2	7.14
Role of pharmacy staff	Pharmacist	16	57.14
	Pharmacy assistant	1	3.57
	Dispenser	10	35.71
	Pharmacy technician	1	3.57
Employment contract	Full-time	17	60.71
	Part-time	11	39.29
Years of experience	< 5	10	35.71
	5-9	9	32.14
	10-19	3	10.71
	20-29	3	0.71
	30+	3	10.71
Pharmacy type	Chain	20	71.43
	Independent	3	10.71
	Locum	5	17.86
Local Authority	Durham	2	7.14
	Gateshead	4	14.29
	Middlesbrough	1	3.57
	Newcastle-upon-Tyne	10	35.71
	North Tyneside	3	10.71

	Northumberland	1	3.57
	South Tyneside	1	3.57
	Stockton-on-Tees	2	7.14
	Sunderland	4	14.29
Services perceived to be provided	Education, counselling information provision	25	89.29
	Screening and identification of service users at risk	22	78.57
	Proper storage and disposal of OTC and prescription opioids	14	50.00
	Needle exchange programmes	9	32.14
	Naloxone dispensing	7	25.00
	Buprenorphine dispensing	20	71.43
	Methadone dispensing	20	71.43
	Hepatitis testing, treatment and vaccination	0	0
	HIV testing and Post Exposure Prophylaxis (PEP)	0	0

*** for service users who are addicted to opioids**

For example, 57.14% (n=16) of the participants were within the ages of 18 to 30 years while 75% (n=21) of the participants were female. The percentage of pharmacists was 57.14% (n=16) while other pharmacy staff consisted of 3.57% (n=1) pharmacy assistants, 35.71% (n=10) dispensers and 3.57% (n=1) pharmacy technicians. Participants with less than five years' experience were 35.71% (n=10) while those who had more than 30 years' experience was 10.71% (n=1). Participants that worked in high street chain pharmacies were 32.14% (n=9), 60.71% (n=17) worked full-time, while 39.29% (n=11) worked part-time. Participants that worked in Newcastle-upon-Tyne had the highest frequency which corresponded to 35.71% (n=10) while the least number of participants which was equivalent to 3.57% (n=1) participants were from Middlesbrough, Northumberland and South Tyneside respectively. 71.43% (n=20) of participants carried out methadone and buprenorphine dispensing while 25% (n=7) carried out naloxone dispensing. None of the participants carried out hepatitis testing, treatment and vaccination, HIV testing and Post Exposure Prophylaxis (PEP) for service users who misuse opioids.

5.3 Capability

As described in the previous chapter, Capability is the 'C' in COM-B and comprises of physical capability and psychological capability. These 2 groups of

capability relates to the pharmacy staff's knowledge and skill regarding opioid misuse prevention services.

5.3.1 Physical capability (physical skills)

Physical capability comprises physical skills or abilities required to carry out opioid misuse prevention services. Subthemes that were identified under this theme are described below.

Communication skills

Majority of participants including pharmacists and other pharmacy staff reported that they knew how to educate, counsel and inform service users who came to the pharmacy to buy OTC opioids about the adverse effects of the medication and safe ways of using opioids.

> *"So the first thing we do is ask the WWHAM questions to the customer, and they are, who's the medication for? what are the symptoms? How long you have the symptoms for, actions already taken, and then medications that I've been taking at the moment."* (Participant 21: dispenser, female, chain pharmacy, 12 years)

When participants were asked whether they advised service users about proper storage and disposal of opioid medication, some replied that they do not talk to service users about storage of their medication because service users could easily read the storage information from the medication packet without informing them. They also reported that though they carry out medication disposal services, they do not tell service users to bring back unused medication because there was already good public awareness that unused or expired medications were disposed of in community pharmacies. This response was similar for both pharmacists and other pharmacy staff.

> *"I mean we have a sign up about, you know unwanted medication. But we don't actually actively say if you've got any medication you don't use, bring it back and I think we did that with inhalers recently, because there was a push on people recycling inhalers but generally we don't say bring them*

back. I think you just rely on the fact that there's posters up." (Participant 3: pharmacist, male, chain pharmacy, 20 years)

Pharmacists and other pharmacy staff that had worked in community pharmacy for at least 10 years reported that they were able to communicate effectively about harm reduction with service users because of the wealth of experience they acquired over the years.

> *"I'm very experienced. I can understand younger pharmacists being intimidated because I was intimidated when I was young, but as you get older, get wiser, you know that you know they try it on. It's just an act. They don't mean what they say, you know, and their aggression is like, is put up. You know it's not real aggression. They just trying to get their own way."* (Participant 8: pharmacist, male, independent, 35 years)

In addition, some pharmacists and other pharmacy staff reported that their communication with GPs was poor while others reported that they communicated well with the GPs, and this has resulted in good pharmacy staff-GP relationship. They added that the number of years that the community pharmacist has worked in a particular pharmacy influences their relationship with GPs. Community pharmacists with longer years of experience tend to have better relationships with GP practices that they are affiliated to.

> *"I know the pharmacist, she's owned that pharmacy now, I think, for like, I want to say like 17 years. It's always been hers, and it's always been in the same place. She's had the past 17 years to build up the relationship with these prescribers."* (Participant 25: pharmacy technician, male, chain pharmacy, 35 years)

Ability to Identify service users who misuse OTC opioids

All participants, both pharmacists and other pharmacy staff reported that they were able to identify service users who might be misusing OTC opioids based on the frequency at which they purchased opioids from the pharmacy. They added that once they suspected that a service user was misusing OTC opioids, they always

refused the sale of the opioids and advised these service users to go and see their GPs.

> *"Obviously the standard is, you know, this is 3 to 4 days use, and if they say, that is, if they tell you that they've already used it 3 to 4 days, then you kind of refuse, and you say go to your GP, or you know you need to be assessed of them and be prescribed that."* (Participant 22: dispenser, male, chain pharmacy, 2 years)

Pharmacists and other pharmacy staff were also capable of screening the prescriptions of service users who came to the pharmacy to collect or buy prescription opioids. This helped the pharmacist or other pharmacy staff to identify service users who were at risk of opioid misuse and refer them to their GP.

> *"I generally just double-check what the item is. I make sure we've got the stock in, check if the item is in stock and then just make sure I read the guidelines and how often they've got to take it and if there are any queries about the dosage, I always double-check with the pharmacist and then I just dispense it and then the pharmacist checks it and just make sure I've got the right product to match the prescription."* (Participant 23: pharmacy assistant, female, chain pharmacy, 2 years)

The majority of pharmacists and other pharmacy staff were capable of identifying service users who were at risk of harm by monitoring their behaviour when they came for supervised consumption of either buprenorphine or methadone. This is then reported to the drug clinics.

> *"Normally, if they miss the dose, if they don't have the prescription but expecting their dose. Someone else has asked to collect their medications, he's been behaving a bit like junk, like normally like a change in behaviour or something we inform them."* (Participant 13: pharmacist, female, chain pharmacy, 2 years)

5.3.2 Psychological capability (Knowledge and skill)

Psychological capability consists of knowledge and skill and refers to the ability to carry out opioid misuse prevention activities. These relate to the psychological capability of the pharmacy staff to provide opioid misuse prevention services.

Subthemes that were identified under psychological capability are described below:

Education and training

Pharmacists reported that they lacked the knowledge on how to communicate with service users who were addicted to opioids because not much was taught about addiction at the undergraduate level. They also added that practice-based training on how to communicate with service users would be more beneficial.

> *"Pharmacists need training on addiction on a deeper level, this would help increase empathy and reduce stigma to this group and create more understanding. Sensitive issue to tackle and will need tact and emotional intelligence to work well. Not a lot is taught in universities about treating addiction in practice past the pharmacology aspect. More of this in uni will help prepare with real life benefits.."* (Participant 12: pharmacist, female, locum, 1 year)

Some other pharmacists reported that they were well trained about opioid misuse at the university level but that they were lacking routine training while on the job and that this was necessary to update their knowledge about the recent trends in the treatment and management of opioid misuse.

> *"…, yes, I think, yes, we have enough training, but obviously we will have to keep up to date as pharmacists ourselves to you know update any knowledge or any sort of updates or any training available. In general, I don't think there is a specific one for the Community pharmacies or a regular one that you need to sort of run and refresh every two years or so, like you know flu jab training. As far as i'm aware there isn't any yeah."* (Participant 7: pharmacist, female, independent pharmacy, 7 years)

One dispenser stated that she had never been trained about opioid misuse but that she had knowledge about this issue from her personal experiences.

> *"It's got in the 12 years that I've done this I haven't actually been given any sort of kind of training on opioid abuse….I know the implications of opioid abuse and things and how it can affect. So I feel like there needs to*

be a lot more training. I know all of this because of my own research, that I've done and with everything that I've been through with my ex-partner, and everything that I've seen." (Participant 21: dispenser, female, chain pharmacy, 12 years)

One pharmacist believes that the poor communication between pharmacists and GPs might be a result of poor pharmacists' knowledge about their roles. This might lead to misunderstandings between pharmacists and GPs.

"I think a lot of pharmacists don't know their place that we are not doctors. We are pharmacists. We can't play the doctor, and I think a lot of pharmacists want to be a doctor and play the doctor, and think they know more better than the doctor, and you've got to give that person respect that person, the doctor. I'm a pharmacist, and that's how it is in this relationship." (Participant 8: pharmacist, male, independent, 35 years)

5.4 Opportunity

Opportunity here refers to environmental factors that could influence the community pharmacists' behaviour. As described in Chapter Three, there are two types of opportunity- physical opportunity and social opportunity. These themes are described below in relation to the data obtained in this study.

5.4.1. Physical opportunity (Physical environment)

Physical opportunity refers to the physical environment where the community pharmacy staff carries out opioid misuse services. Subthemes that were identified under this theme are described below:

Staff and funding

Pharmacists and other pharmacy staff informed that community pharmacies do not have enough staff to carry out opioid misuse prevention services effectively because many pharmacy staff have left the profession due to work pressure in the community pharmacy. They added that more pharmacy staff were needed as this will provide time that will enable the pharmacist to carry out opioid misuse prevention activities optimally.

"There's always staffing shortages in any pharmacy. I think so. It's difficult to manage when you're serving someone, and trying to counsel them. But

then you've also got a queue. you know out the door, or whatever else. so maybe your counselling isn't as thorough, or is you know, is rushed or whatever else. So in terms of that, staffing levels always help" (Participant 22: dispenser, male, chain pharmacy, 2 years)

Others reported that the number of pharmacy staff were important but that trained pharmacy staff were also important to carry out opioid misuse prevention services.

"Okay, but, obviously with lack of staff and training it's quite difficult to carry out, you know, especially if you're a retail pharmacy you're on your own." (Participant 4: pharmacist, female, chain pharmacy, 8 years)

A pharmacy technician t stated that the reason for this shortage was the constant reduction of the funding allocated to pharmacies and the stress resulting from the increasing number of services included in the pharmacy contract.

"What happens is the government starts cutting money from the pharmacy budget, which they do quite regularly. Then what happens? First is that the companies will start reducing staff. Okay?... If someone leaves they don't get replaced….. The Government just says that we got to save money. Let's see now. or they add more things. They add more things in to the pharmacy world, but not add the money." (Participant 25: pharmacy technician, male, chain pharmacy, 35 years)

Few pharmacists and other pharmacy staff iterated that participants need funding to offer advice about OTC opioids because they provide a lot of useful information to the service users and to compensate for the abuse that they receive from some service users. On the other hand, most participants reported that they do not require extra payment to counsel service users about their OTC opioid use because they felt that it was their duty to do so.

"However, I do feel like with everything that we do and like the abuse we get over the counter and just the whole customer service, I do feel like we are massively underpaid. we do try to make them aware of some of the side effects. So for example, co-codamol can cause like nausea or make them sleepy and drowsy" (Participant 20: dispenser, female, chain pharmacy, 2 years)

"To be honest, we're here to help the patients and help the patients get better not to say oh, I'm not motivated, so I'm going to put the money in the till and say goodbye. Then you know, you're in the wrong profession." (Participant 9: pharmacist, female, locum, 6 years)

Tools for identification of service users who misuse opioids

There is no standardised tool or instrument for determining who is misusing OTC opioids. Pharmacists and other pharmacy staff basically identify service users who misuse OTC opioids by asking them relevant questions pertaining to opioid use and monitoring the frequency of purchase of opioids from the pharmacy.

"Yeah, really, observation that's all we've got, no tool at all. It might be a useful idea." (Participant15: pharmacist, male, independent pharmacy, 20 years).

Some pharmacists and other pharmacy staff iterated that service users' responses to their questions should not be criteria for determining service users who were at risk of misusing OTC opioids because service users' responses might not be authentic.

"And they don't want you to ask how long they've been using it for, they don't want you to give them the advice about three days of use, so what I've seen a lot is when counter assistants start asking the questions and they [service users] are like. I know, I know. And then what they do is they quickly answer all the questions before the counter assistant has asked them." (Participant 12: pharmacist, female, locum, 1 year).

Some pharmacists and other pharmacy staff reported that it would be difficult to identify service users who come to the pharmacy to purchase OTC opioids very regularly because there is no pharmacy staff that is always at the counter attending to the service users. They also informed that having a particular staff at the counter could help improve the identification of service users who misuse opioids

"We're all dispensers so back in the day, we used to just have over-the-counter staff so they got to know the people that they were selling to. So, you know if there was a regular person coming in to buy co-codamol or

solpadeine you would recognize the face, because there was that one person always on the counter, always known, so it's easier." (Participant 18: dispenser, female, chain pharmacy, 10 years)

It was also reported that the nature of pharmacy staffing, where staff work flexible and dynamic shift patterns creating irregularity and inconsistency in staffing levels and roles, contributes to the difficulty in delivering information about the frequency of service users' purchase of OTC opioid medication among pharmacy staff. In addition, participants believe that opioid users are served by different pharmacy staff each time they visit the pharmacy, thereby leading to a delay or failure of the pharmacy staff to identify service users who misuse opioids. On the other hand, a small number of participants will enable information to be passed to all staff faster.

"I feel like the more staff it is, I feel like it's more hard to communicate with everyone, because we don't all work on the same day. So I feel like when there's obviously about a couple of staff working together, like you can just easily communicate with them." (Participant 20: dispenser, female, chain pharmacy, 2 years)

However, service users visit other pharmacies also and currently, there is no way of accurately determining the number of opioids that have been purchased across all pharmacies. Though some community pharmacists reported that they contact other pharmacies within their vicinity once they notice misuse by a service user, they acknowledged that this was not a reliable method since the service user can go outside that area to purchase opioids.

"Yes, there's no way of tracking as such, but also in a different pharmacy that I worked with, the pharmacies nearby actually phone and say that they actually know that patient or that customer who is going around to find, you know, like co-codamol or other opioids and then they will also inform other pharmacies." (Participant 7: pharmacist, female, independent pharmacy, 7 years)

Strategies that service users have adopted to obtain more prescription opioids include faking the prescription, consulting with a regular GP and a locum GP from

the same practice. This helps the service user to get high quantity of opioids than they require. However, the pharmacist could identify these service users by checking the Patient Medication Record (PMR).

> *"They'll also speak to a locum GP… and then I'll get duplicate prescriptions. I'll get my normal post-dated one which they know is from a regular doctor. A locum GP who maybe, hasn't read the notes or hasn't looked at it properly, will then prescribe. All of a sudden within two days they've got two weeks' worth because they've got postdated opioids plus what the locum has prescribed. That flags up because you can look on the PMR when you're dispensing it, obviously it's on their record, 'Oh that's just been dispensed that's old and then we'll ring up the doctors sometimes it's legit and it's because they're going on holiday."* (Participant 18: dispenser, female, chain pharmacy, 10 years)

Service users' behaviours that often raise suspicion are negative reactions when denied the sale of an opioid, coming to the pharmacy very early in the morning and on bank holidays to purchase opioids.

> *"Christmas, or Boxing Day, or whatever else, and they make the effort to come for the medication, even though they know that you know shops would have been closed, and they could have planned around this, and yet they're so adamant to makes the slightly more arduous track to make it. To get the medication. You don't judge, but makes you question."* (Participant 22: dispenser, male, chain pharmacy, 2 years)

Referral system for service users who misuse opioids

The majority of pharmacists and other pharmacy staff were unable to refer service users who were suspected of misusing OTC opioids to their GPs because pharmacies do not have any information about the service user's GP. However, some participants said they were able to refer service users that misuse OTC opioids to the GPs that they worked closely with. On the other hand, when a service user is suspected of misusing prescription opioids, majority of the participants could refer them to their GPs

"We may also contact the persons, maybe, doctor, or when we don't know who the patients doctor is, you know, for over the counter sale, anybody could come from anywhere. We don't know that patient. We don't know the name even so we could never check. Let's just say, if we did know who they were, or one of our regulars that's different. We can then contact the GP, to warn them." (Participant 8: pharmacist, male, independent pharmacy, 35 years)

Consultation room and safety

All pharmacists and other pharmacy staff reported that they had a consultation room in their pharmacies where they could have private conversations with service users. The majority of participants felt that it was important for pharmacists and pharmacy staff to see opioid users in the consultation room as it will help the service user to open up about their issues.

"It's about a very sensitive issue. So I think working in community pharmacy, doing all these things etc improving things. But it's difficult because at the end of the day you are in a bit of a retail situation and you do have a till in between you. There is a long queue of patients between them. It's also a confidential issue. It's quite hard for me to start talking to somebody saying you're addicted to Codeine while there are 5 people behind them. That's also inappropriate. I personally think that's the main problem. If I was sitting in a room, If we were in a consultation room we could talk about it." (Participant 12: pharmacist, female, locum, 1 year)

However, other pharmacists and pharmacy staff expressed that it was not safe for them to see service users who were already addicted to opioids in the consultation room because this group of service users were perceived to be aggressive by pharmacists and pharmacy staff.

"I actually got told by like my manager once to not like lock myself in the consultation room with them. And you know you still want to respect the wishes of the person. So if it is a busy pharmacy, and they are a bit like conscious if they are getting like methadone, and they don't want to have it in front of everyone, I'll take them into the consultation, but I leave both

doors open. The one in the dispensary and I'll stand there and then they have to sign in the doorway of the consultation room from the outside, and I wouldn't go in and shut the doors, so they have that bit of privacy still. But I'm still kind of not locked in a room with them." (Participant 23: pharmacy assistant, female, chain pharmacy, 2 years)

Furthermore, some pharmacists and other pharmacy staff added that they felt comfortable seeing opioid users who suffered from addiction issues in consultation rooms that were located near the pharmacy area, had alarm buttons and in pharmacies that had security personnel. One pharmacy staff added that she felt safe because she usually takes another staff into the consultation room with her.

"I feel quite safe doing that, because our consultation room is quite close to our pharmacy. and also because we have security, like an alarm button. So if you feel you're in danger, you press it, and then head off to send out a message to the whole store to say you are being on security watch, you know, you are being recorded, etc.," (Participant 27: dispenser, female, chain pharmacy, 1 year)

Some pharmacists felt that denying service users who use opioids the opportunity to see the pharmacy staff in the consultation room might make these service users feel like they are discriminated against.

"I've never felt unsafe with a patient. Most consultations have an alarm button, and I think it's very important that those patients do still get those reviews and still get that one-on-one access that any other patient would. I think it's a very tricky line to go down. And just because somebody's prescribed an opiate that, you know, then they don't have every right to accessible health care as anybody else." (Participant 13: pharmacist, female, chain pharmacy, 2 years)

"Not for me. No, Obviously it's never been an issue that I've come across. I've never felt that a pharmacy needs a security guard. But again it's about making harm reduction something normal. It's no different than somebody who is getting treatment for high blood pressure or asthma." (Participant 14: pharmacist, female, chain pharmacy, 30 years)

In addition, they felt that community pharmacists could be attacked by any service user and not only opioid misusers and that community pharmacists should learn to see this as a risk that is associated with their role.

> *"I do absolutely agree. So there's certainly been times in the past where I've been threatened in the room, and I've been on my own, and I haven't particularly felt safe enough. It's definitely a challenge, but we also think it's a challenge to all healthcare professionals who are in a patient-facing role. It is just one of those things. Unfortunately, that is just part of the job."* (Participant 16: pharmacist, male, chain pharmacy, 5 years)

One dispenser felt that the decision to have a security in a pharmacy should be based on the frequency at which pharmacy staff experience aggressive behaviour from opioid misusers. This participant also reported that she felt that security personnel was not required in the pharmacy where she worked because pharmacy staff have never experienced aggressive behaviour from service users who are addicted to opioids.

> *"like I said, I have never had an issue with that, but I think it would have to be based on individual circumstances, what type of area that they were in like if the pharmacy dispensers have had a lot of methadone patients, and from my personal experiences, there's never been a need for that. I mean other than the picking things which you do get, some of them do tend to steal, very few, It's not an often thing, but they do tend to steal from the shop. but no need for a security guard to protect against violence, like I said, it would just have to be based on what type of area it is."* (Participant 21: dispenser, female, chain pharmacy, 12 years)

5.4.2 Social opportunity (Social environment)

Social opportunity has to do with the social environment and is made up of social factors that influence pharmacists and other pharmacy staff roles in opioid misuse prevention. These factors are the local health systems, service user's responses, opioid regulation and commissioners' support. These factors will be presented below.

Local health systems

Social opportunity refers to how pharmacists and other pharmacy staff interact with staff of other healthcare centres where opioids are prescribed. Examples of staff that work in other health care centres are the GPs who work in GP practices, staff of the drug clinics, pharmacists working in other community pharmacies, and locum pharmacists. These will each be presented below.

GPs

A challenge that was expressed by some pharmacists and other pharmacy staff is that they cannot offer any intervention to service users who use prescription opioids without first speaking with the service user's GP. This is because they do not have access to service users' medical records.

> *"Another big issue is not having all the information. we're an intermediate supplier of medicine. Really, we don't have the consultations. We don't have the indication of why it's being prescribed. We don't have the patient background, and don't have to social history."* (Participant 13: pharmacist, female, chain pharmacy, 2 years)

As a result, pharmacists reported that they contacted the GPs when they were not sure about the dosage of opioids prescribed by the GP. When contacted, some of the GPs thanked the pharmacist for contacting them. Some other GPs express anger to the pharmacist because they felt that the pharmacist is not in the position to comment about a prescription they have written and ought to have dispensed it to the service user without calling them.

> *"Obviously you wouldn't dispense the medication to the patient. You would speak to the patient first and let them know what's happening, and then you would ring the prescriber. and they are usually very grateful……"* (Participant 11: pharmacist, female, locum, 5 years)

The pharmacist who reported that GPs expressed anger when asked about the dosing of an opioid prescription, also reported that the response of the GPs depends

on the type of query that was raised by the pharmacist. If it was a query that had to do with the dosing of the medication, they were not usually happy about it.

> *"Our relationship with the GP surgeries were relatively good, you know, so we could kind of pass on information….. But these kind of odd not odd times, the pharmacist wasn't happy with the particular dose and the instructions on the prescription as well, because it wasn't quite clear,…. also the pharmacist then rang the prescriber,….and the prescriber was really not happy, and pushed back significantly, saying that you know I've been prescribing for 20 years. I've always done this. You're the first pharmacist to ring me up saying that there's a problem with this. But that conversation I would imagine, makes them not want to question,"* (Participant 6: pharmacist, female, chain pharmacy, 16 years)

In addition, community pharmacists experience long waiting hours on phone while trying to seek clarification about opioid prescriptions from the GPs and this impacts negatively on pharmacists working time.

> *"So I think ultimately the big one that I find on a day to day is just a getting hold of a doctor or someone at Gp Practice. If you do have a query quite often, you'll be on the phone, for, you know, 30 plus minutes whilst trying to run you know a busy pharmacy."* (Participant 16: pharmacist, female, chain pharmacy, 5 years)

Since the pharmacists' message is often passed through the receptionist via phone or email, there is sometimes loss of information or misinformation of the GPs by the receptionist.

> *"I think some messages aren't passed on correctly, and we send a lot of our, and we communicate mostly through email because of how, under pressure, the GPS are, at the minute, ringing them just isn't well, I think sometimes our emails get missed and information just doesn't get passed on correctly."* (Participant 18: dispenser, female, chain pharmacy, 10 years)

Pharmacists and other pharmacy staff suggested that it would be beneficial for the receptionist at the GP to undergo training about opioid misuse so that they can appreciate the urgency involved with forwarding opioid-related queries to the GPs.

They also shared that community pharmacists should be polite, friendly and willing to help the surgery when the GPs request for it.

> *"And making sure that all GP Staff, especially receptionists who don't obviously get this training. They don't know about like, selling them over-the-counter medication because it's just not their job, but I feel like it would be really beneficial if they just had a basic understanding of it. So that, when we're refusing a supply of something, the patient doesn't then just ring the GP and the receptionist is saying, 'Oh, well, I don't know why they are withholding your medication' cause that has happened before, and then the patient comes back to us really agitated."* (Participant 24: dispenser, female, chain pharmacy, 5 years)

The main reasons for contacting the GPs as detailed by the participants are when pharmacists or pharmacy staff send service users to their GPs because they are suspected of being addicted to prescription opioids, when the service user's prescription is not signed properly, or when a service user comes to the pharmacy to collect or buy more opioids than they ought to collect.

> *"I have actually in the past few times, where I've noticed, people come in and they'll try and make excuses like, It's not for me, it's for me next door neighbour. And sometimes I have sort of bit the bullet and got them in the room and said, are you having a problem? do you feel like you're addicted to this? And I have had about three people, they've gone to their GP who then referred them to the drug clinic and it's about six months, where they're on buprenorphine and then that seems to be it, they've conquered it and they've got off the opioid addiction."* (Participant 5: pharmacist, female, chain pharmacy, 25 years)

Other participants affirmed that their communication with the GPs was good and that the GPs contact the pharmacy if they needed to know the available drug brands and to seek the pharmacist's advice about medication. Some of these participants also reported that they felt that they had a good relationship with the GPs because they try to help the GPs when help is needed from them, for example, they informed the GP practice about new services that the pharmacy offers including independent prescribing, the pharmacist also attends meetings organised by the GPs

"Yeah like I said we've got a really good relationship with our GPs next door because we're attached to them not the locums, the regular doctors, to the point where you know, sometimes they'll even nip into our pharmacy. 'If things are out of stock what will you prescribe instead?', they'll have a chat with the pharmacist and say like for instance, 'what dosages do we give?' we're lucky I know it's not the same everywhere." (Participant 18: dispenser, female, chain pharmacy, 10 years)

Some of the pharmacists reported that where the pharmacy is located tends to influence communication between the pharmacist and the GP. Pharmacies that were located together in the same practice as the GP tended to have a better relationship when compared to pharmacies that are not attached to any GP practice.

"I find in general, pharmacies that are situated within a GP practice or within a health centre, have much better relationships than your typical, you know, retail pharmacy on the High Street that kind of deals with multiple different places." (Participant 13: pharmacist, female, chain pharmacy, 2 years)

Pharmacists and other pharmacy staff felt that the GPs might be contributing towards the development of opioid misuse by starting patients on opioid analgesics rather than first prescribing non-opioid analgesics.

"I think it's quite an easy go-to for doctors, and especially during covid they weren't seeing patients, so they will literally give telephone appointments and even from personal experience, I had what I thought at the time was a trapped nerve. So I rang them up, during covid, obviously there was no real consultation, it was just a telephone appointment and the first line was 'let me give you some codeine.'" (Participant 28: dispenser, female, chain pharmacy, 2 years)

Most pharmacists and pharmacy staff added that it was important for community pharmacists and GPs to work together to effectively tackle opioid misuse. They expressed that it would be difficult for community pharmacists to work alone successfully.

"We do have the potential to make much bigger sort of strides ultimately to improve patient care, so I think really would just need them, plus the reliance between a community pharmacy and general practitioners and whoever the prescribers are, and just to work together to sort of overcome those challenges." (Participant 16: pharmacist, male, chain pharmacy, 5 years)

Drug clinics

The relationship with drug clinics was described as good by all participants because they are able to speak directly to the service user's key worker who resolves reported queries within the same day. Some participants informed that it was because communication was straightforward, that is, they informed the drug clinics if they noticed any untoward behaviour of the service user, and if service users do not come for their medication for three consecutive days.

"We have a pretty good working relationship with the drug clinic….. So I know most of the keyworkers that work there, and we have really good relationships in terms of making sure that the key workers are aware of any issues with the patient whatsoever, even if we'll have a refused supply or patient couldn't attend, even if we're just a little bit concerned, that something is not quite right, we contact them straight away… It's just really easy….and usually the issue will be finalized by the end of the working day" (Participant 24: dispenser, female, chain pharmacy, 5 years)

One pharmacist reported that the drug clinics regularly followed up on their patients by calling the pharmacy to ascertain whether patients came to the pharmacy to collect their medication in time, whether they missed any dose and about their behaviour. This participant also iterated that the GPs do not call the pharmacy to seek medication-related information about their patients who were prescribed opioids.

"When it's just a normal prescription from a GP, say for morphine. They don't call up and ask, how were they? Did they collect it on time? Are they taking it appropriately like? Do we know anything else? So the Harm Reduction service actually knows a lot more about their patients than I

would say a practice would." (Participant 10: pharmacist, female, locum, 5 years)

However, some pharmacists reported that when they have queries at the weekend, the drug clinics are not usually open to rectify the queries, hence, service users would have to wait till Monday.

> *"I hope they can open on the weekend because a lot of times the problem happens on Saturday sometimes, like, you have two prescriptions starting on the same day with different doses. And I say, I can't give you. I don't know what to give you. Yea, so they will have to wait till the Monday."* (Participant 5: pharmacist, female, chain pharmacy, 25 years).

Another challenge expressed by both pharmacists and other pharmacy staff was that they think that the harm reduction programmes were not committed to effectively treating opioid users to the extent that opioid users are completely free of receiving buprenorphine or methadone from pharmacy staff.

> *"I feel like the drug addiction team becomes very complacent and gives the prescriptions out, and they don't really try and titrate them down to try and get them of. There are patients that I've known for years, years, years. to be on Methadone and is still on it."* (Participant 21: dispenser, female, chain pharmacy, 12 years)

One pharmacist was emphatic that harm reduction programmes were effective at reducing opioid users' need for these opioid medications but that the adverse effect that these service users experience on tapering down the medication was the main issue.

> *"Obviously they try to put people's methadone doses down, but they usually have withdrawal symptoms, physical ones, or some mental ones. and it usually tends to creep back up, and people are usually on it for years and years and years."* (Participant 12: pharmacist, female, locum, 1 year)

Community pharmacy practice

Communication between pharmacies was said to be poor, especially in rural areas where pharmacists work in isolation. In these areas, information about a service user who is purchasing opioids from multiple pharmacies might not be easily shared. Another challenge expressed by participants was the issue of confidentiality. Participants might be aware that a service user is purchasing more quantities of opioids than they require, but might not be able to inform other pharmacies because they were not sure if they would be breaching confidentiality by passing the information.

> *"There's not really much we can do, and we can't go to the pharmacy and tell this pharmacy what is happening because of data protection. So we'll be breaking data protection"* (Participant 25: pharmacy technician, male, chain pharmacy, 35 years).

Locum pharmacists

Some pharmacists and other pharmacy staff added that locum pharmacists are usually not conversant with the mode of operation of the pharmacy and this slows down the pace of work at the pharmacy and sometimes puts pressure on other staff. This was not the case for locum pharmacists that have worked in the pharmacy for a long period of time and were familiar with the mode of operation of the pharmacy

> *"I think the only challenge that I've ever had is when we had a locum on a Saturday and it's generally sometimes me and a locum pharmacist…they've got no idea how to use pharmacy manager, our system for doing the labels."* (Participant 17: dispenser, female, chain pharmacy, 8 years)

> *"A lot of the pharmacies that I work in they don't have regular pharmacists. That's what it is, you know. Dispensers trying to pull together, working with different locums every day. There are in quite a bit of pressure, and they're sort of struggling to do the main component of that job."* (Participant 12: pharmacist, female, locum, 1 year)

Service users' responses

The majority of the pharmacists felt that service users do not recognise the role pharmacies play in the prevention of opioid misuse and tend not to accept the advice given to them by pharmacy staff.

> *"I don't think a lot of the public realise the actual roles that we have."* (Participant 10: pharmacist, female, locum, 5 years)

> *"People do say can you put the sale through? Really I will say well part of my job is actually to give you advice and you need to listen to it and we just continue saying that but it's becoming more like a robot. So we say automatically and probably 10% of the people we talked to they actually listening what we even say."* (Participant 6: pharmacist, female, chain pharmacy, 16 years)

However, some pharmacists felt that service users' reaction is determined by how well the community pharmacy staff communicates with them.

> *"And I think that initial intervention with a pharmacist has to be very careful with the wording, because what we don't want to do is lose that relationship with the patients, and it has to come from an area of concern about their pain and symptoms. And I always like to come from the aspect of you know you're taking this co-codamol, but you know, it hasn't treated the pain because you're coming back for more. That tells me that it's not working for you, and I'll say, you know you have the right to be accessing proper treatment. So if this over-the-counter isn't working for you, I think what we need to do is get you in with a GP."* (Participant 13: pharmacist, female, chain pharmacy, 2 years)

Opioid regulation

Most community pharmacists reported that the current regulation of OTC opioids need to be changed to prevent the excessive purchase of OTC opioids which contributes to OTC opioid misuse

"And there's no real regulation to over the counter sales, so we can do our best here, and we obviously assume other chemists do that best there. So the problem is that they can also buy these products online as well. So there's a number of outlets that they can purchase from. So we refuse here, which we do quite regular but that doesn't solve the issue with a problem, they can get it online or they could send a relative or friend." (Participant 8: pharmacist, male, independent pharmacy, 35 years)

Commissioners' support

The majority of the pharmacy staff, particularly the dispensers and pharmacy assistants did not know who the commissioners were. On the other hand, the majority of the participants that were pharmacists knew who the commissioners were but were not sure how commissioners could contribute towards improving community pharmacists' role in the prevention of opioid misuse.

"Commissioners? What do you mean?" (Participant 27: dispenser, female, chain pharmacy, 1 year)

"How could they impove? It's an interesting one. Actually. Hmm. Let me have a think so. How could they improve? Oh, do you know what I'll probably have to get back to you on that one. Yeah." (Participant 16: pharmacist, male, chain pharmacy, 5 years)

One pharmacy staff reported that it was difficult contacting the commissioners when pharmacy staff needed support because of change in commissioners' roles.

"yeah well I feel like sometimes it's a bit of a struggle to find out who you need to contact and speak to, so I know we've got ..... in our area, so I kinda email her for help and information or guidance on different services but sometimes its case of oh that's not me, let me pass you on to this person, then they get this another person's name and number, and they say that used to be me, but now it's not me and sometimes you feel get pushed from pillar to post a little bit. Because obviously people change their job roles and it seems nobody has an up-to-date information because that used to be

their job..it can be a struggle." (Participant 18: dispenser, female, chain pharmacy, 10 years)

Few pharmacists and other pharmacy staff felt that the commissioners were in a position of authority and were already supportive but would need to improve the level of support they offer to community pharmacists by communicating and interacting more closely with pharmacy staff, as well as service users.

> *"We already get quite a lot of support from the Pharmacy Commission as we get, or we communicate a lot with them, and whether that be through email or phone. But I think the Pharmacy Commissioners could possibly be more involved with the patients….You know that because she is our governor, as we call it, you know, and everybody has respect for her, and we would do what she would say."*(Participant 24: dispenser, female, chain pharmacy, 5 years)

5.5 Motivation

Motivation refers to the participants' mental processes, which influences their role in the prevention of opioid misuse. As stated in chapter three, there are two types of motivation- reflective and automatic. These will each be discussed in relation to the participants' data.

5.5.1 Reflective motivation

Reflective motivation relates to the participants' attitudes toward their role in the prevention of opioid misuse, which results from their beliefs about this role. Community pharmacists' attitude towards the local health system was identified as a subtheme that was related to reflective motivation.

Attitude towards the local health systems

Some pharmacists were not motivated to report opioid prescription queries to the GPs because of previous unpleasant communication between them and the GPs.

> "*But then you get other ones, who have been taking the opioids for so many years already addicted to it. just continue taking the same script over and over again, regardless of what you say to them. Well, and in that case, I cannot, I cannot intervene. Because if the doctor listens to us they'll be like*

well they've had it for years, what are you asking for." (Participant 6: pharmacist, female, chain pharmacy, 16 years)

The majority of the pharmacists and other pharmacy staff were happy to report any service user or prescription queries to the drug clinic because they had always experienced good communication with the drug clinics.

"*Because we're always in contact with them. we haven't really had an issue with them previously at all. And I feel like the jobs just really straightforward. we just have to make them aware of something. So in a scenario like that I don't really think anything could go wrong. Information getting passed on. Really*" (Participant 20: dispenser, female, chain pharmacy, 2 years)

Attitude towards role

The majority of the pharmacists and other pharmacy staff felt that community pharmacy's main role is the identification of service users who are at risk of misusing opioids and informing service users about opioid misuse. This feeling was believed to motivate most community pharmacists to carry out these services.

"I think community pharmacies have a really big role in identifying possible risk patients and patients at risk of the common addicted opioids. I think all community pharmacies play quite a big role in making sure that staff are all aware of potential opioid misuse. Knowing the signs and symptoms." (Participant 8: pharmacist, male, independent pharmacy, 35 years)

A pharmacist felt that it was challenging for pharmacy staff to effectively carry out their role due to work pressure in the pharmacies.

"you know the way we sort of trained at Uni, and the way we look at each patient's case with so much. you know, observation and care, and in so much depth. It's difficult to reflect that in practice, when this is a sort of quite understaffed and overworked, and under a lot of time constraint." (Participant 12: pharmacist, female, locum, 1 year)

However, some pharmacists and other pharmacy staff felt that even when there are long queues on the counter or when the pharmacy is understaffed, they still advised the service users because they felt that it was their responsibility to advise service users who come to purchase opioids about their medication. Other participants offered advice despite the stated challenges because they received adequate support from their company.

> *"Even if I've got a massive queue, or if I'm understaffed, people are on the break, and it's just me, etc. I always like give full advice. I don't care if I've got a queue. What if they use it wrongly and then something dangerous happens to them like? Even if I've got a huge queue. I just have to. It is what is it?"* (Participant 27: dispenser, female, chain pharmacy, 1 year)

Pharmacists reported they were not inclined to offer OTC opioid misuse services because it was challenging to monitor service users that regularly came to purchase OTC opioids and service users could purchase OTC opioids from other community pharmacies.

> *"Because it's really hard to keep track of who's come in to watch, and you know. So I think that at the moment it is a bit of a hopeless task selling it because you can't be safe, you know people are going to abuse them if they want to."* (Participant 10: pharmacist, female, locum, 5 years)

> *"The trouble that we have as pharmacists is that in this area there are six other pharmacies, they [service users] can quite easily go to another pharmacy. You know, and obtain another box there."* (Participant 5: pharmacist, female, chain pharmacy, 25 years)

With respect to prescription opioids, some pharmacists reported that they were not motivated to screen opioid prescriptions because they felt that this service must have been carried out at the GP practice. In addition, pharmacists are not compelled to intervene when there was a query with opioid prescription or to offer medicines review because they do not have access to complete information about the service user.

"To be honest, I normally just quite like assume, like doctor will do the dose check and everything. I don't really do a lot much intervention. Yeah, I don't. Really. I don't really do much of intervention, like. First of all, I don't have any record. I can't assess the patient record." (Participant 9: pharmacist, female, locum, 6 years)

"I think it's a great idea, and I think community pharmacists would be capable of doing it. But having the appropriate services in the appropriate place when you know it involves a lot of information, quite in-depth, and takes a lot of time,..it might as well go to the point of prescribing in a GP practice as opposed to the point of dispensing in the community pharmacy, because I can't imagine one pain review you did with a patient that wouldn't result in some type of information having to be sent to the GP and some type of intervention happening." (Participant 13: pharmacist, female, chain pharmacy, 2 years)

Attitude towards service users

All participants reported negative experiences with opioid users, especially service users who were addicted to opioids. These encounters restrain some pharmacy staff from carrying out opioid misuse prevention services.

"We've been like a lot of times when they come in. I don't think they really want medication. I think they just want to steal…. They come in for methadone, but actually they'd be running the shops, and sometime we saw them like stealing things all right, asking their friends to steal the things. So to be honest, people here, when they say about drug users, they've been like. associate them with like crime, and in selling things, selling anything stolen from the shops on eBay." (Participant 9: pharmacist, female, locum, 6 years)

One pharmacist felt that some pharmacy staff lacked sympathy for service users who were addicted to opioids and as such are not compelled to carry out harm-reduction services effectively.

"*A lot of them are unfortunately homeless. They've got very, very difficult personal circumstances. So a lot of the time they sort of take their anger*

out on the pharmacy….I think some pharmacists maybe don't understand that as much, and maybe there is a little bit of a lack of sympathy. I just feel really sorry for them. I think it's really sad..." (Participant 12: pharmacist, female, locum, 1 year)

A pharmacy staff felt that many pharmacists were not interested in service users that were addicted to opioids, and this negatively influenced the way pharmacists carried out harm-reduction services.

"There's a lot of pharmacists that when you are having a methadone patients, don't really care about them, whereas personally, from my point of view, they should care about them just as much as they care about any other patient… If patient is going to have supervised consumption, they are supposed to be watched while they take that medication. I've seen this pharmacist hand in that medication by up the door…. They'll not report how that person has presented when you can clearly see that that person is under the influence, and that means they shouldn't be having them. It should be reported." (Participant 21: dispenser, female, chain pharmacy, 12 years)

One pharmacist felt very comfortable with carrying out harm-reduction services because he felt that there were no difficulties associated with interacting with service users who were addicted to opioids.

"So I find them a lot easier to communicate with. I think queries with them are a lot easier to sort because you have one direct person and a direct line. Normally, the patients always are very compliant because they want their prescriptions, they need those prescriptions, and they tend to have already been on the service for a long time. They understand the drill that if we have a query, we can't give it out until the query is solved." (Participant 13: pharmacist, female, chain pharmacy, 2 years)

Two male participants, that is, a pharmacist and a dispenser felt that female pharmacists tend to be afraid when confronted by opioid users in the consultation

room. They thought that this fear dissuaded female pharmacists from carrying out private consultations with opioid users.

> *"In the pharmacy that I work at, the consultation room is very small. and I suppose, particularly if you are a female pharmacist with a big aggressive man in the consultation room, you can be uncomfortable, saying no to them, so I understand that.* (Participant 22: dispenser, male, chain pharmacy, 2 years)

5.5.2 Automatic motivation

Automatic motivation relates to participants' attitude towards their role in opioid misuse that stems from rewards and incentives provided by pharmacy managers.

Attitude of pharmacist or pharmacy manager

Some of the pharmacy staff especially the dispensers think that many community pharmacists or pharmacy managers are interested in making profits rather than monitoring if a service user's drug use is appropriate. This attitude flows to the dispensers, pharmacy assistants, and pharmacy technicians. As a result, the pharmacy staff do not take time to counsel service users about their opioid use.

> "*I think it depends. It all depends on, I think, the attitude of the pharmacy manager and the pharmacist that you're working with, because several, well, many pharmacists treat community pharmacy as just a business as opposed to the supply and just to sell. And others are out for kind of looking for kind of .. appropriateness and helping patients.*" (Participant 22: dispenser, male, chain pharmacy, 2 years)

One pharmacy staff stated that he worked in a pharmacy that was part of a large supermarket, hence the pharmacy was viewed as a means of attracting customers into the store and not a source of profit for the store per se. Therefore, pharmacy staff were concerned with checking if service users' opioid use was appropriate since they were not under any form of pressure to make sales.

> *"So like I said, the pharmacy I worked for the turnover wasn't so important. It was kind of deemed as a way to bring more people into the store at large. You know, there would be a pharmacy, there'd be an optician's, there'd be a*

phone shop. It was treated as a component to bring people into the store, and then hopefully, they would spend elsewhere, and on the shopping and whatever else. So we weren't pushed massively to sell more." (Participant 22: dispenser, male, chain pharmacy, 2 years)

One pharmacy staff stated that in the shop where she worked, pharmacy staff did not have the time to carry out opioid misuse activities because they were more concerned with meeting the shops' sales targets as assigned to them by the pharmacist or pharmacy manager.

"*I think it's because we work in a retail shop so she kind of gives us a lot of targets that maybe won't be necessary for pharmacy if it's still target. But if you work in just a pharmacy, you don't get that. But I mean, she's got quite a good knowledge of pharmacy, so she supports us. She just kind of maybe doesn't realize that things take time, and you might not have that many hours in your day to do it."* (Participant 27: dispenser, female, chain pharmacy, 1 year)

Attitude of locum pharmacist

Pharmacists and other pharmacy staff felt that locum pharmacists were more interested in their pay rather than in carrying out opioid misuse prevention roles. However, one participant observed that most locum pharmacists who worked full-time in a hospital or GP practice were normally more interested in ensuring the safe use of opioid medication when compared to those pharmacists who worked as locum pharmacists full-time.

"Many locums I've experienced have generally just been there to kind of get a wage because they're only for that day or that weekend, or whatever, but then I've had locums who tend to be more patient-focused and have a full-time job elsewhere, either in a hospital setting or a primary care setting, and so they tend to be the locums that are more concerned about patients' safety and supply of opiates, whereas in my experience, locums that are kind of full-time locums are a lot more willing to just supply." (Participant 22: dispenser, male, chain pharmacy, 2 years)

5.6 Summary

The findings of the community pharmacy staff interviews revealed areas of community pharmacy staff's role in opioid misuse prevention that needed to be improved. These factors are displayed in Table 5.2. These factors are pharmacy education and training; a conducive physical and social environment that would enable pharmacists to carry out opioid misuse prevention roles; and the attitude of the pharmacist or pharmacy staff towards carrying out opioid misuse prevention roles.

Table 5.2 Themes and subthemes from the community pharmacy staff interviews

Themes			Subthemes
Capability	Physical capability	Physical skills	Communication skills
			Ability to identify service users who misuse OTC opioids
	Psychological capability	Knowledge and skill	Education and training
Opportunity	Physical opportunity	Physical environment	Staff and funding
			Tool for identification of service users who misuse OTC opioids
			Referral system for service users who misuse opioids
			Consultation room and safety
	Social opportunity	Social environment	Local health systems
			Service users' responses
			Opioid regulation
			Commissioners' support
Motivation	Reflective motivation	Pharmacy staff's attitude	Attitude towards local health system
			Attitude towards role
			Attitude towards service users
	Automatic motivation	Pharmacy staff's attitude	Attitude of pharmacist or pharmacy manager
			Attitude of locum pharmacist

Chapter 6 Commissioners' findings

6.1 Introduction

The preceding chapter describes themes developed from 28 community pharmacy staff interviews and mapped them to the COM-B model of behaviour. This chapter presents and discusses themes identified from commissioners' interviews.

6.2 Participants' demographic information

A total of eight commissioners were interviewed. Table 6.1 displays the commissioners' information. The majority of the participants were males (n=7, 87.5%) while 12.5% (n=1) were female. In terms of their professional background, 62.5% (n=5) were pharmacists while 37.5% (n=3) were GPs. Fifty percent (n=4) of the participants worked in the NENC/ICB, 37.5% (n=3) worked in both the NENC/ICB and the Primary Care Network (PCN) and 12.5% (n=1) worked in the PCN. Fifty percent (n=4) of the participants had 21-30 years of experience, 37.5% (n=3) had 10-20 years of experience and 12.5% (n=1) had 31-40 years of experience.

Table 6.1 Participants' demographic information

Participants characteristics		Number (n)	Percentage (%)
Gender	Female	1	12.5
	Male	7	87.5
Age group (in years)	31-40	1	12.5
	41-50	3	37.5
	51-60	4	50.0
Professional background	Pharmacist	5	62.5
	GP	3	37.5
Organisation	NENC ICB	4	50.0
	NENC ICB/ PCN	3	37.5
	PCN	1	12.5
Years of experience (professional)	10-20	3	37.5
	21-30	4	50.0
	31-40	1	12.5

6.3 Themes identified from the commissioners' interview

Six themes were identified from the commissioners' interviews. These themes are the relationship between commissioners and community pharmacists, the role of commissioners in opioid misuse prevention, contribution of community

pharmacists, potential improvements, public health campaigns and factors limiting commissioners' roles. These themes will be discussed in this chapter individually.

6.3.1 Relationship between commissioners and community pharmacists

This theme describes the levels of interaction between the commissioners and community pharmacists. The levels of interaction that were identified were classified into commissioner level and health practitioner level.

At the commissioner level, participants who were representatives of the LPCs ran projects in community pharmacies and had a close relationship with members of the LPCs, while other participants including the GPs, interacted closely with representatives of the LPCs in routine meetings.

> *"So I'm regularly in touch with commissioners at lots of different organisations, and I'm regularly in touch with leadership within community pharmacy. So the local pharmaceutical committees here in the North East and Yorkshire."* (Participant 1: pharmacist, male, NENCICB, 23 years)

At the health practitioner level, only the GPs shared interactions they had with community pharmacists. They stated that they usually contacted community pharmacists whenever they needed information about patients' prescriptions and the community pharmacists also contacted them when they needed clarification regarding patients' prescriptions.

> *"Occasionally I would make a phone call to a pharmacist and say, can you tell me what's happening with this patient's prescription because they're telling me this. We do get community pharmacists that ring us and say such and such is at the desk. They're desperate for their prescription. They say they asked for it 3 days ago."* (Participant 2: GP, male, NENCICB/PCN, 29 years)

6.3.2 The role of commissioners in opioid misuse prevention

This theme details the activities that commissioners carry out to prevent opioid misuse. Two main groups of activities were identified. There are activities that were

carried out by commissioners who were GPs and those that were carried out by commissioners who were community pharmacists.

Participants who were GPs stated that they were involved in preventing opioid misuse at the GP practices; they described their role as two-dimensional- as GPs and as commissioners. As GPs, they felt that they were directly responsible for the number of opioids being prescribed to individual patients. On the other hand, being commissioners enabled them to promote safe opioid prescribing behaviour among GP practices in the region.

> *"So in my GP role, I would say my role is like every other GP which is to be conscious all the time about the potential for opioid misuse and tolerance and addiction, like when to prescribe them, and how to prescribe them in a responsible way that goes with the evidence…. as commissioners, we have a responsibility to make sure that we have good prescribing practice throughout the NHS Northeast."* (Participant 4: GP, male, NENCICIB/PCN, 17 years)

Participants who were pharmacists reported differing opinions regarding their role in preventing opioid misuse. While some participants iterated that their role as commissioners does not require them to carry out any action regarding opioid misuse, others stated that they were involved in preventing opioid misuse and that their intervention was also prescriber focused. Participants who were involved in preventing opioid misuse stated that they promoted safe and effective opioid prescribing practices across all parts of the health system in the region, encouraged GPs to consider non-drug alternatives and carried out opioids optimisation and review in GP practices.

> *"So my job is really to work across the system to make sure that we are using the medicines that we prescribe appropriately in the right way that benefits patients that reduces health inequalities, and that helps us to get the best outcome for the populations that we serve."* (Participant 5: pharmacist, male, NENCICB, 21 years)

6.3.3 Contribution of community pharmacists

This theme refers to what the commissioners feel about the role of community pharmacists in the prevention of opioid misuse. It highlights services community pharmacists are currently carrying out, services they could potentially carry out and perceived challenges that hindered community pharmacists from carrying out this role.

The majority of the participants reported pharmacists could advise, counsel, monitor and control OTC opioids that were bought in their pharmacies but could not account for those bought in other pharmacies. One of the participants expressed that community pharmacists were doing their best given the resources available to them.

> *"I don't think there's much more than what we're doing currently that we could do in community pharmacy with over-the-counter opioids*." (Participant 1: pharmacist, male, NENCICB, 23 years)

There were differing views participants had about the role of community pharmacists in the identification of opioid misuse. One participant felt they had a role in identifying service users who are suspected of misusing prescription opioids and informing the GPs. Some felt that pharmacists did not screen opioid prescriptions properly and thus were not able to identify service users who misuse prescription opioids. Reasons given for not screening prescriptions properly were pharmacists' assumption that there should be no problems with the prescriptions since they were written by the GP, the heavy workload induced by staff shortages and the perception that the decision on whether to prescribe opioids is determined ultimately by the GPs.

> *"And the pharmacist at the point of dispensing should review the medication and question, is this medication still safe, still appropriate? Still for the benefit of the patients? And that doesn't seem to happen, everyone's so busy that they just carry on issuing the prescriptions."*(Participant 5: pharmacist, male, NENCICB, 21 years)

Some participants added that compared to community pharmacists, the clinical pharmacists who worked in PCN or in general practice settings were more

involved in identifying service users who were at risk of misusing opioids. For these participants community pharmacists could potentially direct or refer patients who use OTC or prescription opioids to other relevant services that could help improve patients' pain and provide data on the number of persons who buy OTC opioids.

> *"what would be really important is if they could then start to signpost them to some of the non-pharmacological alternatives such as the counselling, CBT, physiotherapy, acupuncture, whatever alternative that was appropriate for the patient. So Community pharmacy having almost like a pain tool kit to direct people away from opioids."* (Participant 1: pharmacist, male, NENCICB, 23 years)

Because of community pharmacies' accessibility to this group of patients, some participants felt that community pharmacists were well-positioned to offer intervention to opioid users. However, community pharmacists will require support from other parts of the health system to offer intervention effectively.

> *"It's got a very unique place in the health care system. There's not really anywhere else where you can just walk in and be seen and treated, and have advice almost immediately. So I think that both means that it's got a huge opportunity."* (Participant 5: pharmacist, male, NENCICB, 21 years)

Other perceived challenges to community pharmacists' involvement identified by participants were insufficient time, lack of resources especially full time pharmacists, work pressure, lack of training, poor communication between GPs and community pharmacists, lack of GP-community pharmacist collaborative services, the ability of patients to purchase OTC opioids from multiple pharmacies, no forum for community pharmacists and GPs to meet and discuss collaborative ideas, lack of community pharmacists' knowledge of how the GP practice operates, lack of a referral system for service users suspected of misusing OTC opioids and potential threat to profit.

"I think there's definitely something that community pharmacists can do. It's just to what level and I know the pressures and demands that are in community pharmacy. And they don't have the time and resources to sit and speak with patients and complete these reviews and reductions… If a community pharmacist does look to reduce patients' opioids, that's really good, but they are reducing the amount of items prescribed as well, in effect, get a reduction in their business." (Participant 6: pharmacist, male, PCN, 10 years)

6.3.4 Potential improvements

Potential improvements encompass suggestions that could help improve community pharmacists' role in opioid misuse. Suggestions that were made are: support from other members of the health system; change in classification of OTC opioids; OTC opioids register; community pharmacist-GP collaborative practices such as shared opioid record between community pharmacy and GP practice, use of NHS cards, use of dedicated phone lines, referral of service users who were suspected of misusing opioids from community pharmacies to GPs, registering patients who were suspected of over ordering opioids to one community pharmacy, and computer programmes; funding, communication with other community pharmacists and patient education. These suggestions are expatiated below.

Participants felt that community pharmacists were doing their best to prevent opioid misuse given the resources available to them. As a result, they felt that for community pharmacists to get more involved in the prevention of opioid misuse, support from other members of the health system such as researchers and pharmacy commissioners would be needed.

"I don't think there's anything more that community pharmacists could do right now with the current tools that we have. But if we, in terms of commissioners and researchers or people within the system, if we decide, we want to do something, we need to design it and make sure that it happens to address any problems that we want to address. Okay, it is not. It is not for community pharmacy to do that for themselves." (Participant 1: pharmacist, male, NENCICB, 23 years)

The ability of patients to purchase OTC opioids without a prescription and from any pharmacy prevents community pharmacists from effectively monitoring and identifying service users who might be misusing opioids. Some participants suggested that changing the classification of OTC opioids to prescription opioids would help prevent the indiscriminate purchase of opioids OTC. This change in classification would also help to improve pharmacists' ability to monitor and identify service users who might be misusing opioids.

> *"I think potentially, we need to get to the position that opioids are not available over the counter to purchase. Why don't we change the legal categorisation of them? you know, if it is over-the-counter and make them all prescription only."* (Participant 7: pharmacist, female, NENCICB/PCN, 13 years)

Alternatively, community pharmacists could also consider having a register for taking records of service users as this would also help them monitor and identify service users who might be misusing OTC opioids. It would also be beneficial for pharmacists to refuse the sale of opioids to service users who are suspected of misusing opioids and advise them to consider using other treatment options.

> *"They could make a really strong statement by just refusing to sell them on a repeat basis to individuals so they could, you know they could even register who they're selling them to, and then when somebody comes back in and asks for a second supply, they could say, well, no, you know, you need to think about non-opioid-containing alternatives at this stage."* (Participant 5: pharmacist, male, NENCICB, 21 years)

Other recommendations made by participants required community pharmacists to collaborate with GPs. Examples of such proposals are the adoption of a system that would enable a person's opioid purchase details to be recorded in their GP records and made accessible to all pharmacies as well as other health professionals. This shared care record will promote close monitoring of patients' opioid use, especially opioids purchased from multiple pharmacies.

> *"If all the pharmacies had access into the GP records so that they could enter into that GP record- I've sold Mr. Smith some cocodamol today. Then every pharmacy, when selling it, would be able to have a look at the record and see that information. So I think that would be the way."* (Participant 5: pharmacist, male, NENCICB, 21 years)

The development of a shared record could be facilitated by asking service users who use opioids to present their NHS cards at the point of purchase of opioids. Since a person's NHS number is the same across all parts of the health system, it will help pharmacists access a person's opioid buying history irrespective of the number of pharmacies visited or GP practices consulted by the patient.

> *"Patients needing to produce their NHS number, and register when they are purchasing medications like this, so that you have a shared patient record that you can see what's being used, and where."* (Participant 7: pharmacist, female, NENCICB/PCN, 13 years)

To further emphasise the need for information sharing, some participants felt that for community pharmacists to offer interventions targeted at preventing opioid misuse, community pharmacists should have access to patients' full information which could be obtained from the patients' records as well as the GPs. These were reported to be the reasons why pharmacists who work in PCN could offer interventions towards preventing opioid misuse.

> *"We can work even closer together with them. But actually, our clinical pharmacists are the ones actually who are providing a greater role at the moment, because they're actually employed by us. By the NHS I mean and they've got that access to the medical record which I think is really important. If you're going to be doing anything interventionally, you need to know what the context is."* (Participant 3: GP, male, NENCICB/PCN, 24 years)

Other means through which information could be quickly shared between community pharmacists and GPs is by dedicated phone lines developed solely for communication between community pharmacists and GPs.

> *"I would say that your project should advocate better instant lines of*

communication between the community pharmacy and the local GP surgery. We call it a back phone…The back phone just means a phone that is entirely not, it's not going to be tied up in other conversations. It should be free most of the time." (Participant 4: GP, male, NENCICB/PCN, 17 years)

Apart from information sharing, another opportunity for community pharmacists-GP-collaboration, was for community pharmacists to refer service users who were suspected of misusing OTC opioids to their GPs for a prescription before collecting their medication from the community pharmacy. In cases where the GP identified that certain patients were misusing prescription opioids, these patients should be registered to collect all opioids from only one pharmacy. They added that this pharmacy should have computer programmes that could help detect and signal prescription opioid misuse to the pharmacist. This will allow close monitoring of patients' opioid-buying or opioid-collecting behaviour.

"They could have an agreement for certain cohorts of patients that the prescription should only go to one pharmacy. The patient should not have the flexibility to go to multiple different pharmacies." (Participant 4: GP, male, NENCICB/PCN, 17 years)

Despite the reported benefits of adopting community pharmacists-GP collaborative practices, participants felt that it was not yet time to implement this practice because of a lack of resources and intense work pressure resulting from the increasing responsibilities of the community pharmacist.

"like I say, it's about getting the timing right and ensuring there's enough capacity in the system, enough capacity in the actual community pharmacies because they've just took on another role with urinary tract infections and treating those and moving patients out of general practice. So there's a lot of things going on in community pharmacy." (Participant 8: pharmacist, male, NENCICB, 33 years)

Hence, to motivate community pharmacists to practice collaboratively, it was suggested that collaborative practices should be funded or administered as a contract, based on the number of opioid users who present to the pharmacy, and

sources of profit made by the pharmacy, such as dispensing charges should be increased. These might improve pharmacists' interest in collaborating with GPs despite other competing demands.

> *"If you want them to do something specific, it could be done as a contractual. So a service specification. We would like you to have an intervention with anybody who is on the long-term opioid and try and encourage them to come off and signpost them to a service where they could do that and you could target that with a cost, I guess and the pharmacist will put a claim in."* (Participant 2: GP, male, NENCICB/PCN, 29 years)

In addition to community pharmacists-GP collaborative practices, participants also proposed that pharmacists should also collaborate with each other to share information about feasible strategies that they had used in controlling opioid misuse. This information could be shared in regular meetings held online.

> *"So potentially an organization such as the Royal Pharmaceutical Society could create a forum in a particular area where, like minded pharmacists who have an interest in this, could meet over teams or zoom and discuss this sort of thing which might be helpful to pharmacists"* (Participant 8: pharmacist, male, NENCICB, 33 years)

Participants also proposed that community pharmacists should focus on educating patients about the adverse effects of taking high doses of opioids, taking opioids for long periods, and the benefits of non-medical intervention. It was also suggested that community pharmacists should be equipped to signpost opioid users to non-medical intervention services.

> *"What would be really important is if they could then start to sign post them to some of the non-pharmacological alternatives. So for that there are counselling, CBT, physiotherapy, acupuncture, whatever alternative that is appropriate for the patient. So, community pharmacy having almost like a pain tool kit to direct people away from opioids, whether they are prescription or over the counter, I think, would be very helpful."* (Participant 5: pharmacist, male, NENCICB, 21 years)

Ideas that were suggested to enhance educational services offered by community pharmacists were the use of printed educational materials such as cards, leaflets, QR codes, while dispensing opioids.

> *"So we've done it in the past where we've given community pharmacists, say a load of resources. you know, cards to put in with people's, medicines, or leaflets and things like that, and QR codes, so that people can scan to look at it, and so on. So I think that's the sort of thing we need to be doing more of."* (Participant 5: pharmacist, male, NENCICB, 21 years)

6.3.5 Public Health Campaigns

This theme describes participants' views regarding improving public awareness of opioid misuse. It details their perception and level of involvement in public health campaigns. These are detailed below.

Participants felt that public health campaigns were important in the prevention of prescription and OTC opioid misuse but none of the commissioners had been involved in any health campaign aimed at increasing awareness about the use of opioids.

> *"I think it's a really good idea. I think it's something we don't do enough of…., absolutely, definitely some communication, advertising campaigns to the public about what effect opioids can do is a good idea."* (Participant 6: pharmacist, male, PCN, 10 years)

Participants were generally involved in designing public health campaigns and had been involved in campaigns organised to increase awareness of analgesics, but not specific to opioids and a range of health topics.

> *"So part of our work in the ICB, when it was CCG, we developed a campaign called painkillers don't exist and it's got a website and on that website, it has access to other resources for what non-pharmacological options exist. There's also lots of stuff on there about opioids and the relative risks of opioids." (C5:* pharmacist, male, NENCICB, 21 years*)*

"As a community pharmacist, we used to do health campaigns regularly. So we've done some on pregnancy and breastfeeding local services, mental health, healthy vitamins, smoking cessation. So done quite a lot of them. And you know, alcohol reduction." (Participant 6: pharmacist, male, PCN, 10 years)

They also stated that these campaigns should be targeted at preventing people from using opioids and shifting the public's emphasis from the use of medical intervention to the use of non-pharmacological intervention. However, they also cautioned that care should be taken so that persons who require opioids for the treatment of pain are not dissuaded from taking opioids.

"When you have a sore knee should you be contacting your GP to get a strong painkiller to get rid of your sore knee? Or should you be trying to do more exercise and reduce your weight? You know, and I think there's something about lifestyle choices. But I think educating people so that there's a kind of balance around making it part of normal culture, about how we all behave around pain." (Participant 2: GP, male, NENCICB/PCN, 29 years)

For these campaigns to be effective, participants suggested they should be designed taking into consideration the sociodemographic situation of the target population and should be suited to them.

"We shouldn't be using them but there's also something about recognizing the people, and some people are in very difficult places, and pain's often a symptom of other wider issues taking place going back to the social, wider social determinants." (Participant 3: GP, male, NENCICB/PCN, 24 years)

Participants stated that one-on-one counselling, and education would be more ideal than public-focused forms of education for people who were already addicted to opioids.

"If you're just talking about running some adverts or putting some posters up it It's not gonna have that effect. I think if you were talking about education as in sit down with somebody and have a consultation with them, and they can talk to you, and then they can monitor you, or you know, you

know, some sort of ongoing educational program face to face. I think that would be more likely to succeed." (Participant 1: pharmacist, male, NENCICB, 23 years)

6.3.6 Factors limiting commissioners' roles

These are factors that limit commissioners' efforts toward supporting and collaborating with community pharmacists in the prevention of prescription and OTC opioid misuse. Factors that the commissioners reported were related to the way the previous commissioning body was set up, their job role, and a lack of research on community pharmacists' role in opioid misuse prevention.

Regarding challenges that were related to the setup of the previous commissioning body, participants reported that there was no forum for commissioners who were GPs and those who were pharmacists to discuss and implement potential community pharmacists-GP collaborative ideas. This was because community pharmacy services were not commissioned by the previous commissioning body.

> *"The fact that community pharmacy was always commissioned nationally and general practice was commissioned locally. That was one thing, because when in my previous role in the CCG, we commissioned general practice to do things but we couldn't really commission community pharmacy to do something in a joined-up way, so we couldn't kind of encourage them to speak to each other, or to work alongside each other in any sort of productive way, really so that is the one thing that's being removed."* (Participant 5: pharmacist, male, NENCICB, 21 years)

However, with the abolishment of the previous commissioning group (CCG) and the recent establishment of the current commissioning body (ICB), commissioners who are GPs and those who are pharmacists could potentially have the opportunity to discuss collaborative ideas since this commissioning group is now responsible for commissioning both GP and community pharmacy services.

> *"Only through our pain management subgroup of our area prescribing committee, and there is representation from the LPC, the Local Pharmaceutical Committee on that group, but that is the extent of our*

involvement with them at present." (Participant 7: pharmacist, female, NENCICB/PCN, 13 years)

Participants who were pharmacists stated factors that were related to their job role as their main challenge in supporting and collaborating with community pharmacies. They explained that they had not been authorised to commission opioid misuse services in community pharmacies and this prevents them from supporting community pharmacists in carrying out this service.

> *"I collaborate specifically around the project that I'm running currently and to be honest, that's good enough for me, I think, when I need to I collaborate and when I don't need to, I just get on with, you know, with what I need to get on with so. And obviously people come to me and ask me things as well. So it's not just one way. It's not when I need to. It's when they need to speak to me. I'll often respond to their questions and queries as well, so I think I've got a good relationship. But I've got limited capacity."* (Participant 1: pharmacist, male, NENCICB, 23 years)

The commissioning body also placed much emphasis on reducing inappropriate opioid prescribing in GP practices rather than seeking ways in which all sections of the health system involved in the treatment of patients could combine efforts toward preventing opioid misuse.

> *"I think there's an opportunity for all parts of the system, whether it's secondary care or general practice or community pharmacy just to say, hang on a minute. Let's just think about why we're doing this. And is there a better alternative than the path that we're currently going down? And I don't think that happens enough."* (Participant 8: pharmacist, male, NENCICB, 33 years)

In addition, these participants reported that their job role does not provide the opportunity for them to interact closely with community pharmacists. They interacted with pharmacists when they needed to assess the feasibility of implementing services in community pharmacies and during routine meetings with LPCs. They added that this level of interaction was not enough to fully understand how the community pharmacies or the GP practices operate and that

closer interaction or communication with these two settings was essential to proffer solutions, especially in improving community pharmacy and GP communication.

> *"I meet with the LPCs, probably every fortnight as do a couple of members of my team... I think something I'd be keen to do is to start to develop relationships outside of just the LPCs because that feels like a much more kind of contractual type of discussion and I'd rather have more of a discussion about actually, not just what people are contracted to do, but actually learning from different parts of the system."* (Participant 5: pharmacist, male, NENCICB, 21 years)

Another challenge that was stated was the lack of feasibility research on strategies that could improve community pharmacists' role in the prevention of opioid misuse. The availability of this research would provide evidence of what strategies could be implemented successfully in community pharmacies.

> *"We need some research, and there might be already research done, and to understand well what best way is to make that intervention as a community pharmacist. And what do we need to do in terms of actions If we want to reduce somebody's use of opioids or contact a prescriber? etc."* (Participant 1: pharmacist, male, NENCICB, 23 years)

6.4 Summary

This chapter highlights a gap in the relationship between community pharmacists who are commissioners and the community pharmacists. Commissioners who were pharmacists related with community pharmacists at the commissioner level and there had no close engagement with community pharmacy practice. On the other hand, GPs who were commissioners still worked in GP practices while still acting in their role as commissioners, thereby providing an opportunity to observe challenges in GP practices and intervene. Commissioners who were pharmacists and were involved in the prevention of opioid misuse provided interventions that were focused on ensuring appropriate opioid prescribing in GP practices only. Commissioners acknowledged that community pharmacists had roles that they could play in the prevention of opioid misuse but also reported a wide range of

challenges that limited community pharmacists from carrying out these roles. They also suggested ways through which challenges could be overcome and community pharmacists' roles in the prevention of opioid misuse enhanced. These challenges and suggestions are displayed in Table 6.2.

Table 6.2: Challenges to community pharmacists' roles and suggested ways of improving them

Aspects of community pharmacists' roles	Challenges	Suggestions for enhancement of community pharmacists' roles
Identification of service users who misuse OTC opioids	Patients' ability to visit multiple pharmacies	Change in classification of OTC opioids; OTC opioid register; community pharmacists-GPs shared records of opioids sold.
Referral of service users who are suspected of misusing OTC opioids	Lack of a referral system for service users suspected of misusing OTC opioids	A referral system that will enable referral of service users who are suspected of misusing opioids from community pharmacies to the GPs
Identification of service users who misuse prescription opioids	Pharmacists' attitude towards screening opioid prescriptions	Community pharmacists-GPs shared records of opioids sold or dispensed.
Screening, identification, and referral of service users who are at risk of opioid misuse	Poor relationship between community pharmacists and GPs	Community pharmacists-GP collaboration: use of shared records, use of NHS cards while purchasing OTC opioids, dedicated phone lines between community pharmacy and GP practice, referral of patients from community pharmacies to GPs, registering patients who are suspected of over ordering opioids to one pharmacy, and computer programmes
No specific opioid misuse prevention role	Poor communication networks between community pharmacists	Fora for community pharmacists to share experience about opioid misuse
No specific opioid misuse prevention role	Lack of resources: insufficient staff, lack of time, inadequate support from researchers and the commissioners	Funding of community pharmacists-GP collaborative practices; Administering collaborative practice as a contract
Educating service users about measures that will help prevent opioid misuse	Lack of pharmacists' involvement in educating service users about non-pharmacological alternatives	Use of printed material to enhance education

Chapter 7 Intervention Development

7.1 Introduction

In the previous chapter, themes from a thematic analysis of eight commissioners' interview transcripts were presented. This chapter sets out to develop intervention strategies by using the behaviour change wheel (BCW) model (Michie, Van Stralen and West, 2011b). The BCW model is made up of three stages which are: understanding the target behaviour (community pharmacists' roles in the prevention of prescription and OTC opioids), identify intervention options, and identify content and implementation options. These stages will be described individually below, in line with the data collected in this study.

7.2 Stage 1: Understanding the target behaviour

Understanding community pharmacy staff's' roles in the prevention of prescription and OTC opioid misuse was informed by community pharmacy staff findings in Chapter 5. In chapter five, the factors that influence community pharmacy staff's roles in the prevention of prescription and OTC opioid misuse were identified using the COM-B model, which is the core of the BCW model. In order to improve community pharmacists' role in the prevention of prescription and OTC opioid misuse, it is necessary to 'identify what needs to change' in the target behaviour. This means recognising potential targets for behaviour change or aspects of community pharmacists' role in the prevention of opioid misuse that need to be improved. Based on the community pharmacy staff findings, 22 potential targets for behaviour change items (five items for capability, 12 items for opportunity, and five items for motivation) were identified which enabled the systematic development of strategies that will target each item. These items are displayed in Table 7.1 and are described in detail below in line with the components of the COM-B model.

7.2.1 Capability

Five potential targets for behaviour change were identified under the capability component. Two items were classified under physical capability- pharmacists' communication with service users who are addicted to opioids and advise on proper storage and disposal, while three items were classified as psychological

capability- pharmacy staff's knowledge about addiction, knowledge about recent trends in the prevention of opioid misuse, and knowledge about their own role.

Table 7.1: COM-B components and potential targets for behaviour change items

COM-B components	Potential targets for intervention	Change needed	Type of change required
Physical capability	Communication with service users who are addicted to opioids	Yes	Increased training on how to communicate with service users who are addicted to opioids
	Advise on proper storage and disposal	No	The majority of service users have good awareness about where to access storage information and proper disposal
Psychological capability	Knowledge about addiction	Yes	Improved education and training about addiction
	Knowledge about recent trends in the prevention of opioid misuse	Yes	Improved education and training about recent trends in the prevention of opioid misuse
	Knowledge about role	Yes	Improved education about pharmacists' role in relation to that of a GP
Physical opportunity	Staff (pharmacist, support staff)	Yes	Increased number of staff
	Funding	Yes	Increased funding
	Identification of service users who misuse OTC opioids	Yes	Provision of standard tool for identification of service users who misuse opioids
	Referral system for service users who are suspected of misusing OTC opioids	Yes	Provision of referral system for service users who are suspected of misusing OTC opioids
	Safety in the consultation room	Yes	Improving safety in the consultation room
Social opportunity	Relationship with GPs	Yes	Improved community pharmacists-GP relationship
	Opening times of drug clinics	Yes	Extended open hours in drug clinics
	Communication between community pharmacists		Increased communication fora where community pharmacists can share their experience of service users who misuse opioids.
	Competence of locum pharmacists	Yes	Improved training of locum pharmacists
	Service users' attitude and behaviour towards community pharmacists	Yes	Improved service users' education about the role of community pharmacists
	OTC opioid regulatory practices	Yes	Regulation that will restrict sales of OTC opioids
	Level of commissioners' support	Yes	Improved support from commissioners
Reflective motivation	Pharmacists' attitude towards reporting prescription opioid queries to GPs	Yes	Increased motivation to report prescription opioid queries to the GPs
	Pharmacists' attitude towards educating service users who buy OTC opioids	Yes	Increased motivation to educate service users who buy OTC opioids
	Pharmacists' attitude towards screening opioid prescriptions	Yes	Increased motivation to screen opioid prescriptions

	Pharmacists' attitude towards service users who are addicted to opioids	Yes	Increased motivation to offer harm reduction services to service users who are addicted to opioids
Automatic motivation	Pharmacists' attitude towards profit-making or incentives	Yes	Increased motivation to ensure safe and appropriate opioid use rather than profit-making

However, one of the items identified under physical capability (that is, advise on proper storage and disposal) was not considered for further analysis because community pharmacy staff reported that it was not important to change this aspect of behaviour since the majority of service users already knew that they needed to read the instructions on the drug leaflet to obtain storage information. In addition, pharmacy staff felt that service users are already aware that they could dispose of unused or expired medication in the pharmacy. This resulted in the eventual grouping of one item (pharmacists' communication with service users who are addicted to opioids) under the physical capability category in subsequent analysis.

The physical capability target of pharmacists' communication with service users addicted to opioids needed addressing as pharmacy staff with less than 10 years' experience lacked the confidence to communicate about harm reduction with service users who are addicted to opioids. Hence, there is a need for improvement in pharmacy staff's communication skills in this area. For psychological capability, aspects of the target behaviour that needed to change were pharmacy staff's knowledge about addiction, recent trends in the prevention of opioid misuse, and their own role. Community pharmacy staff findings showed that staff lacked knowledge in these areas. Hence, change is needed in these aspects of the target behaviour for community pharmacists' role in the prevention of prescription and OTC opioid misuse to be improved.

7.2.2 Opportunity

Twelve potential targets for behaviour change items were grouped under opportunity. Five of these 12 items were classified as physical opportunity while the other seven items related to social opportunity. With respect to physical opportunity, aspects of the target behaviour that needed to change were staff, funding, identification of service users who misuse OTC opioids, referral of service users who are suspected of misusing OTC opioids, and safety in the consultation room. Pharmacy staff reported that they lacked resources such as staff

(both pharmacists and support staff), and funding. They also lacked resources that would enable them to identify service users who misuse OTC opioids and refer service users who are suspected of misusing OTC opioids. These need to change to improve community pharmacy staff's role in the prevention of prescription and OTC opioid misuse. Items that were grouped under social opportunity were relationship with GPs, opening times of drug clinics, communication between community pharmacists, competence of locum pharmacists, patient's attitudes and behaviour towards pharmacists, OTC opioid regulatory practices, and level of commissioners' support. Community pharmacists reported the need for change in these areas in order for their role in the prevention of prescription and OTC opioid misuse to be improved.

7.2.3 Motivation

For the motivation component, five 'potential targets for behaviour change' items were identified. Four of these items were grouped as reflective motivation while one item was classified as automatic motivation. Items that were grouped as reflective motivation were pharmacists' attitude towards: reporting prescription opioid queries to GPs, educating service users who buy OTC opioids, screening prescription opioids and service users who are addicted to opioids. A change in these aspects of behaviour is needed for community pharmacists' role in the prevention of opioid misuse to be improved. With respect to automatic motivation, the aspect of the target behaviour that needed to change was pharmacists' attitude towards profit-making or incentives.

Table 7.2 displays potential targets for intervention and evidence of targets for intervention. This evidence was obtained from the articles that were selected for the systematic review, and the community pharmacists and commissioners' interviews. Based on these, intervention options were identified which will be explained below.

Table 7.2: COM-B components, potential targets for intervention and evidence of targets for intervention

COM-B components	Potential targets for intervention	Evidence of targets for intervention
Physical capability	Communication with service users who are addicted to opioids	*"I understand that but I think it also changes with training the pharmacists get. So I think pharmacy in general is kind of shifting massively. Isn't it to a bit more of a kind of clinically assessing and diagnosing patients role as well. which I think changes the confidence that the pharmacists have in their ability" (PS 6)*- Pharmacy staff interviews
Psychological capability	Knowledge about addiction	*"One is the school, the university. It can be taught there, you know. That would be the best way to teach them before they get out of the university."* (pharmacist 8) – Pharmacy staff interviews *"Education of pharmacists, regarding empathy"* (Makdessi et al, p 970) – Systematic review
	Knowledge about recent trends in the prevention of opioid misuse	*"I would say, in terms of opioid misuse, I feel there could be further regular training. I feel like all the staff should be up to date with the latest knowledge, latest products, and legislation but I think maybe for something as serious as opioids, there could be sort of more regular reminders and updates about that in particular."* (pharmacy staff 12) – Pharmacy staff interviews *"Formal training. Like we have an MTM (Medication Therapy Management) certificate, we would need one for controlled substance."* (Fleming, 2019, p.995)- Systematic review
	Knowledge about role	*"I think for the good of the patient, I think everybody has to work together. People have to respect each other and people have to show us respect for us to respect them, and then we respect the surgeries too, you know, to work with us. You know we work together, and if everybody works together, then the patient gets the correct dose and the correct treatment. It's only when people aren't talking to them, and you know, uh making silly decisions, and you know, being disrespectful. That's when things go wrong."* (PS 8) – Pharmacy staff interviews

Physical opportunity	Staff (pharmacy staff)	*"So we need help, we need obviously more support staff that can help obviously run the pharmacy better you've got more time to solve do more services or other things that you need to." (PS 7)* – Pharmacy staff interviews *"Participants reported that when they have enough workflow support from technicians, they are more able to move away from the workflow and speak to patients for longer periods of time."* (Fleming et al, 2019, p.997) – Systematic review
	Funding	*"I think if some provision were in place to help support that, you know that additional funding could make that difference"* (PS 13) – Pharmacy staff interviews *"Because if we're asking pharmacists to do extra work, there needs to be some financial incentive for them to do it. Some financial support for the extra work."* (C8) – Commissioners' interviews *"The, erm, funding, I think that it's one of the things that they probably might need to kind of fund to sort of, as a service…."*(Alenezi et al, 2021) – Systematic review
	Identification of service users who misuse OTC opioids	*"If everybody was given a card with the NHS number, and we swiped it every time that we sold, or it went on a database, or we went on their records that's the only way forward. And then we've got all on one record."* (PS 8) – Pharmacy staff interviews *"I don't know if community pharmacies have computer records that can flag these people, or if they rely on the person working in the pharmacy, the community pharmacy worker to recognize these people, because that's not a very safe system, is it? That's not a very reliable system, you know. They would need to get themselves computerized to spot these people." (C4)*- Commissioners' interviews
	Referral system for service users who are	*"I think we're very limited in community because we don't have referral schemes to GPS direct for appointment. We are not involved in the pain clinics on the hospitals as to how we can fit*

	suspected of misusing OTC opioids	*into that referral scheme of being involved in the patient's care, and we don't have access to a lot of the clinical records."* (PS 13)- Pharmacy staff interviews *"People who were suspected of misusing OTC opioids should be registered to see a GP for a prescription before they collect their medication from the community pharmacy. This will allow tight monitoring of these patients' opioid-buying behaviour."* (C7) – Commissioners interviews *"I put having resources for referrals, because we are not trained mental health professionals……we would need to know who to turn them to with that expert care in that field. A company approved resource…Yeah, a pamphlet.'" (Fleming, 2019, p.997)*- Systematic review
	Safety in the consultation room	*"Quite a lot of pharmacies, though they do have a panic alarm. So there is, like, you know, some sort of procedure in place... For pharmacies that have a lot of substance-dependent patients, security could be put in place. So that's also like another sort of mechanism to help prevent you know, any attacks."*(PS 16)- Pharmacy staff interviews *"Well, the room, like she was saying, poses another risk, because you're alone with them in a room.' 'Private, but not too private." (Fleming,2019, p.997)* – Systematic review
Social opportunity	Relationship with GPs	*"In general pharmacies that are situated within a Gp practice or within a health centre, have much better relationships than your typical you know, retail pharmacy on the High Street."* (PS 13)- Pharmacy staff interviews *"I would say that your project should advocate better instant lines of communication between the community pharmacy and the local GP surgery. We call it a back phone…The back phone just means a phone that is entirely not, it's not going to be tied up in other conversations. It should be free most of the time."* (C4) – Commissioners' interviews

		"So, you'd say you have more confidence when you're dealing with or communicating with prescribers that you're more familiar with in your town?" (Hagemeier, 2018, p.92) – Systematic review
	Opening times of drug clinics	'*I hope they can open on the weekend because a lot of times the problem happens on Saturday sometimes, like, I have 2 prescriptions starting on the same day with different dose. And I say, I can't give you. I don't know what to give you. Yeah, I go on the Saturday, so they will have to wait till the Monday*.' (pharmacist 9)- Pharmacy staff interviews
	Communication between community pharmacists	*"If there was some way that you could have a bit more communication between the pharmacies about what other pharmacies are doing and give it a try, and know if there's anything different they are doing."* (PS 1) – Pharmacy staff interviews *"So potentially an organisation such as the Royal Pharmaceutical Society could create a forum in a particular area,.. where, like minded pharmacists who have an interest in this, could meet over teams or zoom and discuss this sort of thing which might be helpful to pharmacists"* (C8) – Commissioners' interview
	Competence of locum pharmacists	"*These days the company will not ask the locum what training they have because they are desperate, absolutely desperate because of the shortage in community pharmacies. So when you have a locum, you'll be lucky if they even check the prescription that gets dispensed. It's an absolute waste of time. Training should be a must, if they don't do their training, they don't get a job*." (PS 6) pharmacy staff interviews
	Service users' attitude and behaviour towards community pharmacists	*"there needs to be more sort of materials out there to say that you know a pharmacy, speak about any issues that you have. If you feel like you have an opioid addiction, or any other kind of addiction, this is where you can come. This is the type of help that you can get." (PS 21)* – Pharmacy staff interviews

	OTC opioid regulatory practices	*They're being very freely giving in this country. I come from a different country and back in my country, codeine generally is only given on prescription, even the one that's combined with paracetamol. So we could change the regulations, I mean only be able to sell low concentration codeine medications over the counter and get the extra ones on prescription the extra ones (PS 10).* – Pharmacy staff interviews *"I think potentially, we need to get to the position that opioids are not available over the counter to purchase. Why don't we change the legal categorisation of them? you know, if it is over-the-counter and make them all prescription only."* (C7) – Commissioners' interviews *"then at least you've, sort of, a blame mechanism saying I'm not allowed to sell anymore^. Then it's not your fault, it's removed from you."* (Carney et al, 2016 p.360) -Systematic review
	Level of commissioners' support	*"I suppose, by putting legislation in place and some sort of rules, to make it not as easy, perhaps, to make it readily available, you know, to put, I know at the moment we're handing out card safety cards with the medication. So things like that just to ensure the patients know this is a short-term product. Things like that, just to make it really clear that this medication is short-term."* (PS12) – Pharmacy staff interviews *"If you want them to do something specific, it could be done as a contractual. So a service specification. We would like you to have an intervention with anybody who is on the long-term opioid and try and encourage them to come off and signpost them to a service where they could do that and you could target that with a cost, I guess and the pharmacist will put a claim in."* (C2) – Commissioners' interviews

		"Important individuals/groups that pharmacists identified as influential in their decision to engage patients were regulatory organisations (e.g., pharmacy boards and law enforcement)." (Fleming et al 2018, p997) – Systematic review
Reflective motivation	Pharmacists' attitude towards reporting prescription opioid queries to GPs	*"We have good relationship with the doctors when it comes to other services and stuff, but when it comes to talking about a specific dose about a patient or what technically should the doctor prescribe or not, they kind of look down on us, kind of like who are you to even question that, so it's like that patient already been on that dose for a while, so it's like, what you're asking me for. In that concept, the doctor don't listen to us as a pharmacist."* (PS 6) *"And if we could then find ways to incentivise or support general practice and community pharmacy working together to bring that down."* (C5) – Commissioners' interviews
	Pharmacists' attitude towards educating service users who buy OTC opioids	*"I feel like we can only say to the patient, I'm sorry you can't have this medication but like they can go to a new pharmacy and collect that medication."* (PS 20) *"So having more community pharmacists. To provide resource to community pharmacy which allows them to provide more community pharmacists, so that they can do more of the work which is more personal to patients."* (C2) – Commissioners' interviews
	Pharmacists' attitude towards screening prescription opioids	*"It's limited because we are dispensing with prescriptions, you kind of fall back to the idea that I suppose the prescribers have done that due diligence and have deemed it appropriate. There would be a bit more scrutiny if doses, or if the directions for use weren't clear, but other than that, you kind of default to assuming that the prescribers have done their due diligence."* (PS 22)- pharmacy staff interview
	Pharmacists' attitude towards service users who are addicted to opioids	*"We don't have any training on how to deal with substance misuse patients because at the end of the day, they are usually sort of more sensitive, and I think they need a bit more emotional intelligence to help.. obviously, pharmacists usually have no experience in substance, so we can't*

		really relate. We would definitely need more training on that because it's a difficult one to handle." (PS 12) – Pharmacy staff interviews *"Education of pharmacists, regarding empathy"* (Makdessi et al, p 970) – Systematic review
Automatic motivation	Pharmacists' attitude towards profit-making or incentives	*"I do feel like if there was an incentive put in place. Then more pharmacies would offer more services to opioid users."* (PS 21) – Pharmacy staff interviews *"we need a nationally commissioned public health campaign where community pharmacies are funded properly to be able to spend time on patients* (C7)- Commissioners' interviews

7.3 Stage 2: Identification of intervention options

Identification of intervention options is made up of two steps which are the identification of intervention functions and the identification of policy categories. These are displayed in Table 7.3 and are described below.

Table 7.3: Links between the COM-B components and the intervention functions

Potential targets for behaviour change	Education	Persuasion	Training	Modelling	Environmental	Restriction	Enablement	Incentivisation
Physical capability								
Communication with service users who are addicted to opioids			✓	✓				
Psychological capability								
Knowledge about addiction	✓							
Knowledge about recent trends in the prevention of opioid misuse			✓					
Knowledge about role	✓							
Physical opportunity								
Staff (pharmacist, support staff)					✓		✓	
Funding					✓			
Identification of service users who misuse OTC opioids					✓		✓	
Referral system for service users who are suspected of misusing OTC opioids					✓		✓	
Safety in the consultation room					✓			
Social opportunity								
Relationship with GPs					✓		✓	
Opening times of drug clinics							✓	
Communication between community pharmacists							✓	
Competence of locum pharmacists			✓				✓	
Service users' attitude and behaviour towards community pharmacists	✓	✓			✓			
OTC opioid regulatory practices						✓		
Level of commissioners' support							✓	
Reflective motivation								
Pharmacists' attitude towards reporting prescription opioid queries to GPs								✓
Pharmacists' attitude towards educating service users who buy OTC opioids	✓	✓			✓			
Pharmacists' attitude towards screening opioid prescriptions								✓
Pharmacists' attitude towards service users who are addicted to opioids	✓	✓	✓		✓			
Automatic motivation								
Pharmacists' attitude towards profit-making or incentives								✓

7.3.1 Step 1: Identification of intervention functions

This step has to do with matching the findings of the COM-B model to the relevant intervention functions. Intervention functions were selected by identifying interventions that will improve each of the potential targets for behaviour change. Selection was made from the nine intervention functions stated in the BCW model and eight intervention functions were identified by mapping the potential targets for behaviour change to the appropriate intervention that could help to improve it. As displayed in Table 7.3, these eight intervention functions were education, persuasion, training, modelling, environmental restructuring, restrictions, enablement, and incentivisation. The intervention function that was not selected was coercion because the use of this intervention might not be useful in addressing any of the potential targets.

7.3.2 Step 2: Identification of Policy Categories

Policy categories represent policy options that are most suited to help deliver the intervention functions. Identification of policy categories consists of mapping relevant policy categories from the BCW model to the eight intervention functions that were identified.

As displayed in Table 7.4, four policy categories out of the seven categories recommended by the BCW model were selected. Namely guidelines, regulation, communication/marketing, and environmental/social planning.

Table 7.4: Links between policy categories and intervention functions

Policy categories	Education	Persuasion	Training	Modelling	Environmental restructuring	Restriction	Enablement	Incentivisation
Communication/marketing	✓	✓	✓				✓	
Guidelines	✓		✓	✓	✓		✓	
Regulation	✓		✓	✓		✓	✓	✓
Legislation						✓	✓	
Environmental/social planning					✓		✓	

7.4 Stage 3: Identify content and implementation options

This stage consists of identifying appropriate behaviour change techniques and mode of delivery. These will be detailed below.

7.4.1 Step 1: Behaviour change techniques

Behaviour change techniques also known as the 'active components' in intervention development were identified by selecting techniques that were relevant to improving the potential targets for intervention from the BCTTv1 (See Appendix A: Behaviour Change Technique Taxonomy Version 1). As displayed in Table 7.5, out of the 93 active components presented in this taxonomy, 13 were identified to be appropriate to improve the potential targets for intervention. These are:

i. Credible source.
ii. information about health consequences.
iii. information about social and environmental consequences.
iv. knowledge about antecedents.
v. instruction on how to perform the behaviour.
vi. demonstration of the behaviour.
vii. social support (practical).
viii. restructuring the physical environment
ix. adding objects to the environment.
x. restructuring the social environment.
xi. material incentive.
xii. incentive (outcome).
xiii. reduce negative emotions.

Intervention strategies were then recommended considering the selected BCTs. Specific practicable strategies that could help improve the potential targets for intervention are then developed based on the selected BCTs and are listed in Table 7.5.

Table 7.5 Links between COM-B model, intervention functions, policy categories, BCTS, strategies and mode of delivery

Potential targets for intervention	Intervention functions	Policy categories	BCTs	Strategy	Mode of delivery
Physical capability					
i. Communication with service users who are addicted to opioids	Training, modelling	Guidelines, regulation	4.1 Instructions on how to perform the behaviour 6.1 Demonstration of the behaviour 3.2 Social support (practical)	Experienced or trained pharmacists show early career pharmacists how to communicate with service users who are addicted to opioids	Face-to-face. Mandatory one-on-one training carried out in the pharmacy routinely
Psychological capability					
i. Knowledge about addiction	Education	Guidelines, regulation, communication/ marketing	9.1 credible source 5.1Information about health consequences 5.3 Information about social and environmental consequences 4.2 Information about antecedents	University lecturer providing information to undergraduate pharmacy students about the effects of addiction and factors that might give rise to addiction; Support of regulatory body	Face-to-face. Carried out during university education via lectures
ii. Knowledge about recent trends in the prevention of opioid misuse	Training	Guidelines, regulation	4.1 Instruction on how to perform the behaviour	Pharmacists receive routine training regarding updates relating to the	Face-to-face. Experienced pharmacy demonstrating behaviour in pharmacy.

				prevention of opioid misuse	Distance via online training videos
iii. Knowledge about role	Education	Guidelines, regulation	5.3 Information about social and environmental consequences	University lecturer providing information to undergraduate pharmacy students about pharmacists' roles and how to communicate with other health professionals, resources to guide communication between GP and community pharmacists Support of regulatory body	Face-to-face. Carried out during university education via lectures
Physical opportunity					
i. Staff (pharmacist, support staff)	enablement, environmental restructuring	environmental/ social planning	12.1 Restructuring the physical environment 12.5 Adding objects to the environment	Employing staff	One-on-one in pharmacy
ii. Funding	Environmental restructuring	Environmental/ social planning	12.1 Restructuring the physical environment	Increased government funding for dispensing	General

			12.5 Adding objects to the environment	opioids and collaborative practice with GP.	
iii. Identification of service users who misuse OTC opioids	Enablement, environmental restructuring	Environmental/ social planning	12.5 Adding objects to the environment	i. Use of a computerised system of recording OTC opioid dispensing across all pharmacies and shared with GP practices iii. development of a list of questions that will enable community pharmacists identify persons who misuse OTC opioids.	In every pharmacy
v. Referral system for service users who are suspected of misusing OTC opioids	Enablement, environmental restructuring	Environmental/ social planning	12.5 Adding objects to the environment	Referral system to GPs or other appropriate centres	Every pharmacy
iv. Safety in the consultation room	Environmental restructuring	Environmental/ social planning	12.1 Restructuring the physical environment 12.5 Adding objects to the environment 3.1 Social support	Presence of security (in community pharmacies with high numbers of opioid users), availability of panic alarm, reconstruction of the consultation room, presence of another staff	Individual pharmacy
Social opportunity					

i. Relationship with GPs	Enablement, environmental restructuring	Environmental/ social planning, Guidelines	12.2 Restructuring the social environment 12.5 Adding objects to the environment	i. Formal collaborative practice between community pharmacists and GP ii. A direct phone line between the GP practice and community pharmacy	All pharmacies Each pharmacy
ii. Opening times of drug clinics	Enablement	Environmental/ social planning	12.2 Restructuring the social environment	i. Extending opening hours ii. Use of helplines	One-on-one General
iii. Communication between community pharmacists	Enablement	Environmental/ social planning,	3.1 Social support (practical) 12.2 Restructuring the social environment	i. Regular meetings with pharmacists	General
iv. Competence of locum pharmacists	Training Enablement	Regulation	3.1 Social support (practical)	Pharmacy managers or pharmacy regulators support locum pharmacists to receive training regarding updates relating to the prevention of opioid misuse	Face-to-face. Experienced pharmacy demonstrating behaviour in pharmacy.
v. Service users' attitude and behaviour towards community pharmacists	Education, persuasion, Environmental restructuring	Communication/ marketing, Environmental/social planning	Service users: 5.1Information about health consequences 5.3 Information about social and environmental consequences Pharmacist:	Inform the service user about the role of community pharmacists. Inform the service users about the effects of misusing OTC opioids.	Face-to-face: In community pharmacy, through use of leaflets, or verbal Mass media, campaigns For pharmacists Face-to-face

			12.2 Restructuring the social environment	Collaboration with GP for referral of service users that are suspected of misusing OTC opioids. Collaboration with GPs so that service users on prescription opioids are referred from the GPs to the pharmacists for education.	
v. OTC opioid regulatory practices	Environmental restructuring, Restriction	Regulation, Legislation	12.2 Restructuring the social environment 12.5 Adding objects to the environment	Applying rules that will help to minimise the sale of OTC opioids eg conversion of OTC opioids to prescription opioids, use of NHS cards while purchasing OTC opioids, and reduction of the quantity of OTC opioids per pack.	Face-to-face, group, mass media
vi. Level of commissioners' support	Environmental restructuring, Enablement	Communication/ marketing, regulation, legislation, Environmental/ social planning	12.2 Restructuring the social environment 3.2 Social support (practical)	Commissioners should be supported to work in the pharmacy on designated days Commissioners should be supported to ensure that	Face-to-face, group. All pharmacies

				recommended rules to minimise the sale of OTC opioids in community pharmacies are applied Change in commissioners' contact information should be communicated regularly	
Reflective motivation					
i. Pharmacists' attitude towards reporting prescription opioid queries to GPs	Incentivisation	Regulation	10.1 Material incentive 10.8 Incentive (outcome)	Provision of funding by the government for collaborative practice with GPs	Distance, digital media. All pharmacies
ii. Pharmacists' attitude towards educating service users who buy OTC opioids	Education Persuasion Environmental restructuring Restriction	Communication/ marketing, Environmental/social planning	5.1 Information about health consequences 5.3 Information about social and environmental consequences 12.2 Restructuring the social environment	Informing community pharmacists of the consequences of not educating persons who buy OTC opioids and the benefits of educating them. Applying rules that will help to minimise the sale of OTC opioids.	Face-to-face. Group. All pharmacies
iii. Pharmacists' attitude towards	incentivisation	Regulation	10.1 Material incentive 10.8 Incentive (outcome)	Provision of funding by the government for	

screening opioid prescription				collaborative practice with GPs	
iv. Pharmacists' attitude towards service users who are addicted to opioids	Education, Training, Persuasion, Environmental restructuring	Communication/ marketing, Environmental/social planning	11.2 Reduce negative emotions 4.2 Information about antecedents 12.1 Restructuring the physical environment	i. Community pharmacists should be informed about strategies that could be adopted to reduce negative emotions eg communication skills, support and training from experienced pharmacists, understanding the sociodemographic situation of the opioid user that might elicit such behaviour ii. Improving the safety conditions in the community pharmacy by providing security (in community pharmacies with high numbers of opioid users), availability of panic alarm, reconstruction of the consultation room, presence of another staff	Face-to-face. Group. All pharmacies

Automatic motivation					
i. Pharmacists attitude towards profit-making or incentives	Incentivisation	Regulation	10.1 Material incentive 10.8 Incentive (outcome)	Provision of funding by the government to carry out patient-centred roles	Distance, digital media. All pharmacies

7.4.2 Step 2: Mode of delivery

This step has to do with the selection of the most suitable mode of delivering the intervention strategies. The selected mode of delivery was made based on the component behaviour that needed to be changed and the target population. Identification of the appropriate mode of delivery was selected from the collection of taxonomy of modes of delivery presented in the BCW guide. The selected mode of delivery is face-to-face and distance. Face-to-face delivery which could be individual-based or group-based was identified to be most suitable for strategies that are related to education and training of pharmacists. However, for intervention strategies that are targeted at changing service users' behaviour towards pharmacists, distance modes of delivery such as broadcast media, digital media and print media would be most suitable. The mode of delivery that was selected for each intervention is displayed in Table 7.5.

7.5 Worked examples of methods

This example will explain how an intervention strategy developed to improve community pharmacy staff's communication with service users who are addicted to opioids was developed. The three stages in the development of strategies described by the BCW model was used in developing this intervention strategy. These stages will each be explained below:

Stage 1: Understanding the target behaviour

The target behaviour was understood by applying the COM-B model to the pharmacy staff interviews. In this research, the target behaviour was community pharmacy staff's role in the prevention of opioid misuse. Understanding this behaviour enabled me to identify the potential targets for intervention or the aspects of community pharmacy staff's behaviour that require change or improvement. In this example, the potential target for intervention was- community pharmacy staff's communication with service users who are addicted to opioids. This potential target for intervention was identified in the physical capability category of the COM-B model.

Stage 2: Identification of intervention options

Identification of intervention options consist of two steps- identification of intervention functions and identification of policy categories.

Step 1: Identification of intervention functions

Intervention functions that could improve the identified potential target, that is, community pharmacy staff's communication with service users who are addicted to opioids were selected from the BCW model. Two intervention functions were identified from the nine interventions proposed by the BCW model. These intervention functions were training and modelling.

Step 2: Identification of policy categories

Four intervention policy categories that were identified to be most suitable for the delivery of the identified intervention functions (training and modelling) were selected from the seven policy categories proposed in the BCW model. The policy categories identified are guidelines, regulation, communication/marketing and environmental/social planning.

Stage 3: Identify content and implementation options

This stage consists of two steps- identification of the BCTs and the mode of delivery.

Step 1: Identify BCTs

Three BCTs that were relevant for improving potential targets were identified from the 93 BCTs recommended for intervention development. These BCTs are instructions on how to perform behaviour, demonstration of the behaviour, and social support (practical).

Step 2: Identify modes of delivery

The most suitable modes of delivering the intervention strategies were then selected. These are routine face-to-face, and mandatory one-on-one training in the pharmacy.

Based on the information obtained from the different stages of intervention development, the intervention strategy that was developed to improve community pharmacy staff's communication with service users who are addicted to opioids were developed. This intervention strategy was 'experienced or trained pharmacists show early career pharmacists how to communicate with service users who are addicted to opioids.' Please see the first row in **Table 7.5**.

7.6 Details of identified intervention functions and their potential targets for intervention

According to the data in Table 7.6, intervention functions such as education could improve potential targets for intervention that are related to psychological capability such as pharmacists' knowledge about addiction and their roles.

A combination of education and persuasion might improve potential targets for intervention that are related to reflective motivation such as pharmacists' attitude towards service users who are addicted to opioids and educating service users who buy OTC opioids. Education and persuasion also improve social opportunity such as service users' attitude and behaviour towards community pharmacists.

Training could potentially improve psychological capabilities, and reflective motivation in the areas of pharmacists' knowledge about recent trends in the prevention of opioid misuse, attitude towards service users who are addicted to opioids and competence of locum pharmacists. Training and modelling might improve physical capability like communication with service users who are addicted to opioids.

Environmental restructuring and enablement will lead to desirable changes in physical and social opportunities. Examples of these opportunities are the identification of service users who misuse opioids, referral system for service users who are suspected of misusing opioids, staff, funding, service users' attitudes and behaviour towards community pharmacists, competence of locum pharmacists, etc.

Table 7.6 Summary table of links between intervention functions and potential targets for intervention

Intervention functions	Potential targets for intervention
Education	Pharmacists' knowledge about addiction and their role
Education, persuasion	Pharmacists' attitude towards educating people who buy OTC opioids and service users who are addicted to opioids
	Service users' attitude and behaviour towards community pharmacists;
Training	Knowledge about recent trends in the prevention of opioid misuse; attitude towards service users who are addicted to opioids; competence of locum pharmacists
Training, modelling	Communication with service users who are addicted to opioids
Environmental restructuring and/or enablement,	Identification of service users who misuse OTC opioids,
	Referral system for service users who are suspected of misusing OTC opioids
	Relationship with GP
	Opening times of drug clinic
	Safety in the consultation room; Pharmacists' attitude towards service users who are addicted to opioids;
	Staff (support staff);
	Funding;
	Communication between community pharmacists;
	Competence of locum pharmacists
	Level of commissioners' support
	Service users' attitudes and behaviour towards community pharmacists
Environmental restructuring, restriction	OTC opioid regulatory practices: Pharmacists' attitude towards educating service users who buy OTC opioids
Incentivisation	Reporting prescription opioid queries to GPs and screening opioid prescriptions; Pharmacists' attitude towards profit making/incentives.

Targets for intervention that are linked to reflective motivation such as attitudes towards service users who are addicted to opioids could also be improved through environmental restructuring and enablement.

Environmental restructuring and restriction will improve targets for intervention that are related to social opportunity and reflective motivation such as OTC opioid regulatory practices and pharmacists' attitudes towards educating service users who buy OTC opioids.

Incentivisation may potentially improve reflective and automatic motivation in the area of pharmacists' attitudes towards reporting prescription opioid queries to GPs, screening opioid prescriptions and profit-making/incentives.

Specific strategies that could be used to effect positive changes in the identified targets for intervention, BCTs and modes of delivery are listed in Table 7.5.

7.7 Explanation of strategies based on the opioid misuse services carried out by community pharmacists

For practicability purposes, the intervention strategies that were developed would be discussed based on the opioid misuse prevention services that were discussed in Chapter 1. These opioid misuse services are education or information provision, screening and identification of at-risk service users, proper storage and disposal of opioids, and harm reduction services.

7.7.1 Education or information provision

The potential targets for intervention that were closely related to education or information provision were communication with the service users who are addicted to opioids, service users' attitude and behaviour towards community pharmacists, and pharmacists' attitude towards educating service users who buy OTC opioids. Since the communication with the service users who are addicted to opioids target is closely related to harm reduction services, it will be more logical to discuss it under the harm reduction services sub-heading and not here. Table 7.7 shows the intervention strategies that have been identified for the other two targets, that is, service users' attitude and behaviour towards community pharmacists and pharmacists' attitude towards educating service users who buy OTC opioids. Strategies targeted at improving service users' attitude and behaviour towards community pharmacists are: inform the patient about the role of community pharmacists, about the effects of misusing OTC opioids; and collaboration with GP so that service users on prescription opioids are referred from the GPs to the pharmacists for education.

Table 7.7 Strategies for education or information provision

Potential targets for intervention	Strategies
Social opportunity	
Service users' attitude and behaviour towards community pharmacists	Inform the patient about the role of community pharmacists. Inform the patients about the effects of misusing OTC opioids.

	Collaboration with GPs so that patients on prescription opioids are referred from the GPs to the pharmacists for education.
Reflective motivation	
Pharmacists' attitude towards educating service users who buy OTC opioids	Informing community pharmacists of the consequences of not educating persons who buy OTC opioids and the benefits of educating them. Collaboration with GPs so that patients on prescription opioids are referred from the GPs to the pharmacists for education.

The strategies that were identified to improve pharmacists' attitude towards educating service users who buy OTC opioids are informing community pharmacists of the benefits/consequences of educating/not educating service users who buy OTC opioids and again collaboration with GPs so that service users on prescription opioids are referred from the GPs to the pharmacists for education.

The intervention functions, policy categories, BCTs, and mode of delivery for these strategies are displayed in Table 7.5. An improvement in service users' attitude and behaviour towards community pharmacists could make them receptive to the advice of the pharmacists. An improvement in pharmacists' attitude towards educating service users who buy OTC opioids would help to improve pharmacists' disposition towards educating service users who buy OTC opioids, thus contributing towards achieving effective communication between pharmacists and service users. Overall, targeting the service users' and pharmacists' attitude could improve pharmacists' role in educating and informing service users about opioid misuse.

7.7.2 Screening, identification, and referral of service users who are at risk of opioid misuse

Targets that were related to screening, identification and referral of service users who are at risk of opioid misuse are knowledge about role, identification of service users who misuse OTC opioids, referral system for service users who are suspected of misusing OTC opioids, relationship with GPs, OTC opioid regulatory practices, pharmacists' attitude towards reporting prescription opioid queries to GPs, and pharmacists' attitude towards screening opioid prescriptions.

Intervention strategies that were developed to improve each of these targets are listed in Table 7.8.

Table 7. 8 Strategies for screening, identification, and referral of service users who are at risk of opioid misuse

Potential targets for intervention	Strategies
Psychological capability	
Knowledge about role	University lecturer providing information to undergraduate pharmacy students about pharmacists' roles and how to communicate with other health professionals. Resources to guide communication between GPs and community pharmacists.
Physical opportunity	
Identification of service users who misuse OTC opioids	Use of a computerised system of recording OTC opioid dispensing across all pharmacies and sharing with GP practices. Development of a list of questions that will enable community pharmacists to identify persons who misuse OTC opioids.
Referral system for service users who are suspected of misusing OTC opioids	Referral system to GPs or other appropriate centres
Social opportunity	
Relationship with GPs	Formal collaborative practice between community pharmacists and GP A direct phone line between the GP practice and community pharmacy
OTC opioid regulatory practices	Applying rules that will help to minimise the sale of OTC opioids eg conversion of OTC opioids to prescription opioids; Use of NHS cards while purchasing OTC opioids, and reduction of the quantity of OTC opioids per pack.
Reflective motivation	
Pharmacists' attitude towards reporting prescription opioid queries to GPs	Provision of funding by the government for collaborative practice with GP
Pharmacists' attitude towards screening opioid prescriptions	Provision of funding by the government for collaborative practice with GPs

Application of these strategies to their corresponding targets could cause an improvement in community pharmacists' roles in screening, identification, and referral of service users who are at risk of misusing opioids. When community pharmacists recognise how to communicate with GPs effectively by receiving relevant education at universities and following expert guidelines developed to enable effective communication between community pharmacists and GPs, the relationship between community pharmacists and GPs might improve. This improvement could be due to the resultant clear established protocol of

communication between the community pharmacists and GPs that might be produced on application of the strategies.

For community pharmacists to effectively identify and refer service users who might be misusing opioids to GPs, the following strategies were developed: provision or development of: a shared computerised system for recording OTC opioids prescribed and sold in GP practices and community pharmacies respectively; an instrument that can potentially aid identification of service users who might be misusing OTC opioids; and a referral system from community pharmacies to GPs or other appropriate centres.

To further strengthen professional relationships between community pharmacists and GPs, collaborative practices between community pharmacists and GPs could be developed coupled with the establishment of direct lines of communication between community pharmacists and GPs, which may contribute towards improving referral of service users suspected of misusing OTC and prescription opioids from community pharmacies to the GPs. OTC opioid regulations that aim at restricting the sale of OTC opioids could contribute towards minimising inappropriate sale of OTC opioids. Setting up government funded GP-pharmacist collaborative practices could also improve pharmacists' attitude towards screening prescription opioids and reporting prescription queries to the GPs.

Ultimately, these strategies could improve community pharmacists' roles in the screening, identification and referral of service users who are suspected of misusing OTC and prescription opioids. Intervention functions, policy categories, BCTs and mode of delivery for the strategies are listed in Table 7.5.

7.7.3 Proper storage and disposal of opioids

No potential target for intervention was identified for community pharmacists' role in the proper storage and disposal of opioids. This was because pharmacy staff that participated in the interview reported that there was no need for an

improvement in this role since service users were already aware of how to store and dispose of opioids properly.

7.7.4 Harm reduction services

The strategies listed in Table 7.9 might help improve potential targets that are related to community pharmacists' roles in harm reduction services.

Table 7.9 Strategies for harm reduction services

Potential targets for intervention	Strategies
Physical capability	
Communication with service users who are addicted to opioids	Experienced or trained pharmacists show early-career pharmacists how to communicate with harm-reduction patients
Psychological capability	
Knowledge about addiction	University lecturer providing information to undergraduate pharmacy students about the effects of addiction and factors that might give rise to addiction
Physical opportunity	
Safety in the consultation room	Presence of security (in community pharmacies with high numbers of opioid users), availability of panic alarm, reconstruction of the consultation room, presence of another staff
Social opportunity	
Opening times of drug clinic	Extending opening hours, Use of helplines
Reflective motivation	
Pharmacists' attitude towards service users who are addicted to opioids	Community pharmacists should be informed about strategies that could be adopted to reduce negative emotions eg communication skills, support and training from experienced pharmacists, understanding the sociodemographic situation of the opioid user that might elicit such behaviour Improving the safety conditions in the community pharmacy by providing security (in community pharmacies with high numbers of opioid users), availability of panic alarm, reconstruction of the consultation room, presence of another staff

The corresponding intervention functions, policy categories, BCTs, and mode of delivery of this strategy are listed in Table 7.5. To change community pharmacists' behaviour towards service users who use the harm reduction services, there must be improvement in the following areas: communication with service users who are addicted to opioids, knowledge about addiction, opening times of drug clinics, and pharmacists' attitude towards service users who are addicted to opioids. A regulation that could potentially enable pharmacy schools to teach students about

addiction, based on expert-developed guidelines should be adopted by universities. This guideline will highlight steps that community pharmacists could use to communicate with service users who are addicted to opioids effectively and should encompass concepts such as empathy. This might enable community pharmacists to acquire the necessary knowledge to communicate with service users who are addicted to opioids during their studies.

While practising in community pharmacies, early career pharmacists should be asked to shadow an experienced pharmacist, in order to develop the skill of communicating with service users who are addicted to opioids. By doing this, the experienced pharmacists model the act of communicating with service users who are addicted to opioids, thereby training the early career pharmacists. To make these younger pharmacists more confident to carry out this activity, especially in cases where the opioid user might want to discuss with the pharmacist in the consultation room, the room could be restructured to include alarm buttons. The pharmacy could be structured in such a way that the consultation room is situated near the pharmacy area. Social restructuring could also be adopted by supporting a second staff to accompany the pharmacist into the consultation room. Security staff could also be employed in pharmacies that attend to a large population of people who misuse opioids. These modifications of pharmacy structure together with education of pharmacists about how to communicate with service users who are addicted may improve community pharmacists' attitude towards service users who are addicted to opioids.

Furthermore, extending the opening times of drug clinics or creating means of communicating with drug clinics after closing hours, such as with the aid of helplines might help community pharmacists to promptly clarify issues regarding service users who use harm reduction services after the drug clinics must have closed.

Overall, these strategies will improve community pharmacists' role in carrying out harm reduction services.

7.7.5 Strategies that could help improve all community pharmacists' services

Nine strategies that are not specific to any pharmacists' services were also identified. These strategies could help improve any of the pharmacists' services and are: pharmacists receive routine training regarding updates relating to the prevention of opioid misuse, employing staff, increased government funding for dispensing opioids and collaborative practice with GP, regular meetings with other pharmacists, pharmacy managers or pharmacy regulators support locum pharmacists to receive training regarding updates relating to the prevention of opioid misuse, commissioners should be supported to work in the pharmacy on designated days, commissioners should be supported to ensure that recommended rules to minimise the sale of OTC opioids in community pharmacies are applied, change in commissioners' contact information should be communicated regularly, and provision of funding by the government to carry out patient-centred roles.

These strategies and their potential targets are listed in Table 7.10.

Table 7.10 Strategies that could help improve all community pharmacists' services

Potential targets for intervention	Strategies
Psychological capability	
Knowledge about recent trends in the prevention of opioid misuse	Pharmacists receive routine training regarding updates relating to the prevention of opioid misuse
Physical opportunity	
Staff (pharmacist, support staff)	Employing staff
Funding	Increased government funding for dispensing opioids and collaborative practice with GP.
Social opportunity	
Communication between community pharmacists	Regular meetings with other pharmacists
Competence of locum pharmacists	Pharmacy managers or pharmacy regulators support locum pharmacists to receive training regarding updates relating to the prevention of opioid misuse
Level of commissioners' support	i. Commissioners should be supported to work in the pharmacy on designated days ii. Commissioners should be supported to ensure that recommended rules to minimise the sale of OTC opioids in community pharmacies are applied iii. Change in commissioners' contact information should be communicated regularly
Reflective motivation	
Pharmacists' attitude towards profit-making or incentives	Provision of funding by the government to carry out patient-centred roles

A chart that shows how the strategies affect each identified target to enhance community pharmacists' roles is displayed in Figure 7.1.

Collaboration with GPs refers to all strategies that are targeted at improving the professional relationship between the community pharmacists and the GPs. Regulation of OTC opioids include those strategies that can help to minimise the sales of OTC opioids while commissioners' support has to do with strategies that can promote the application or implementation of other intervention strategies. The classes of intervention that were developed are indicated in Figure 7.1.

7.8 Summary

This chapter is focused on developing intervention strategies that could be used to improve the role of community pharmacists in categories the prevention of prescription and OTC opioid misuse using the BCW model. The BCW model enabled the identification of intervention functions, policy and BCTs which helped in the development of specific strategies that are aimed at improving targets of intervention, that is, aspects of community pharmacists' role in the prevention of opioid misuse that need to be improved upon. These findings will be discussed in the subsequent chapter.

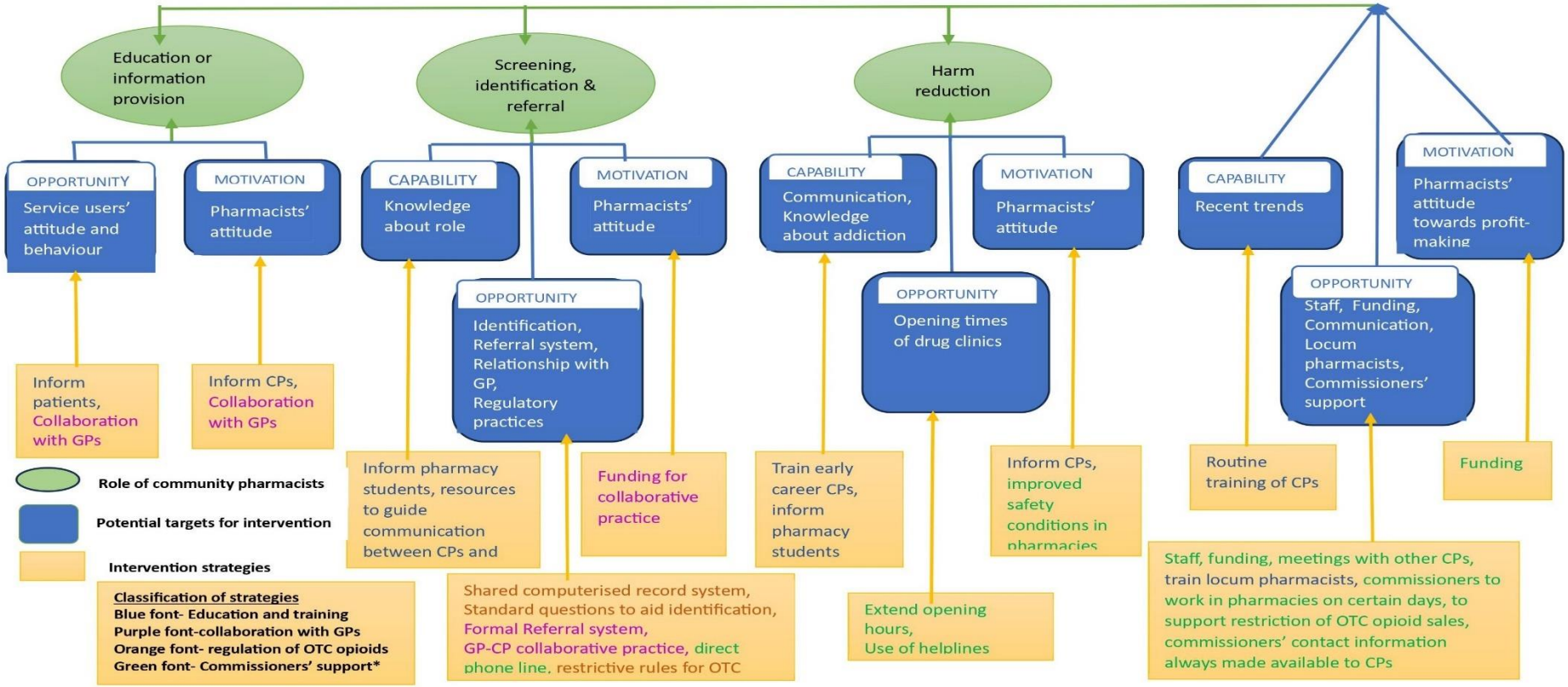


Figure 7.1 Relationship between intervention strategies, potential targets for intervention and pharmacists' roles

*commissioners' support can directly influence other strategies by promoting their application and implementation

`Chapter 8 Discussion

8.1 Introduction

The chapter restates the study aims and objectives, presents the key findings from the systematic review and qualitative studies, demonstrating that each of the original research objectives have been met. Next, the main findings of this research alongside extant literature are discussed and the strengths and limitations of the study are reported. The implications of the findings for practice and policy in relation to the role of community pharmacists in the prevention of opioid misuse are then highlighted. The chapter concludes with recommendations for future research.

Since the definition of misuse provided by United Nations Office on Drugs and Crime, 2011 and National Institute on Drug Abuse, 2021 was used in this study, the intervention strategies developed was not only focused on managing the consequences of opioid misuse such as opioid intoxication, dependence and addiction, but is also aimed at developing intervention strategies that are aimed at preventing the level of opioid use that could lead to intoxication, dependence and addiction.

8.2 Reviewing Study Aims and Objectives

In line with the research Aims and Objectives (See page 55 of Chapter 2 Literature Review), intervention strategies that could help to enhance community pharmacists' roles in the prevention of prescription and OTC opioid misuse were developed. The research developed intervention strategies that could help to enhance community pharmacists' roles in the prevention of prescription and OTC opioid misuse. The first objective, to identify, collate, and appraise existing evidence of barriers and facilitators to community pharmacists' role in the prevention of prescription and OTC opioid misuse, was achieved by conducting a systematic review of qualitative studies that was subsequently published in the International Journal of Pharmacy Practice (Offu *et al.*, 2022). The systematic review identified factors that could help improve community pharmacists' roles in the prevention of opioid misuse. These factors might need to be enhanced in order

for community pharmacists' role in the prevention of opioid misuse to improve. The systematic review showed that community pharmacists' capabilities needed to improve. This highlights the importance of upskilling, capacity building and improving the knowledge and skills of community pharmacists regarding opioid misuse and to equip them with necessary skillset for counselling, identification of service users who were misusing opioids, and referrals. Motivation was a key factor affecting community pharmacist performance and productivity. Data from the systematic review showed that community pharmacists were not sufficiently remunerated and motivated. Community pharmacists needed more motivation to improve their attitude towards seeking clarification about prescription opioids from physicians, as well as their attitude towards people who are addicted to opioids. There was also a need for improving opportunities, both social opportunities like relationship with physicians, and physical opportunities, such as staffing levels, private consultation room, remuneration, OTC opioid regulatory practices and system resources (Offu *et al.*, 2022).

The second objective, which aimed to identify pharmacy staff views regarding factors that influence community pharmacists' roles in the prevention of prescription and OTC opioid misuse in the UK, was addressed by conducting interviews with 28 staff working in pharmacies across North East England. The resulting data were analysed thematically, and the identified themes were then mapped to the COM-B model. Pharmacy staff findings highlighted factors that influence the role of community pharmacists in the UK and revealed that pharmacy staff lacked capabilities, both physical and psychological, in their knowledge and skill regarding opioid misuse. They also lacked opportunities, such as, physical opportunities (staff, funding, resources to aid identification and referral of service users who use opioids) and social opportunities which affect their relationship with GPs, colleagues, locums, patients, and commissioners. Social opportunities such as opening times of drug clinics and OTC opioid regulatory practices need urgent improvement. In addition, a lack of reflective and automatic motivation significantly affects pharmacists' attitudes toward carrying out opioid misuse services and needs to be improved.

The third objective was to identify commissioners' views about community pharmacists' roles in the prevention of prescription and OTC opioid misuse in the UK; this was met by thematic analysis of data from eight commissioners' interviews. Findings from the interviews with commissioners revealed a significant gap in the level of relationship between commissioners and community pharmacists. These findings also revealed that community pharmacists have the potential to contribute towards the prevention of OTC and prescription opioids but were limited by a lack of resources. The findings emphasised the need for: commissioners to work closely with pharmacists; community pharmacists to work in collaboration with other members of the health system, including GPs and other community pharmacists; stricter rules guiding the sale of OTC opioids; shared patient data between community pharmacists and GPs and improved patient education.

The fourth objective of this research was to develop intervention strategies that could enhance community pharmacists' roles in the prevention of prescription and OTC opioid misuse. These strategies were designed by first obtaining potential targets for intervention from the pharmacy staff interviews and then mapping relevant data from the systematic review, pharmacy staff, and commissioners' interviews to the targets using the BCW model. Intervention strategies that were developed from the finding include strategies that are aimed at improving the knowledge and skill of the community pharmacists. Examples of these strategies are experienced or trained pharmacists showing early career pharmacists how to communicate with harm-reduction patients, routine training and upskilling of pharmacists on updates relating to mental health and the prevention of opioid misuse, and knowledge on how to communicate with other health professionals. Strategies that targeted improving physical and social opportunities were also identified. These include increased number of staff; improved funding; provision of tools for the identification and referral of people who misuse opioids; establishment of collaborative practice between community pharmacists and GPs; extending opening hours of drug clinics; and application of rules that can help to minimise the sale of opioids. To improve pharmacists' motivation to carry out these roles, increased funding was mainly identified. A comprehensive list of these

strategies is displayed in Table 7.5. (See page 165 of Chapter 7 Intervention Development).

8.3 Comparison of main findings with relevant literature

The main findings that were identified in this study are the need for education and training, collaboration with GPs, regulation of OTC opioids, and commissioners' support. These findings highlight the overall aim of this study which focuses on developing intervention strategies to mainstream issues. The intervention strategies are classified and discussed in line with identified main findings under various subheadings below.

8.3.1 Education and training

Education and training were identified as key factors that could improve community pharmacists' roles in many ways including provision of quality and reliable information; screening, identification and referral; and harm reduction. As earlier stated in the intervention development chapter, community pharmacists need to improve their involvement in these three roles which are also displayed in Table 8.1.

Table 8.1 Table showing how education and training affects community pharmacists roles

Role of community pharmacist	Potential targets for intervention	Intervention Strategies
Education or information provision	Social opportunity: Service users' attitude and behaviour towards community pharmacists	Inform the patient about the role of community pharmacists. Inform the patients about the effects of misusing OTC opioids.
	Reflective motivation: attitude towards educating people who buy OTC opioids	Informing community pharmacists of the consequences of not educating persons who buy OTC opioids and the benefits of educating them.
Screening, identification, and referral of service users who are at risk of opioid misuse	Psychological capability: knowledge about role	University lecturer providing information to undergraduate pharmacy students about pharmacists' roles and how to communicate with other health professionals. Resources to guide communication between GPs and community pharmacists.
Harm reduction services	Physical capability: Communication with people who are addicted to opioids	Experienced or trained pharmacists show younger pharmacists how to communicate with harm-reduction patients
	Psychological capability: Knowledge about addiction	University lecturer providing information to undergraduate pharmacy students about the effects of addiction and factors that might give rise to addiction

	Reflective motivation: Pharmacists' attitude towards people who are addicted to opioids	Community pharmacists should be informed about strategies that could be adopted to reduce negative emotions eg communication skills, support and training from experienced pharmacists, understanding the sociodemographic situation of the opioid user that might elicit such behaviour
All community pharmacists' roles	Psychological capability: Knowledge about recent trends in the prevention of opioid misuse	Pharmacists receive routine training regarding updates relating to the prevention of opioid misuse

Education and training were identified to be useful in causing this change. This finding is consistent with results obtained from studies carried out in the USA (Eukel *et al.*, 2019; Eukel *et al.*, 2020b; Skoy and Werremeyer, 2019; Hohmann *et al.*, 2022; Hohmann *et al.*, 2018). In one of these studies, an educational intervention programme improved community pharmacists' confidence in providing a harm reduction service, specifically naloxone dispensing (Hohmann *et al.*, 2022). The findings from this study suggest that undergraduate education about opioid misuse needs improvement, which is supported by previous research by Werremeyer et al who found that improving undergraduate pharmacy curricular content increased pharmacy students' confidence in counselling service users who use opioids and screening for service users who are at risk of opioid misuse (Werremeyer *et al.*, 2019). This finding also shows that education and training may improve community pharmacists' capabilities, that is, knowledge about opioid misuse; and motivation, specifically, the attitude pharmacists towards carrying out opioid misuse roles. An improvement in the knowledge and attitude of pharmacists could result in improved behaviour regarding their role in the prevention of opioid misuse. To support this finding, other studies carried out in the USA have shown that educational programmes, including Continuing Education may improve community pharmacists' attitude toward educating service users about the benefits and dangers of opioid use; the use of screening tools and naloxone dispensing (Eukel *et al.*, 2019; Eukel *et al.*, 2020a).

Education and training have been effective in improving community pharmacists' knowledge and attitude towards other health conditions. In Malaysia, education and training improved knowledge and attitude of community pharmacists towards

obesity and weight management (Verma *et al.*, 2021). In Iran, training improved community pharmacists' knowledge and attitude towards irritable bowel syndrome (Mahmoudi *et al.*, 2019). Studies have also shown that education and training improved knowledge and attitude of community pharmacists towards asthma counselling, diabetes, hypertension and peptic ulcers (Nguyen *et al.*, 2018; Durai *et al.*, 2016; Noda *et al.*, 2020). Knowledge and attitude of community pharmacists towards mental health, pharmacovigilance, antimicrobial stewardship and nutrition have also been reported to be improved through education and training (Crespo-Gonzalez *et al.*, 2022; Deepalakshmi *et al.*, 2019; Jha *et al.*, 2017; Saleh, Abu Farha and Alefishat, 2021; Afzal *et al.*, 2024; Douglas *et al.*, 2019). The existence of wide range of literature around the use of education and training as a strategy for improving community pharmacists' roles might be an indication of its effectiveness in improving community pharmacists' knowledge and attitude. Furthermore, the use of education and training is in line with key policy documents that guide community pharmacy practice in the UK (NHS England and NHS Improvement, Pharmaceutical Services Negotiating Committee and care, 2019; Department of health and social care, 2021a).

A finding of this study is that service users are unclear about the role of community pharmacists, and this can demotivate pharmacists from engaging in educational services aimed at preventing opioid misuse. An improvement in service users' attitude would motivate pharmacists to improve their involvement in educating service users. Studies that assessed patients' attitude towards community pharmacists' roles in the prevention of opioid misuse were not found. However, research on patients' attitude regarding community pharmacists' services in general were identified. Like the findings of this research, other studies have indicated that patients have poor attitude towards community pharmacy services and do not have sufficient understanding of community pharmacists roles (Awad, Al-Rasheedi and Lemay, 2017; El Hajj, Salem and Mansoor, 2011; Hindi, Schafheutle and Jacobs, 2018). Unlike this findings, other studies showed that attitude of community pharmacists was good, and that patients were satisfied with community pharmacists' services and had good understanding of pharmacists' roles (Almohammed and Alsanea, 2021; Sarah *et al.*, 2021; Kelly *et al.*, 2014).

8.3.2 Collaboration with GPs

Collaboration with GPs may help to improve community pharmacists' roles in education or information provision; and screening, identification and referral of service users who are at risk of opioid misuse as presented in Table 8.2.

Table 8.2 Table showing how collaboration with GPs affect community pharmacists' roles

Role of community pharmacist	Potential targets for intervention	Intervention Strategies
Education or information provision	Social opportunity: Service users' attitude and behaviour towards community pharmacists	Collaboration with GPs for referral of patients who are suspected of misusing OTC opioids. Collaboration with GPs so that patients on prescription opioids are referred from the GPs to the pharmacists for education.
	Reflective motivation: Pharmacists' attitude towards educating people who buy OTC opioids	Collaboration with GPs so that patients on prescription opioids are referred from the GPs to the pharmacists for education.
Screening, identification, and referral of service users who are at risk of opioid misuse	Physical opportunity: referral system for people who are suspected of misusing OTC opioids	Referral system to GPs or other appropriate centres
	Social opportunity: relationship with GPs	Formal collaborative practice between community pharmacists and GP
	Reflective motivation: pharmacists' attitude towards reporting prescription opioid queries to GPs	Provision of funding by the government for collaborative practice with GP
	Reflective motivation: pharmacists' attitude towards screening opioid prescriptions	Provision of funding by the government for collaborative practice with GPs

A finding from this study is that according to pharmacists, collaboration with GPs might help improve patients' willingness to listen and accept the pharmacist's advice. This finding corroborates the findings of other studies that reported higher service users' trust in GPs when compared with pharmacists (Jarab *et al.*, 2023; Awad, Al-Rasheedi and Lemay, 2017). Therefore, referral of patients by the GP might improve patient's confidence and attitude towards receiving pharmacist's advice, thus making the pharmacist to feel valued and respected as a member of

the healthcare team. This could result in improved pharmacist's motivation to educate and advice patients.

Another finding of the research is that formal collaborative system between the pharmacist and the GP could motivate pharmacists to screen prescriptions, report any prescription issues to the GP and to refer service users who are identified to misuse OTC opioids to GPs. This formal collaboration will improve the relationship between the pharmacists and GPs and providing a clear line of communication between the pharmacist and the GP. Similarly, a study carried out by Jove et al have demonstrated that collaboration improves the relationship between GPs and community pharmacists (Jové *et al.*, 2014). Furthermore, establishing a clear line of communication between community pharmacists and GPs was highlighted in this research. This finding was also reported in a study carried out previously in which it was acknowledged that developing a direct and straightforward means of communication between community pharmacists and GPs may enhance collaborative practices between them (Löffler *et al.*, 2017). This could contribute towards improving positive expectations of pharmacists concerning how the GPs would react when contacted about a medication query and thus improve referral pathway between community pharmacists and GPs. As a result, pharmacists in this study were not motivated to report issues regarding prescription opioids to GPs due to previous incidences of poor communication between them. This finding corroborates the finding of other studies that show that community pharmacist-GP collaborative practices improves communication (Jové *et al.*, 2014; Hinata *et al.*, 2019a), professional value (Jové *et al.*, 2014) and the motivation of community pharmacists to offer patient-centred roles (Piquer-Martinez *et al.*, 2022). Collaboration has been suggested to result in improved care delivery (Jové *et al.*, 2014; Munger, Sundwall and Feehan, 2017), patient safety (Jové *et al.*, 2014), continuity of care (Munger, Sundwall and Feehan, 2017), and patient outcomes (Jové *et al.*, 2014; Munger, Sundwall and Feehan, 2017). Community pharmacists and GP collaboration has also been proven to improve detection of cognitive impairment in Spain (Ramos *et al.*, 2021), health outcomes of opioid users in areas in the USA where there was a lack of buprenorphine-waivered physicians (Wu *et al.*, 2021b), and the implementation

of a medication adherence programme in community pharmacies in Switzerland (Marquis *et al.*, 2014).

Collaboration with GPs is also encouraged by policy makers like the NHS. The NHS Long Term Plan supports the formation of local Primary PCN comprising of GPs, and other health professionals like community pharmacists, to promote collaboration in the provision of clinical services (NHS England and NHS Improvement, Pharmaceutical Services Negotiating Committee and care, 2019). This long-term plan proposes the CPCS which can enable formal referral of service users from GP practices to the community pharmacies for treatment. Other collaborative practices advanced are referral of persons attending smoking cessation programmes in secondary care to community pharmacy, carrying out non-steroidal anti-inflammatory drugs (NSAIDs) audits by pharmacists, reporting all identified concerns to the GPs, and sharing the data with GPs and the NHS (NHS England and NHS Improvement, Pharmaceutical Services Negotiating Committee and care, 2019).

8.3.3 Regulation of OTC opioids

Regulation is a key factor in the monitoring and delivery of efficient service especially as it relates to the sale and purchase of OTC opioids. The findings of this study argue for provision of strong and effective regulation and intervention strategies that would help prevent the misuse of opioids. Intervention strategies identified in this research to support the regulation of OTC opioids were the use of a computerised system of recording OTC opioid dispensing across all pharmacies and sharing with GP practices; development of a list of questions that could enable community pharmacists to identify persons who misuse OTC opioids; and applying effective rules that will help to minimise the sale of OTC opioids. The use of a computerised, shared system might allow both the community pharmacists and the GPs to view the service users' OTC opioids use history.

This result supports the finding of Tolley et al in which it was highlighted that community pharmacists should have access to complete computerised patients record (Tolley *et al.*, 2023). A shared record system would help community

pharmacists and GPs to identify when a patient is taking more opioids than medically required and intervene promptly to prevent misuse of opioids. The UK government supports the use of a shared computerised system for recording OTC opioids sold in community pharmacies as this could potentially help to effectively monitor medication use (Department of health and social care, 2021a).

There is also the need to formulate a checklist of questions that would guide and/or enable community pharmacists to recognise whether the service user is misusing OTC opioids. This could help in the early detection of persons who might be misusing opioids so that early intervention is administered to curb its misuse. Checklists are currently used in the UK to help ensure safe use of oral contraceptives and hormonal therapy for post-menopausal symptoms (Lupin, no date; Hana, 2020)

The findings of this study suggests that the Introduction of opioid regulatory practices or rules that are restrictive could also prevent inappropriate purchase of OTC opioids. Examples of such regulatory practices are conversion of OTC opioids to prescription opioids, use of NHS cards while purchasing OTC opioids, and reduction of the quantity of OTC opioids per pack. In 2005, restrictions were introduced to the supply of codeine and dihydrocodeine containing medicines in the UK, based on the recommendation of Commission on Human Medicine (CHM) (Gov.UK, 2014) in order to reduce the risk of addiction. Restrictions included reduction in pack size, increased consumer warning on labels and leaflets to discourage long term use, unavailability of pack sizes greater than 32 as pharmacy medicine, advertisements containing instructions about its addiction causing potency, and 6- and 12-month ongoing monitoring by the UK Government (Gov.UK, 2014). In spite of these restrictions, the codeine containing analgesic co-codamol was the second most common pain killer to be dispensed in the UK with more than 15 million items sold in 2022 (Statista, 2024). Furthermore, a qualitative study on OTC medication misuse revealed that addiction resulted from a genuine need for OTC medicines like codeine and dihydrocodeine containing medicines and that these medication were readily available (Cooper, 2013).

As reported in this study, the ease at which these medicines can be obtained have also been reported in other studies (Nielsen, Cameron and Pahoki, 2013; Van Hout, 2015). Studies have also shown that restrictive measures such as placing warning signs on the leaflets or packets of OTC codeine containing medication are not usually read by service users, might not be effective in preventing misuse among students in England and people who were already addicted to OTC codeine (Zhao *et al.*, 2020; Cooper, 2013; Wells *et al.*, 2018). There are also concerns regarding crude extraction of codeine from combination products in order to achieve intoxication when consumed (Van Hout, 2014; Guirguis, 2023a). Despite these issues raised about codeine use, the MHRA, based on its review in 2019, recommended that co-codamol should remain as a pharmacy only medicine (Guirguis, 2023a). However, more recently researchers and the MHRA have expressed a need for tighter restrictions such as, the re-classification of codeine and dihydrocodeine containing medicines from OTC to prescription only medicines (Guirguis, 2023a). As a result, the MHRA launched consultations in 2023 to obtain views and opinions of health professionals as well as the public regarding the potential recategorization of codeine containing linctus from OTC to prescription only medicines (Medicines and Healthcare products Regulator Agency, 2023).

There are varying levels of restrictions and regulatory frameworks on opioid use and misuse across countries. In 2008, restriction was placed on the supply of codeine in Australia by scheduling it from pharmacy-only to pharmacist only medicines (Tobin, Dobbin and McAvoy, 2013; Cairns *et al.*, 2020; Guirguis, 2023a). Warnings printed on the package was not adopted but medicine information material with the warning 'codeine may be habit forming' was made available at pharmacies and sales were restricted to a 5-day supply (Tobin, Dobbin and McAvoy, 2013). Studies have reported that these restrictions reduced codeine sale and misuse in Australia (Cairns *et al.*, 2020). In New Zealand, codeine combination analgesics that have more than 15mg of codeine per unit dose was revised from Pharmacy-only to prescription only medicines but was later changed to pharmacist only medicine to match the medicine policy in Australia. In addition, a maximum daily dose of 100mg was set and supply was limited to no more than

a five-day supply in New Zealand. Unlike the policy in Australia, warnings were printed on the labels of all codeine-containing medicines in New Zealand (Tobin, Dobbin and McAvoy, 2013). However, in 2018, codeine was rescheduled to prescription only medicine in Australia because research showed that its classification as pharmacist only medicines did not result in reduction in its use and misuse in the country (Frei *et al.*, 2010; Degenhardt *et al.*, 2016). Rescheduling to prescription only medicines produced reduction in codeine use, misuse, codeine-related poisoning and deaths (McCoy, Nielsen and Bruno, 2022; Cairns *et al.*, 2020; Bishop *et al.*, 2021; Therapeutic Goods Administration, 2016). Globally, about 25 countries including Germany, Japan, and the USA has banned OTC sales of codeine containing medication due to its high tendency of misuse (Guirguis, 2023a). Hence, it might be beneficial for the UK to consider reclassifying OTC opioids to prescription only medicines as this could reduce the use and misuse of OTC opioids in the UK. Table 8.3 demonstrates how regulation of OTC opioids affects the services of community pharmacists in the prevention of opioid misuse.

Table 8.3 Table showing how regulation of OTC opioids can affect community pharmacists' roles in the prevention of opioid misuse

Role of community pharmacist	Potential targets for intervention	Intervention Strategies
Screening, identification, and referral of service users who are at risk of opioid misuse	Physical opportunity: identification of people who misuse OTC opioids	i. Use of a computerised system of recording OTC opioid dispensing across all pharmacies and sharing with GP practices ii. development of a list of questions that will enable community pharmacists to identify persons who misuse OTC opioids.
	OTC opioid regulatory practices	Applying rules that will help to minimise the sale of OTC opioids such as, conversion of OTC opioids to prescription opioids, use of NHS cards while purchasing OTC opioids, and reduction of the quantity of OTC opioids per pack.

8.3.4 Commissioners' support

The need for commissioners' support is one of the main findings in this study as commissioners could positively influence all community pharmacists' roles in the

prevention of opioid misuse, since they are involved in assessing the needs of the pharmacy. They ensure that pharmacies carry out services that are relevant to the community where they are located, and ascertain whether the community pharmacy has competent staff and other relevant resources to carry out services (Young, 2023; National Institute for Health and Care Excellence, 2020).

As a result, commissioners could help by highlighting and promoting the application and implementation of strategies that could help improve community pharmacists' roles in the prevention of prescription and OTC opioid misuse. For example, commissioners could promote the development of collaborative practices between the community pharmacists and the GPs.

Based on findings of this research, improving GP-pharmacist collaboration would likely improve community pharmacists' involvement in education and information provision, screening, identification and referral of service users who are at risk of opioid misuse.

Commissioners could also contribute towards improving community pharmacists' education and training by creating opportunities for experienced pharmacists to mentor early career pharmacists in best ways of supporting service users who use opioids, especially those who are addicted to opioids. This would help the early career pharmacist acquire the skills that might enable them to effectively communicate with service users who use opioids to implement practices that could reduce opioid misuse. In order to remain up to date about the current trends around opioid use, community pharmacists could also be supported to undergo routine training. Commissioners could also focus on establishing fora where community pharmacists could meet regularly to discuss issues surrounding opioid use to enable best practice being shared between community pharmacists. This could also serve as an opportunity for early career pharmacists to be educated and trained. These findings are supported by the guidelines developed by the Office of Health Improvement and Disparities which states that commissioners must make sure that pharmacists, including locums participate in compulsory training before carrying out substance misuse services (Office for health improvement and disparities, 2024b). In addition, commissioners could consider implementing systems at

community pharmacy level that would help improve the competence of locum pharmacists (Jacobs *et al.*, 2013).

Commissioners could advocate for an increase in the content of opioid misuse focused topics, particularly addiction related topics in the pharmacy curriculum by making recommendations to the General Pharmaceutical Council (GPhC). Education and training could also emphasise person-centred care and shared decision making which might enhance effective communication with people who are addicted to opioids. This could help improve interactions between community pharmacists and people who are addicted to opioids.

Systematic changes that commissioners can lobby are needed to help community pharmacists to easily and promptly identify service users who are misusing OTC opioids. Commissioners recognised the need for shared patient records in addressing OTC opioid misuse. As key stakeholders in commissioning services, they could be encouraged to lobby for changes such as introduction of computerised, shared record of patients' OTC opioid purchase history, the development of a questionnaire that would help in identifying persons who misuse OTC opioids and supporting the application of rules to restrict the sale of OTC opioids, such as, reduction of quantity of OTC opioids per pack.

Remuneration was one of the challenges identified in this research. Commissioners could pressure for changes in funding and that payment model for pharmacy services and incentives should be based on the range of services offered rather than the number of medicines sold (Jacobs *et al.*, 2018). To achieve this, the type of payment used in the Pharmacy Quality Scheme (PQS) could be adopted to reward pharmacies for offering patient-centred services (NHS England, 2023d). Payment that is focused on service provision could improve community pharmacists' interest in carrying out patient centred roles such as education, screening, identification of service users who might be misusing opioids and referral to GP.

A suggestion from this study is that extension of opening times of drug clinics or adoption of help desks are needed to help prevent gaps in the therapy of people who are addicted to opioids. Community pharmacists reported that this can help

them clarify queries that arise after regular working hours, thereby promoting effective treatment of persons who are addicted to opioids.

8.4 Strengths and limitations

8.4.1 Strengths

A key strength of the systematic review is that a rigorous process according to PRISMA guidelines was adopted for the review. This rigour was especially evident in the process of selecting the articles retrieved from all databases. The exclusion of articles that did not meet inclusion criteria was carefully carried out to ensure that only articles that were relevant to the research were assessed. Two researchers at least were involved in each step of the systematic review (screening of titles and abstracts, full-text screening, and data extraction) (Stoll *et al.*, 2019; Waffenschmidt *et al.*, 2019).

Strengths of the qualitative research include the standards that were followed before and during the interview. These include procedures such as the development of the topic guide, the use of open-ended questions during the interview, use of probes, and reflexivity of the interview process. These processes facilitated pharmacy staff and commissioners to describe their experiences and behaviours easily and extensively (Anderson, 2010).

An important strength of the research is the use of data triangulation, that is, the collection of data from various sources such as online databases, pharmacy staff, and the commissioners. The combination of data from these sources enabled me to develop an in-depth understanding of the research topic. It also helped me to identify patterns, that is, findings were compared and contrasted to discuss discrepancies and what might have resulted in these differences, thereby, improving the interpretation of the findings, and thus its robustness (Joint United Nations Programme on HIV/AIDS, 2010; Abbadia, 2023; Tsindos, 2023).

Another strength of the qualitative research is that the COM-B model was used to identify factors that could influence community pharmacists' behaviours which contributed to developing effective interventions. The COM-B model has been extensively used to identify factors that influence health professionals' behaviours

(Maxwell-Smith *et al.*, 2024; Blebil *et al.*, 2022; Lewis *et al.*, 2023; Egerton *et al.*, 2018; Spillane *et al.*, 2021). It is also a rigorous, evidence-based, and comprehensive process of identifying these factors since it also considers components, such as opportunities that are outside the study persons, that is, the community pharmacists (Michie, Atkins and Robert, no date; Michie, Van Stralen and West, 2011b; West and Michie, 2020).

In addition, the Behaviour Change Wheel (BCW) is a systematic, evidence-based method of developing interventions (Michie, Atkins and West, 2014a). It was also formed from the synthesis of 19 previous behaviour change models (Michie, Van Stralen and West, 2011b). The BCW enabled the development of strategies that are focused on improving the targets for behaviour change that were identified by the COM-B model. It also helped to identify BCTs that could be utilised in developing interventions (Michie, Van Stralen and West, 2011b; Michie, Atkins and West, 2014a).

Furthermore, another key strength of this research is that data was obtained from key stakeholders, that is, pharmacists, dispensers, pharmacy assistants and policymakers, who are directly involved or associated with community pharmacists' roles in opioid misuse, thereby enabling me to answer my research questions.

8.4.2 Limitations

A major limitation of the systematic review is the location. Most of the studies included in the systematic review were carried out in high-income countries. This limited broader application of the findings to middle and low-income countries due to likely differing sociodemographic factors and policies that guide pharmacy practice in different countries.

Another limitation of the systematic review was lack of positionality, as only few authors in the articles positioned themselves culturally or theoretically (My positionality statement). It is expected that researchers who carry out qualitative studies sufficiently reflect on their positionality in research as this enables the reader to understand researchers' potential biases and perspectives in interpreting

research data and allows readers to engage critically with the research (Rosa, 2023). Furthermore, it improves researchers' awareness of potential biases in their research and promotes their efforts to limit such biases throughout the research process (Robinson and Wilson, 2022). Thereby, improving research rigor, credibility, and validity (Rosa, 2023; Massoud, 2022).

The narrative literature review, in which searches were conducted using the Google and Google Scholar databases, was used in carrying out the literature search in the literature review chapter of this thesis. As a result, some articles might have been missed during the search process since these search engines do not identify articles published in journals that are indexed in certain databases. Nevertheless, deliberate attempts were made to obtain a wide range of literature relating to the research topic, which enabled the discussion of patterns and identification of gaps in the literature.

The qualitative research was carried out in the northeast region of England and thus its research findings cannot be generalised to other parts of the UK. Differences in sociodemographic conditions that exist between the Northeast and other regions in the UK might result in the contrasting behaviours and responses of service users and pharmacy staff respectively across different regions in the UK. However, it is believed that the findings of this study might be transferable to other regions because the study sample consisted of a range of different types of pharmacies, that is, chain pharmacies and independent pharmacies across nine (out of 12) local authorities in the Northeast region of the UK. It is expected that since this a good representation of community pharmacies, it could be applicable to other regions in the UK. Besides, it was also difficult to recruit certain groups of pharmacy staff, such as, pharmacy technicians into the study, since the convenience sampling method was adopted.

In addition, the subjectivity involved in the qualitative research process might have inadvertently introduced some form of bias to the study. However, this was mitigated by collecting data from different sources (which helped in validating findings), following a rigorous research process including acknowledging my

reflexivity and positionality throughout the research process and oversight of the coding process by my supervisors.

Another challenge in carrying out this study was the process of matching themes to the COM-B model, and identifying other components of the BCW model, including the identification of BCTs was cumbersome and time consuming. However, research has shown that the development of a proposed online system that utilises Machine Learning and Natural Language to evaluate, select and synthesise relevant findings, could simplify and facilitate this process and provide real time answers regarding behaviour change (Michie *et al.*, 2017). This may also enhance the findings of the BCW model due to the specificity of strategies developed for potential targets identified across the capability, opportunity and motivation components.

Topic guides were assessed by three lecturers who were also pharmacists, at the School of Pharmacy in Newcastle University. This was the extent to which PPIE was used in this study. There was neither involvement of the wider public nor participation of patients in this research. Involving broader population groups and patients in the design and conduct of the study could have enabled the development of highly feasible intervention strategies that are patient centred.

In addition, the service users' perspective was not considered in this research because it was not within the scope of this study. However, including the service users' perspective in this research would have helped in identifying targets for intervention and appropriate intervention strategies that were developed based on the service users' experience. This could help improve community pharmacy staff's delivery of patient-centred roles that might contribute towards prevention of opioid misuse in service users.

8.5 Implication for Practice

The findings of this study indicate that community pharmacists' roles, knowledge and skills about opioid misuse prevention needs to improve through education, training and re-training. An implication of this is the need for recognition that

currently community pharmacy teams lack sufficient and comprehensive knowledge that would enable them to intervene appropriately on opioid prevention matters. As the evidence of this study suggests, they do not have sufficient skill set to perform opioid misuse prevention roles. There is urgent need to reform existing training models and curriculum to better equip the future workforce to be able to identify and intervene in opioid misuse cases. This can enhance pharmacists proficiency in ensuring safe supply of OTC and prescription opioids and opioid misuse management and prevention (Eukel *et al.*, 2019). A practical implication is ensuring mentorship training models for early career pharmacists shadowing experienced pharmacists, and regular participation in online training for continued professional development. Findings of this study also suggest that in addition to LPC meetings, community pharmacy team would benefit from attending meetings and workshops organised by other pharmacists and leaders in the industry to provide opportunities for upskilling and reskilling.

In addition, findings of this research have implications for developing collaborative working practices and networks between community pharmacists and GPs. This is important given that community pharmacists are not able to carry out certain opioid misuse roles while working in isolation. Examples of such services include education or information sharing and provision; and screening, identification, and referral of service users who are at risk of opioid misuse. Development of local professional networks between community pharmacists and GPs can improve expertise and competencies, boost knowledge about their roles, and improve communication between community pharmacists and GPs (Löffler *et al.*, 2017; Munger, Sundwall and Feehan, 2017). Increased interaction between service providers could also increase service users' confidence in the community pharmacist and make them more receptive to the education provided by the community pharmacists. A potential way of achieving this is by developing referral networks in which GPs can send patients to receive education about their medicines from the pharmacist while the pharmacist can refer service users suspected of misusing OTC opioids to the GPs for assessment (Algarni *et al.*, 2022). Other studies have also suggested that the referral of patients to community pharmacists by GPs, increased patients' confidence in the pharmacist, thereby

enabling them to be receptive to education delivered by the pharmacist (Jacobs *et al.*, 2018).

Furthermore, collaborative networks could help to reduce misunderstanding and power dynamics that exist between the community pharmacists and the GPs while improving effective communication, confidence, capacity building, and professional practice that are necessary for opioid misuse prevention roles. Though community pharmacists in this study reported that they had a good relationship with the staff at the drug clinics, for community pharmacists' opioid misuse preventive measures to be effective, there is a need for the collaboration of services of all health professionals that are involved in the prescription, sale or supply of opioids.

8.6 Implication for Policy

Findings of this research highlight the need for policy change in OTC opioid regulatory practices. The findings from this study strongly recommend introducing policies to enhance better monitoring and/or advanced professional oversight of OTC opioid sales, use, and medications as appropriate. The policy change needed includes the restriction of the sale of OTC opioids from multiple pharmacies; the conversion of OTC opioids to prescription opioids; the use of NHS cards while purchasing OTC opioids; and the reduction of the quantity of OTC opioids per pack.

The findings support a need for a policy to ensure pharmacists who are commissioners work closely with community pharmacies, just as commissioners who are doctors work in GP practices (Paloumpi *et al.*, 2023). This can enable the commissioners to have prima facie experience and evidence of the limitations and areas of need of the community pharmacy team (Jacobs *et al.*, 2018). The implication is that the commissioners who are placed in public positions of trust for procuring services for the local area might be able to leverage appropriately from the interactions and experiences to commission community pharmacists' services to better prevent prescription and OTC opioid misuse. Findings from this study suggest that this would lead to the development of appropriate and well-

targeted interventions and regulations that promote effective and efficient community pharmacy services and patient safety.

The study implicates the need for a policy framework that promotes collaborative practices between community pharmacists and GPs. Implementation of a good and proactive policy could improve community pharmacists' roles in the prevention of opioid misuse, especially in the areas of identification and referral of people who misuse OTC opioids, and screening and reporting of opioid prescription queries to GPs. In addition, policymakers could also improve community pharmacists' roles in the prevention of opioid misuse by making provision for adequate physical and social opportunities such as staff, funding, provision of shared electronic system (data bank) for storing OTC opioid purchase data of service users, communication between community pharmacists, and competence of locum pharmacists. Adopting the PQS for funding community pharmacy practice might encourage them to be more involved in providing opioid misuse prevention services (NHS England, 2023d). The PQS is a component of the CPCF and promotes the delivery of the NHS long term plan. This scheme incentivises community pharmacy contractors to provide three aspects of quality criteria. Namely, patient experience, patient safety, and clinical effectiveness (NHS England, 2023d). Implementation of the PQS in community pharmacies has been recorded to reduce harm from the use of non-steroidal anti-inflammatory drugs (NSAIDs) in older patients by promoting the identification of patients who are at risk of harm and referring them to the prescribers (Parekh *et al.*, 2018). It also increased community pharmacists' use of the Treat Antibiotic Responsibly, Guidance, Education and Tools (TARGET) antibiotic checklist (See Appendix M: The TARGET antibiotic checklist) to aid individualised advice regarding the use of antimicrobials. Thus, enhancing the delivery of antimicrobial stewardship in community pharmacies (Parekh, Livingstone and Jani, 2023). This incentivisation resulted in improvement of advice offered by community pharmacists, thereby promoting the safe use of antibiotics in women with symptoms of urinary tract infections (UTI) (Parekh *et al.*, 2023).

Policymakers could also improve the education and training of community pharmacists by implementing compulsory routine training regarding recent trends

in opioid misuse among pharmacy staff and by developing and broadening the scope and content of addiction-related courses in the pharmacy undergraduate curriculum and postgraduate research programmes in the UK. It can improve targeted interventions based on regional mapping of opioid misuse prevalence leading to general upskilling of professional practice and competencies in opioid misuse management. In order to boost competencies of locum pharmacists, policy makers could also make it compulsory for locum pharmacists to undergo training at the pharmacies where they are to work. Policy makers could also advocate for interprofessional education (IPE) of pharmacy and medical students in university as this could result in improved relationship that build good collaborative practice among health professionals and enhance better understanding of their roles and collaborative networks. IPE has also been highlighted as a means of improving interprofessional and interdisciplinary cooperation and collaboration in a systematic review (Bollen *et al.*, 2019). In support of this finding, the GPhC has recommended that the initial education and training of pharmacists should incorporate opportunities for IPE (General Pharmaceutical Council, 2021). The inclusion of IPE in the training of pharmacy students might enable them to develop the level of knowledge and skill that they require to interact with other health and social care professionals in practice (The Centre for the Advancement of Interprofessional Education, 2017). There is also the obvious need for review of community pharmacist conditions of service and roles regionally and nationally. This would sufficiently boost commitment, resilience, patriotism and loyalty in service.

8.7 Recommendations for future research

Further research is required to develop effective interventions using the updated MRC framework (See Appendix K: The MRC Framework) for the development of interventions while applying the Acceptability, Practicability, Effectiveness and cost-effectiveness, Affordability, Side-effects and Equity (APEASE) criteria (See Appendix L: The APEASE Criteria) to determine which intervention strategy is inappropriate for the community pharmacy setting that is being studied (Craig *et al.*, 2008). In line with this framework, findings of this research could provide a good baseline for the development of interventions to enhance community

pharmacists' roles in the prevention of opioid misuse. The most appropriate intervention could be selected by testing the feasibility and acceptability of the developed interventions (by carrying out pilot studies) in UK pharmacies. Consequently, these findings could inform the studies proposed by the MRC framework, such as the evaluation studies consisting of effectiveness and cost-effectiveness studies and the implementation studies. Empirical research that underpins the suggested strategies displayed in Table 7.5 are sparse in the literature and emphasises the need to conduct more empirical research in the future. Evidence from these empirical studies is necessary for the development of practicable, appropriate, effective and cost-effective interventions that might improve community pharmacy staff's roles in the prevention of opioid misuse.

To further strengthen evidence and practice in measuring and determining appropriate intervention, the views of service users regarding the role of community pharmacists in the prevention of opioid misuse should also be explored through qualitative interviews. This would help to capture aspects of community pharmacists' roles that service users find useful and develop interventions that are targeted at improving those roles.

Furthermore, this research could be carried out among other group of public health commissioners that are involved in commissioning substance misuse services in community pharmacies. An example of such an organisation is the local authority. The views of members of the local authority might contribute towards obtaining a wide range of varied experiences and suggestions which could contribute towards developing more comprehensive intervention strategies. .

To help reduce high rates of opioid misuse and opioid related deaths, further research should focus on developing interventions that would promote safe and effective use of opioids. Examples of such interventions are those that are focused on promoting stricter regulation of OTC opioids and improving the participation of community pharmacists in opioid stewardship activities.

In addition, future research should consider using the trauma-informed approach in developing interventions. The trauma informed approach is a practice that is based on the premise that there is a relationship between opioid misuse and trauma

(Substance Abuse and Mental Health Services Administration, 2014). Thus, implying that there is a high likelihood that persons who misuse opioids have previously experienced trauma (University at Buffalo, 2024). Traumatic experiences have lasting untoward effects on individuals which gives rise to challenges in their physical, social, mental, emotional and spiritual wellbeing (Weisner, 2024).

Healthcare professionals in the UK are encouraged to follow a trauma-informed approach, otherwise known as trauma informed practices when relating with service users (Office for Health Improvement and Disparities, 2022c). This will enable practitioners to be aware of how trauma adversely affects individuals and the impact it has on their ability to build trusting relationships with healthcare professionals (Safeguarding Board for Northern Ireland, no date). This knowledge will enable practitioners to make efforts to prevent re-traumatisation that is, re-experiencing the feelings that the individual experienced during the traumatic event (Office for Health Improvement and Disparities, 2022c). This approach does not seek to treat trauma-related challenges but focuses on addressing the barriers that people who experience trauma related challenges face while accessing healthcare (Office for Health Improvement and Disparities, 2022b). The key principles of trauma-informed approach are to ensure that the physical, psychological and emotional safety of service users is ensured, that a transparent organisational policy is being operated by the practitioner to help build trust in the service user (Office for Health Improvement and Disparities, 2022c), that service users are supported to make shared decisions and choices regarding their health, and promoting collaboration and empowerment of service users to make contributions towards improving the health system and encouraging the promotion of a culturally sensitive intervention (Department for levelling up, 2023). Hence, considering the trauma-informed approach in developing interventions for service users who misuse opioids may produce effective interventions that can promote service users' engagement and participation with the health system, thereby improving their health outcomes.

8.8 Conclusion

This research was undertaken to develop intervention strategies that will enhance community pharmacy staff's role in the prevention of prescription and OTC opioid misuse using the COM-B and BCW models. To develop these interventions, factors that influence community pharmacists' role in the prevention of prescription and OTC opioid misuse were obtained from pharmacy staff interviews using the COM-B model. These factors include poor ability of community pharmacists to communicate with service users who are addicted to opioids, lack of resources such as staff, funding and tools for identification and referral of service users who are suspected of misusing opioids. Poor communication channels between community pharmacists and other health professionals, insufficient support from commissioners and OTC opioid regulatory framework are other factors that could inhibit community pharmacists' roles in the prevention of opioid misuse.

Intervention strategies targeted at improving the identified factors were then developed using the BCW model and were based on suggestions obtained from the systematic review, community pharmacy staff interviews and commissioners' interviews. These intervention strategies are education and training of pharmacy students as well as community pharmacists, development of programmes that can enable collaboration between community pharmacists and GPs, tight regulation of the supply of OTC opioids, and improved commissioners' support for community pharmacists' roles. To develop specific interventions that are feasible and effective to improve community pharmacy staff's role in a community pharmacy, further research that considers the characteristics or features of that community pharmacy whilst applying the APEASE criteria and MRC framework should be carried out. In addition, service users' views should be considered in future research as this will enable the development of patient-centred interventions.

This research has filled an identified research gap by developing theory informed intervention strategies that can enhance community pharmacists' role in the prevention of prescription and OTC opioids misuse in the UK using the evidence-based and widely used COM-B and BCW models.

Apendices

Appendix A: Behaviour Change Technique Taxonomy Version 1

BCT Taxonomy (v1): 93 hierarchically-clustered techniques

Page	Grouping and BCTs	Page	Grouping and BCTs	Page	Grouping and BCTs
1	**1. Goals and planning**	8	**6. Comparison of behaviour**	16	**12. Antecedents**
	1.1. Goal setting (behavior) 1.2. Problem solving 1.3. Goal setting (outcome) 1.4. Action planning 1.5. Review behavior goal(s) 1.6. Discrepancy between current behavior and goal 1.7. Review outcome goal(s) 1.8. Behavioral contract 1.9. Commitment		6.1. Demonstration of the behavior 6.2. Social comparison 6.3. Information about others' approval		12.1. Restructuring the physical environment 12.2. Restructuring the social environment 12.3. Avoidance/reducing exposure to cues for the behavior 12.4. Distraction 12.5. Adding objects to the environment 12.6. Body changes
3	**2. Feedback and monitoring**	9	**7. Associations**	17	**13. Identity**
	2.1. Monitoring of behavior by others without feedback 2.2. Feedback on behaviour 2.3. Self-monitoring of behaviour 2.4. Self-monitoring of outcome(s) of behaviour 2.5. Monitoring of outcome(s) of behavior without feedback 2.6. Biofeedback 2.7. Feedback on outcome(s) of behavior		7.1. Prompts/cues 7.2. Cue signalling reward 7.3. Reduce prompts/cues 7.4. Remove access to the reward 7.5. Remove aversive stimulus 7.6. Satiation 7.7. Exposure 7.8. Associative learning		13.1. Identification of self as role model 13.2. Framing/reframing 13.3. Incompatible beliefs 13.4. Valued self-identify 13.5. Identity associated with changed behavior
5	**3. Social support**	10	**8. Repetition and substitution**	18	**14. Scheduled consequences**
	3.1. Social support (unspecified) 3.2. Social support (practical) 3.3. Social support (emotional)		8.1. Behavioral practice/rehearsal 8.2. Behavior substitution 8.3. Habit formation 8.4. Habit reversal 8.5. Overcorrection 8.6. Generalisation of target behavior 8.7. Graded tasks		14.1. Behavior cost 14.2. Punishment 14.3. Remove reward 14.4. Reward approximation 14.5. Rewarding completion 14.6. Situation-specific reward 14.7. Reward incompatible behavior 14.8. Reward alternative behavior 14.9. Reduce reward frequency 14.10. Remove punishment
6	**4. Shaping knowledge**	11	**9. Comparison of outcomes**	19	**15. Self-belief**
	4.1. Instruction on how to perform the behavior 4.2. Information about Antecedents 4.3. Re-attribution 4.4. Behavioral experiments		9.1. Credible source 9.2. Pros and cons 9.3. Comparative imagining of future outcomes		15.1. Verbal persuasion about capability 15.2. Mental rehearsal of successful performance 15.3. Focus on past success 15.4. Self-talk
7	**5. Natural consequences**	12	**10. Reward and threat**	19	**16. Covert learning**
	5.1. Information about health consequences 5.2. Salience of consequences 5.3. Information about social and environmental consequences 5.4. Monitoring of emotional consequences 5.5. Anticipated regret 5.6. Information about emotional consequences		10.1. Material incentive (behavior) 10.2. Material reward (behavior) 10.3. Non-specific reward 10.4. Social reward 10.5. Social incentive 10.6. Non-specific incentive 10.7. Self-incentive 10.8. Incentive (outcome) 10.9. Self-reward 10.10. Reward (outcome) 10.11. Future punishment		16.1. Imaginary punishment 16.2. Imaginary reward 16.3. Vicarious consequences
		15	**11. Regulation**		
			11.1. Pharmacological support 11.2. Reduce negative emotions 11.3. Conserving mental resources 11.4. Paradoxical instructions		

Appendix B: PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	

Section and Topic	Item #	Checklist item	Location where item is reported
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	
Study characteristics	17	Cite each included study and present its characteristics.	
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	

Section and Topic	Item #	Checklist item	Location where item is reported
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	
	23b	Discuss any limitations of the evidence included in the review.	
	23c	Discuss any limitations of the review processes used.	
	23d	Discuss implications of the results for practice, policy, and future research.	
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

Appendix C: Participant information sheet for community pharmacy teams

Title of the study:

Enhancing the role of UK community pharmacists in the prevention of prescription and over-the-counter opioid misuse: developing intervention strategies using established behaviour change models

Invitation

You are invited to participate in this research study. It is important that you understand the purpose of this research before you decide whether or not to participate. Take your time and feel free to contact us with any questions. You will be asked to sign a consent form if you decide to participate in the research. You are free to withdraw from this research at any time without giving any reason. There is no penalty or loss to benefits from withdrawing.

What is the purpose of the research?

This research seeks to explore the views of community pharmacists and other stakeholders about community pharmacists' role in the prevention and management of opioid misuse in the North East of England. The prevalence of opioid misuse in our region is the highest in England. This research will help to develop intervention strategies that would enhance community pharmacists' roles in the prevention of opioid misuse. Findings from this study will help to inform commissioners about ways in which community pharmacist's roles could be enhanced. It will also contribute to existing research on opioid misuse.

What does taking part involve?

You will be invited online via Zoom or Teams for a one-to-one interview which will last for about 30-45 minutes. There will only be one interview session. You will be asked questions that will aim to explore your experiences in the prevention and management of opioid misuse.

What information will be collected and who will have access to the information collected?

Information that focuses on community pharmacists' role in opioid misuse will be collected. Your name and work email address will be needed, in order to contact you to arrange interview. Your age, gender, ethnicity and years of experience will be collected as background information. Audio recordings will also be used to analyse the interview responses. This information will only be accessed by the researchers involved in this study and will not be shared. Recordings, transcripts and notes will be transferred into a passworded electronic file on the University secure network. The password will only be known by only the researchers.

Why have I been invited to take part?

You have been invited to take part in this study because you are a community pharmacist practicing in the North East of England.

What are the possible benefits of taking part?

Your participation in this research will contribute towards developing interventions aimed at improving community pharmacists' role in the prevention of opioid misuse. It is hoped that this would inform the decision of commissioners regarding potential interventions that could help enhance community pharmacists' roles in the prevention of opioid misuse. This intervention could result in a reduction in hospitalisation and death rates that arise from opioid misuse, in the long term.

What are the possible disadvantages and risks of taking part?

There is no risk in participating in this research. Personal information will be treated with highest confidentiality.

Who is the sponsor and data controller for this research?

Newcastle University is the sponsor of this research and will also be the data controller for this research. This means that Newcastle University will be in

charge of managing your information. Personal information obtained from you will be very minimal so the risk of information leakage is very low.

Who is funding this research?

The funders of this research, which is part of a PhD programme, is The Tertiary Education Trust Fund (TETFUND), Nigeria.

Has this study received ethical approval?

This study has received ethical approval from the Faculty of Medical Sciences (FMS) research ethics committee at Newcastle University (Ethical approval letter).

Who should I contact for further information relating to the research?

For further information about this research, contact Ogochukwu Offu (doctoral researcher) at:

Faculty of Medical Sciences
King George VI Building
Newcastle upon Tyne
NE1 7RU

Who should I contact in order to file a complaint?

You can contact the Data Protection Officer (DPO) of Newcastle University if you are not satisfied with how your personal data is handled. The DPO's contact details are: email address: rec-man@ncl.ac.uk and phone number is (0191) 208 6000. You can also contact the researcher with this email: O.F.Offu2@ncl.ac.uk. Additionally, the project supervisors for this research could be contacted via the following emails: shelina.visram@ncl.ac.uk and laura.lindsey@ncl.ac.uk. If you are not satisfied with the DPO's responses, report to the Information Commissioner's Office (ICO). Please check this website- https://ico.org.uk/ for information on how to contact the ICO.

16/06/2021 (Version 1)

Appendix D: Participant information sheet for commissioners

Title of the study:

Enhancing the role of UK community pharmacists in the prevention of prescription and over-the-counter opioid misuse: developing intervention strategies using established behaviour change models

Invitation and Brief Summary

You are invited to participate in this research study. It is important that you understand the purpose of this research before you decide whether or not to participate. Take your time and feel free to contact me with any questions. You will be asked to sign a consent form if you decide to participate in the research.

What happens if you decide to withdraw from the research?

You are free to withdraw from this research at any time without giving any reason. However, if you decide to withdraw from this study, please inform me. There are no consequences for withdrawing. You will still get your full voucher if you complete the interview before withdrawing. All data provided by you prior to your withdrawal will be used in this study and all personal data will be anonymised and securely stored.

What is the purpose of the research?

This research seeks to explore the views of community pharmacists and other stakeholders about community pharmacists' role in the prevention of prescription and OTC opioid misuse in North East England. The findings of this study will contribute to existing research on opioid misuse and potentially help policy makers and professionals make decisions about how to support community pharmacists' role in the prevention of prescription and OTC opioid misuse. Policies made by policy makers could increase community pharmacists' professional capabilities and provide opportunities for community pharmacists to carry out their role in the prevention of prescription and OTC opioid misuse. In addition, the findings could also be beneficial to community pharmacists, as it would help them to offer an effective prescription and OTC opioid misuse

prevention service in North East England. This will hopefully contribute towards improving patient care by reducing hospitalisation and early deaths due to prescription and OTC opioid misuse.

What does taking part involve?

You will be invited online via Zoom or Teams for a one-to-one interview which will last for about 30-45 minutes. There will only be one interview session. The interview questions will focus on your experiences and opinions on the prevention of prescription and OTC opioid misuse.

What information will be collected and who will have access to the information collected?

Your name and contact details will be needed, in order to contact you to arrange an interview. Your age, gender, ethnicity and years of experience will be collected as background data. Audio recordings will also be used to collect data from the interview. This data will only be accessed by the researchers involved in this study. Recordings, transcripts and notes will be transferred into a passworded electronic file on the University secure network. The password will only be known by only the researchers. Once data has been anonymised (removing your name, contact details and anything that could identify you as a participant) data will be analysed and maybe shared for education, research and teaching purposes.

Why have I been invited to take part?

You have been invited to take part in this study because you are a policy maker or commissioner (that is, you represent one of the following groups: Integrated Care Board (CCGs), Primary Care Networks (PCNs) working in England.

What are the possible benefits of taking part?

You will get a 35 pounds voucher for participating in this research. Your participation will contribute towards improving community pharmacists' role in the prevention of prescription and OTC opioid misuse. It is hoped that this will

result in reduction in hospitalisation and death rates that arise from opioid misuse in the long term.

What are the possible disadvantages and risks of taking part?

There is minimal risk in participating in this research since this topic is not sensitive.

Who is the sponsor and data controller for this research?

Newcastle University is the sponsor of this research and will also be the data controller for this research. Personal information obtained from you will be very minimal so that risk of data leakage is very low.

Who is funding this research?

The funders of this research which is part of a PhD program is The Tertiary Education Trust Fund (TETFUND), Nigeria.

Has this study received ethical approval?

This study has received ethical approval from Faculty of Medical Sciences (FMS) ethics committee at the Newcastle University (ethical approval letter).

Who should I contact for further information relating to the research?

For further information about this research, contact Ogochukwu Offu via email-O.F.Offu2@ncl.ac.uk or at:

The School of Pharmacy,
The Faculty of Medical Sciences
King George VI Building
Newcastle upon Tyne
NE1 7RU

Who should I contact in order to file a complaint?

You can contact the Data Protection Officer (DPO) of Newcastle University if you are not satisfied with how your personal data is handled. The DPO's contact details are: email address: rec-man@ncl.ac.uk and phone number is (0191) 208

6000. You can also contact the researcher with this email: O.F.Offu2@ncl.ac.uk. Additionally, the project supervisors for this research could be contacted via the following emails: laura.lindsey@ncl.ac.uk and adam.rathbone@ncl.ac.uk. If you are not satisfied with the DPO's responses, report to the Information Commissioner's Office (ICO). Please check this website- https://ico.org.uk/ for information on how to contact the ICO.

How do I join this study?

If you are interested in joining this study please click on the link below to fill the demographic form.

https://forms.office.com/r/QmSy1dSyJd

Thank you.

Appendix E: Consent form for community pharmacy teams and commissioners

CONSENT FORM

Title of Study: The Role of Community Pharmacists in the Management and Prevention of prescription and illicit Drug Misuse in the United Kingdom

Thank you for agreeing to participate in this research. Please complete this form after you have read the Information Sheet.

		Please tick this box to confirm consent
1.	I confirm that I have read the information sheet dated 16/06/2021 (version 1) for the above study. I have the chance to think carefully about the information and to make enquiries about this study. I am also satisfied with the responses to my questions.	
2.	I understand that my participation is not compulsory and that I am free to withdraw at any time without permission.	
3.	I consent to the processing of my personal information [contact address, email, phone number] for the purposes of this research study, as described in the information sheet dated 16/06/2021 (version 1).	
4.	I understand that my de-identified/anonymized data may be published in peer reviewed journals, conference posters and presentations, as well as potentially being used in teaching materials and future research.	
5.	I consent to being audio recorded and understand that the recording will be kept in a secure, restricted place which only the researchers can access. The discussion will be transcribed and the anonymised transcript will also be stored on password-protected software and used for research purposes only.	
6.	I agree to participate in this research project.	
	Participant _____ _____ _____ Name of participant Signature Date	
	Researcher _____ _____ _____ Name of researcher Signature Date	
7.	Would you like to know the findings of this research? (Answer 'Yes' or 'No') _____	
8.	If your answer is 'Yes', enter your email here: _____	

Appendix F: Topic guide for community pharmacy teams

Topic guide for community pharmacy teams

OPENING

Good morn../aft../eve... My name is Ogochukwu Offu. I am a PhD student at the Newcastle University. I am carrying out a research on community pharmacy and opioid misuse. I'd like to hear your views about this. The interview will last for about 30 – 45 minutes, and we can stop or pause the interview at anytime. Are you happy to take part? I'd like to record the audio, but only I will have access to the recordings. I will write out what you say and remove any identifiable information then delete the audio recording. Is that okay? Do you have any questions before I begin?... [The record button will be pressed]

QUESTIONS

1) **Before we start, I'd like to get some demographic information from you [check form is complete]**
2) **Now would like to start quite broad, so first I'd like to know what you think are the main role(s) of community pharmacy in the UK?**
3) **Now thinking about community pharmacy in relation to opioids**
   - **a)** How are you involved in supplying opioids?
     - **i)** For example, OTC, prescription, misuse services
     - **ii)** If not already provided, could you provide an example of when you were last involved in supplying opioids?
   - **b)** Could you talk me through what you might think about when supplying opioids
     - **i)** over the counter?
     - **ii)** What about supplying opioids on prescription?
       - **(1)** Does this feel the same as over the counter? Could you explain why?
   - **c)** How do you feel about your role in supplying opioids?
       - **(1)** Do you have any concerns about opioid misuse with your patients? Why?
4) **Now thinking about opioid misuse a little more, could you tell me how you feel about opioid misuse?**
   - **a)** How do you assess if opioids are being misused?
     - **i)** Frequency of use? Checking prescriptions for high doses, high quantity, long duration of use?
     - **ii)** Do you use screening tools? Which ones?
     - **iii)** Are other staff involved?
       - **(1)** If so, who? How do you work with them?
   - **b)** What do you do if you suspect opioid misuse?
     - **i)** How does the **patient** respond to this action?
       - **(1)** How do you feel about this? Why do you feel this way?
     - **ii)** How does the **prescriber** respond to this?
       - **(1)** How do you feel about this? Why do you feel this way?

iii) Does your approach change for different opioids, for example, codeine, naloxone, buprenorphine, methadone?

5) **How do you think community pharmacy could help reduce opioid misuse?**
   - **a)** How could you be supported to do this?
     - **i)** Managers, commissioners, colleagues, patients**,** electronic programmes
   - **b)** What challenges are there to dealing with opioid misuse?
     - **i)** Other people have mentioned not feeling safe seeing patients alone in the consultation room. What do you think of that?
     - **ii)** Other people have mentioned working in collaboration with other healthcare professionals. What do you think of that?
     - iii) You have responded to all the questions I had. Please, is there any other thing you would like to add to what is already been discussed

CLOSING

It was great interviewing you. Thank you so much for your time. Please if you later remember any other relevant information that you did not reveal in this interview, please feel free to contact me via email (O.F.Offu2@ncl.ac.uk).

Appendix G: Topic guide for commissioners

TOPIC GUIDE FOR commissioners

OPENING

Good morn../aft../eve... My name is Ogochukwu Offu. I am a PhD student at Newcastle University. I am carrying out a research on community pharmacy and opioid misuse. I'd like to hear your views about this. The interview will last for about 30 - 45 minutes, and we can stop or pause the interview at any time. Are you happy to take part? I'd like to record the audio, but only me will have access to the recordings. I will write out what you say and remove any identifiable information then delete the audio recording. Is that okay? Do you have any questions before I begin?... [The record button will be pressed]

QUESTIONS

1. Could you tell me about your role in the prevention of prescription and OTC opioid (substance) misuse in the UK?
2. How do you feel about the role of community pharmacists in the prevention of prescription and OTC opioid misuse?
3. In what ways do you feel that community pharmacists could contribute towards preventing prescription and OTC opioid misuse in the UK?
4. In what ways do you support or collaborate with community pharmacists in this role?
5. Are there other ways that you could potentially support or collaborate with community pharmacists in this role?
6. What other ways do you feel that community pharmacists role in the prevention of OTC and prescription opioid misuse could be improved?
7. What do you think about educating the public about the long-term effects of opioids? How do you feel about this?
8. We have come to the end of this interview; are there other things you would like to add to what we have discussed?

Thank you very much for your time.

Appendix H: Demographic form for pharmacy teams

Name	
Gender	
Age group	18-30 31- 40 41- 50 51-60 61-70
Work address	
Email	
Job title	
Employment status	Full time Part time Locum
Years of experience	
Please specify your educational qualification(s)	
Which of these services do you offer OTC and/or prescription opioid users?	- Education, counseling or information provision - Screening, identication and referral - Disposal of OTC and prescription opioids - Needle exchange programmes - Buprenorphine dispensing - Methadone dispensing

Appendix I: Demographic form for commissioners

Name	
Gender	
Age group	18-30 31- 40 41- 50 51-60 61-70
Work address	
Email	
Job title	
Years of experience	
Please specify your educational qualification(s)	
Region/Cities covered	
Please list the services that you carry out	

Appendix J: Ethical approval letter

23 November 2021

Faculty of Medical Sciences
Newcastle University
Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH

Ogochukwu Fidelia Offu
Population Health Sciences Institute

FACULTY OF MEDICAL SCIENCES: ETHICS COMMITTEE

Dear Ogochukwu

Title: The role of community pharmacists in the management and prevention of prescription and illicit opioid misuse in the United Kingdom
Application No: 2142/13442/2020
Start date to end date: 12/07/2021 to 30/11/2023

On behalf of the Faculty of Medical Sciences Ethics Committee, I am writing to confirm that the ethical aspects of your proposal have been considered and your study has been given ethical approval.

The approval is limited to this project: **2142/13442/2020**. If you wish for a further approval to extend this project, please submit a re-application to the FMS Ethics Committee and this will be considered.

During the course of your research project you may find it necessary to revise your protocol. Substantial changes in methodology, or changes that impact on the interface between the researcher and the participants must be considered by the FMS Ethics Committee, prior to implementation.*

At the close of your research project, please report any adverse events that have occurred and the actions that were taken to the FMS Ethics Committee.*

Best wishes,

Yours sincerely

Marjorie Holbrough
On behalf of Faculty Ethics Committee

cc.
Professor Daniel Nettle, Chair of FMS Ethics Committee
Mrs Kay Howes, Research Manager

*Please refer to the latest guidance available on the internal Newcastle web-site.

Appendix K: The MRC Framework

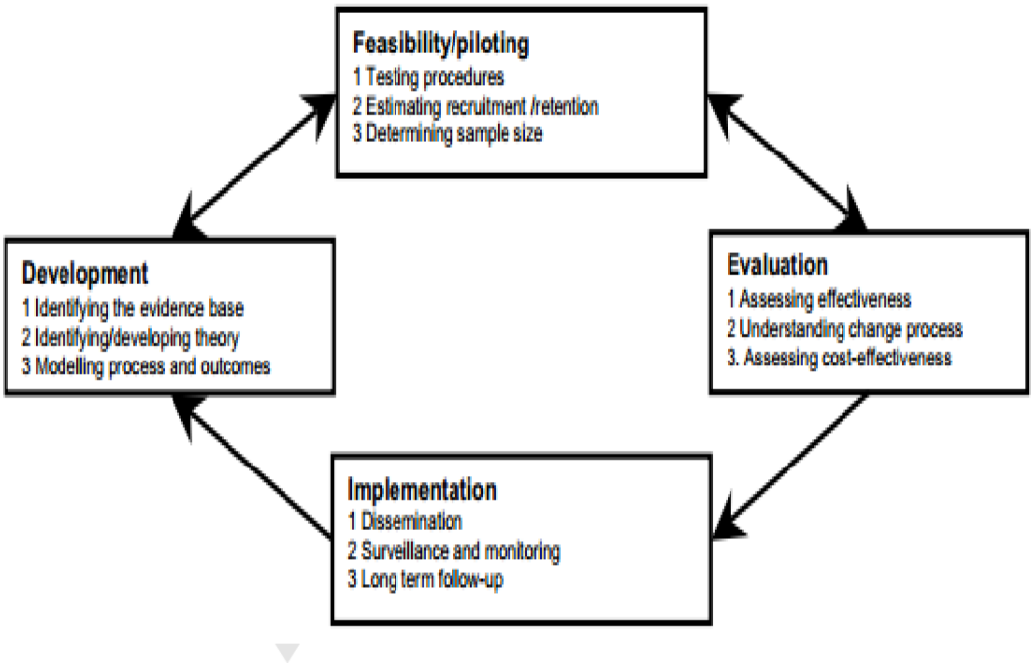


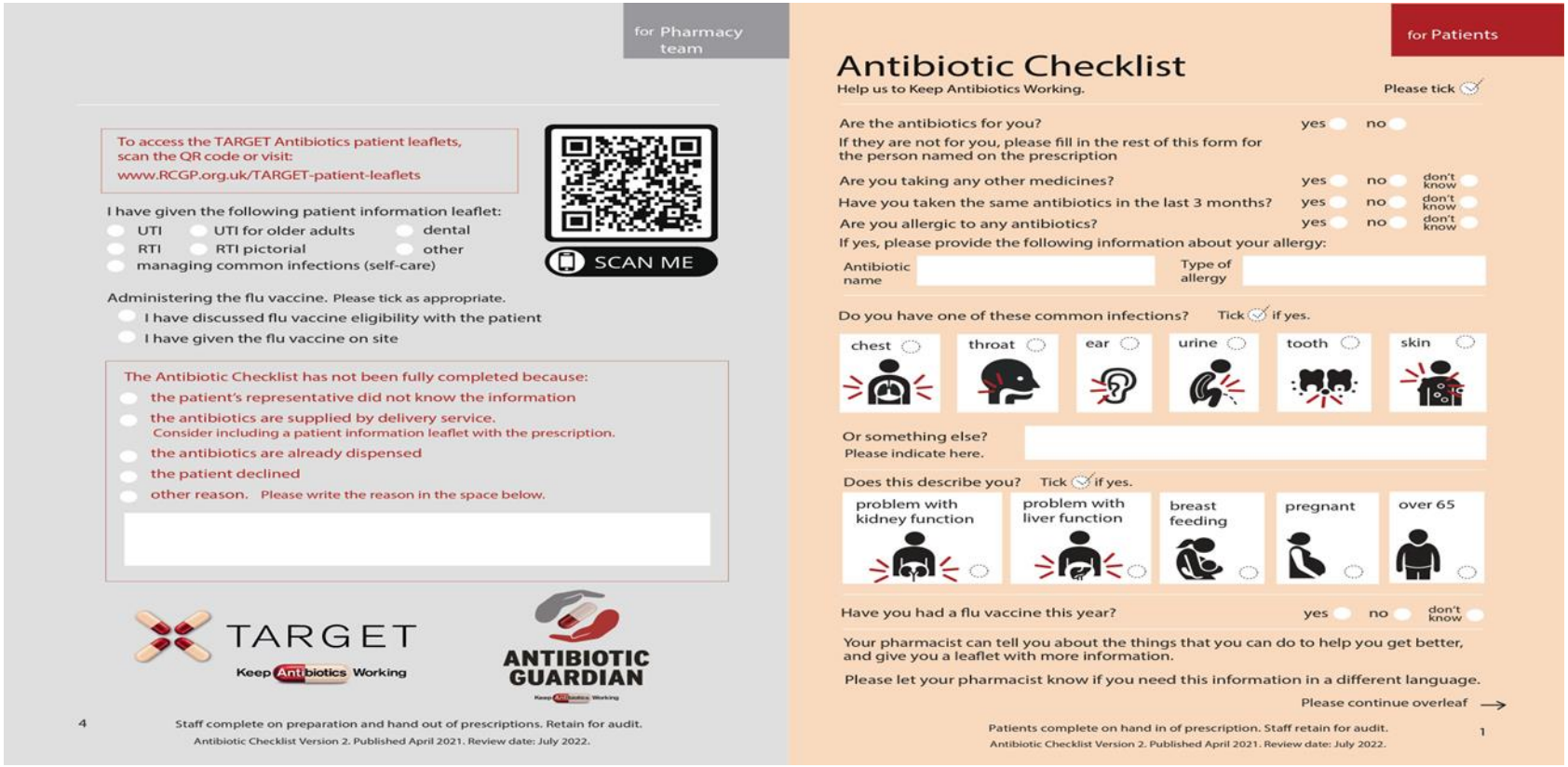
Figure showing the MRC framework (Obtained from Craig et al 2008)

Appendix L: The APEASE Criteria

Table showing the APEASE Criteria

Criterion	Description
Affordability	Affordability helped me to determine if the identified strategy could be applied at the intended scale, and on an acceptable budget.
Practicability	This criterion helped to decide whether the strategy was practical to carry out in the community pharmacy, given existing resources.
Effectiveness/cost-effectiveness	This criterion enabled me to determine if the identified strategy would be able to improve the target behaviour. In instances where different strategies have the same effectiveness, the most cost-effective was selected. Where a strategy showed higher effectiveness than others, its affordability and practicability were also considered.
Acceptability	This criterion helped me to determine if the identified strategy was acceptable to the community pharmacists, commissioners and service users.
Side-effect/ safety	This criterion helped me to consider whether a strategy has an unwanted effect or whether it is safe to apply.
Equity	Equity helped me to consider whether the application of the strategy would increase or decrease health disparities within sectors of the population

Appendix M: The TARGET antibiotic checklist



for Pharmacy team

To access the TARGET Antibiotics patient leaflets, scan the QR code or visit:
www.RCGP.org.uk/TARGET-patient-leaflets

SCAN ME

I have given the following patient information leaflet:
- UTI
- UTI for older adults
- dental
- RTI
- RTI pictorial
- other
- managing common infections (self-care)

Administering the flu vaccine. Please tick as appropriate.
- I have discussed flu vaccine eligibility with the patient
- I have given the flu vaccine on site

The Antibiotic Checklist has not been fully completed because:
- the patient's representative did not know the information
- the antibiotics are supplied by delivery service. Consider including a patient information leaflet with the prescription.
- the antibiotics are already dispensed
- the patient declined
- other reason. Please write the reason in the space below.

TARGET Keep Antibiotics Working

ANTIBIOTIC GUARDIAN

4

Staff complete on preparation and hand out of prescriptions. Retain for audit.
Antibiotic Checklist Version 2. Published April 2021. Review date: July 2022.

for Patients

Antibiotic Checklist

Help us to Keep Antibiotics Working.

Please tick

Are the antibiotics for you? yes no
If they are not for you, please fill in the rest of this form for the person named on the prescription

Are you taking any other medicines? yes no don't know
Have you taken the same antibiotics in the last 3 months? yes no don't know
Are you allergic to any antibiotics? yes no don't know
If yes, please provide the following information about your allergy:

Antibiotic name | Type of allergy

Do you have one of these common infections? Tick if yes.

chest | throat | ear | urine | tooth | skin

Or something else? Please indicate here.

Does this describe you? Tick if yes.

problem with kidney function | problem with liver function | breast feeding | pregnant | over 65

Have you had a flu vaccine this year? yes no don't know

Your pharmacist can tell you about the things that you can do to help you get better, and give you a leaflet with more information.

Please let your pharmacist know if you need this information in a different language.

Please continue overleaf →

Patients complete on hand in of prescription. Staff retain for audit.
Antibiotic Checklist Version 2. Published April 2021. Review date: July 2022.

1

→ Continued from overleaf

for Patients

Help us to help you by ticking yes or no by the following statements:

I know what to do if I miss a dose of my antibiotics.
yes ○ no ○

I know whether my antibiotics should be taken with or without food.
yes ○ no ○

I know why I must take my antibiotics as advised by my doctor, nurse or pharmacist.
yes ○ no ○

I know about the side effects that I might get from my antibiotics.
yes ○ no ○

I know whether I need to avoid alcohol whilst I am taking my antibiotics.
yes ○ no ○

I know why I must never share my antibiotics or keep for later use.
yes ○ no ○

I know how long my symptoms are likely to last.
yes ○ no ○

I know when I should seek further help with my infection.
yes ○ no ○

I know why I must return any unused antibiotics to the pharmacy.
yes ○ no ○

If needed, I am happy for someone on behalf of Public Health or TARGET Antibiotics to contact me about my visit today.

I would like to be contacted ○ by mobile ○ by email. Tick where appropriate.

Please write your email or mobile number below, using one letter or number per box.

Patients complete on hand in of prescription. Staff retain for audit.

Antibiotic Checklist Version 2. Published April 2021. Review date: July 2022.

for Pharmacy team

Checklist points

Date this checklist was completed:

Assessing the antibiotic prescription. Please tick as appropriate.

I have checked	n/a	yes	no
… for allergies, risk factors, other medication interactions.	○	○	○
… treatment with the same antibiotic in the previous 3 months. This information is collected from page 1.	○	○	○
… the antibiotic against the local guidance.	○	○	○
… the antibiotic is appropriate for the infection indicated.	○	○	○
… the dose is correct for the indication and patient.	○	○	○
… the duration is correct for the indication.	○	○	○

I have contacted the prescriber about this antibiotic prescription. Please write the reason and outcome below.	n/a	yes	no
	○	○	○

The following antibiotics have been dispensed

○ None ○ Amoxicillin ○ Flucloxacillin ○ Nitrofurantoin
○ Doxycycline ○ Clarithromycin ○ Phenoxymethylpenicillin (Penicillin V)
○ Metronidazole ○ Trimethoprim ○ Co-Amoxiclav
○ other Please specify the antibiotic in the space below.

Giving advice on antibiotics. Please tick as appropriate.	n/a	yes	no
I have discussed antibiotic resistance with the patient/carer as the patient has had the same antibiotics in the last three months.	○	○	○
I have checked the Patient responses to the statements overleaf and given advice as required.	○	○	○

Tick the circles ⊘ next to the statements opposite when the advice has been given.

Please continue overleaf →

Staff complete on preparation and hand out of prescriptions. Retain for audit.

Antibiotic Checklist Version 2. Published April 2021. Review date: July 2022.

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