Community pharmacists' role in preventing opioid substitution therapy-related deaths: an investigation into current practice in England

Yadav, Ramesh

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University of Bath

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Ramesh Yadav

A thesis submitted for the degree of Doctor of Philosophy

University of Bath
Department of Pharmacy and Pharmacology

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Candidate's signature

Declaration of authorship

I am the author of this thesis, and the work described therein was carried out by myself personally.

Candidate's signature

You have come too far, not to go further.
You have done too much, not to do more.

Sir James Henare (1989)

Abstract

Opioid substitution therapy involves prescribing opioid substitutes, most commonly methadone and buprenorphine, to those who are addicted to opioids. The community pharmacist undertakes the majority of the dispensing of the substitute and often sees the patient daily. They also provide other related services like supervised consumption of the prescribed substitute, needle and syringe, and take-home naloxone service. The introduction of supervised consumption of methadone in the UK community pharmacies in the mid-1990s saw a four-fold reduction in methadone-related deaths. All these services are intended to reduce the risk of harm and prevent overdose deaths. It is hypothesised that the policy to prevent opioid overdose deaths is not fully implemented by community pharmacists in England, and more could be done to avoid these deaths.

This study aimed to investigate the English community pharmacists' role in preventing opioid substitution therapy-related deaths and exploring what more can be done to prevent such deaths.

A mixed-method sequential exploratory design was used to answer the research question. Qualitative interviews with 24 community pharmacists gave a nuanced picture of pharmacists' understanding of the risks associated with substitution therapy and their perceived role in preventing overdose deaths. A subsequent qualitative observation at nine community pharmacies further explored the delivery of these services in pharmacy. A cross-sectional telephone survey of English community pharmacies was then utilised to quantify pharmacists' reported practice and describe whether more can be done to prevent opioid overdose deaths.

The findings of the three studies undertaken in fulfilment of this thesis demonstrate that community pharmacists' current practice is not optimal to the national guidance and the practice policy intended for preventing overdose deaths. The findings supports the hypothesis that more could be done by community pharmacists to prevent opioid overdose deaths. Local

commissioning of OST services has led to variations in the delivery of service. Pharmacists' knowledge and skills gap mean some patients at high risk of harm may not have their risks acted upon. Inaction by pharmacists, for example, not checking patient medication record for possible interactions, not talking to patient about possible side effects and outcomes of OST, dispensing OST doses to intoxicated patients can all increase the risk to the patient. The privacy and dignity of OST patient are not always given the due consideration. Delivery of the service outside of the consulting room and the rushed nature of the interaction between CPs and OST patients did not provide a conducive environment for patients to engage in their treatment. The practice of community pharmacists in England is centred on the mechanics of delivery of the service, and the notion of preventing opioid overdose death appears to be peripheral. Clarity in the guidance for pharmacists and a national commissioning framework specifying the training requirements and standardised service protocol could improve community pharmacists' role in preventing opioid substitution therapy-related deaths.

Acknowledgements

I would like to thank all the many people and organisations who helped me in completing my PhD.

Firstly, I would like to thank my supervisory team of past and present; Dr Jenny Scott, Dr Denise Taylor, Dr Philip Rogers and Dr Gordon Taylor. I am grateful to Jenny, my lead supervisor, for believing in me and giving me the opportunity to undertake this PhD. Your constructive critique and your push for improvement have made me a more accomplished researcher. I want to thank you for keeping your faith in me and guiding me when things were not going well. Jenny, you have indeed been a great inspiration to me. I cannot thank enough Denise for her guidance and support during this PhD's ups and downs. Denise, you are an amazing person to know. I have learned immensely from you, not just about research but also about life. I would also like to thank Dr Philip Rogers and Dr Gordon Taylor who were involved for short but at crucial stages of my research.

A big thank you to the University of Bath for my research scholarship. My thanks also go towards Pharmacy Research UK for the fellowship, which allowed me to complete my research. I am also thankful to the National Pharmacy Association, Health Education Foundation and Harold and Marjorie Moss Charitable Trust Fund for their bursaries. I am also thankful to all the participants of my research who took the time to take part. A big thanks to all those I work with for their consideration of my study. Thank you to my friend Dr Vibhu Paudyal for listening to my writing updates patiently, despite his busyness. Massive thanks to all my friends (many to name), who constantly encouraged me to complete my PhD.

My family have been a great support in my academic journey from Nepal to Pakistan for graduation and then to the UK for further studies. My father, Bramhadev Ray Yadav, instilled the 'can-do' attitude in me, which was critical in ploughing through the difficult periods. He sadly passed away after I passed my viva exam. I cannot be thankful enough for my mother's sacrifice

in sending me away to study from an early age for the sake of my future. Thank you to my sisters and brothers, nephew and nieces who have always been there for me during good and bad times. As I write the concluding sentences of my thesis, I would like to remember my mother, father-in-law and my uncle who passed away during my PhD. They would have been so proud to see me complete my PhD.

Above all, I would like to thank my wife, Rubina, to who I owe a lot for the times I have not been able to be with her. She has shared an unfair burden of work and family while I have been busy with my study. Lastly, I am so thankful to god for the joy he/she sends to us in the form of our son ‘Dakshya'. Son, it is the University of Bath, not University of Bathtub!

In loving memory of my father.

Buwa, I miss you dearly.

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Key Abbreviations

ACMD	Advisory Council on the Misuse of Drugs
BANES	Bath and North East Somerset
CCG	Clinical Commissioning Group
CD	Controlled Drug
CNS	Central Nervous System
CP(s)	Community Pharmacist(s)
CPCF	Community Pharmacy Contractual Framework
CPD	Continuing Professional Development
CPPE	Centre for Pharmacy Postgraduate Education
EU	European Union
GP(s)	General Practitioner(s)
GPhC	General Pharmaceutical Council
IPA	Interpretative Phenomenological Analysis
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NSP	Needle and Syringe Programme
NTA	National Treatment Agency
ONS	Office of National Statistics
OST	Opioid Substitution Therapy
PHE	Public Health England
PRUK	Pharmacy Research UK
PWUD	People who use drugs
PWID	People who inject drugs
REACH	Research Ethics Committee, University of Bath
RPS	Royal Pharmaceutical Society
SC	Supervised Consumption
SD	Standard Deviation
SLA	Service Level Agreement
THN	Take-Home Naloxone
UK	United Kingdom
WHO	World Health Organisation

Glossary

Drug-related deaths (DRDs) or Drug poisoning deaths

Drug-related deaths include deaths where the death's underlying cause has been established as either drug poisoning, drug abuse or drug dependence. The current Office of National Statistics definition of deaths related to drug poisoning includes accidents, suicides and assaults involving drug poisoning, as well as deaths from drug abuse and drug dependence. It does not include other adverse effects of drugs (for example, anaphylactic shock or transport accidents where the driver was under the influence of drugs).

Drug misuse deaths (DMDs)

Drug misuse deaths include deaths where the underlying cause of death is drug abuse or drug dependence and where any of the substances controlled under the Misuse of Drugs Act (1971) are involved.

Opioid-related deaths

Drug misuse deaths where an opioid was mentioned on the death certificate as the underlying cause of death.

Opiates

Opiates are a group of psychoactive substances derived from the poppy plant that include opium, morphine and codeine. The term 'opiate' is also used for the semi-synthetic drug diamorphine (heroin), which is produced from poppy compounds.

Opioids

Opioids refer to opiates and other semi-synthetic and synthetic compounds with similar properties.

Community-based treatment

A structured drug and alcohol treatment setting where residence is not a condition of engagement with the service. This will include treatment within

community drug and alcohol teams and day programmes (including rehabilitation programmes where residence in a specified location is not a condition of entry).

Primary care treatment

Structured substance misuse treatment is provided in a primary care setting with a General Practitioner, who often has a special interest in addiction treatment, and holds clinical responsibility.

External Outputs

1. **Peer reviewed conference abstract**

   Yadav R, Scott J, Taylor G, Taylor D. Community pharmacists' role in preventing methadone related deaths: a qualitative exploration. International Journal of Pharmacy Practice. 2014;
   (Oral presentation at Health Service Research and Pharmacy Practice Conference: 3-4 April 2014, Aberdeen.)

2. **Peer reviewed journal article**

   Yadav R, Scott J, Taylor G, Taylor D. Community pharmacists' role in preventing opioid substitution therapy-related deaths: a qualitative investigation into current UK practice. International journal of clinical pharmacy, 2019. 41(2): p. 470-477.

3. **Peer reviewed conference**

   Yadav R, Scott J, Taylor D. Community pharmacists' role in preventing Opioid Substitution Therapy-related deaths: A national survey of English community pharmacists.
   (Oral presentation confirmed at Health Service Research and Pharmacy Practice Conference: 16-17 April 2020 Cardiff. Conference cancelled because of Covid-19)

4. **Draft article intended for peer reviewed journal**

   Yadav R, Scott J, Taylor D. Can community pharmacy teams do more to prevent drug-related deaths? An observational study of pharmacy opioid substitution therapy services.

5. **Draft article intended for peer reviewed journal**

   Yadav R, Scott J, Taylor D, Rogers P. Can community pharmacists do more to prevent opiate-related deaths in people who use drugs? A national survey of community pharmacists in England.

Two papers are in a draft format aimed at peer reviewed journals and have been included in this thesis (chapter 4 and 5).

Awards and scholarships

Apart from the University of Bath Graduate School Scholarship, I have been privileged to have won the following competitive grants.

1. National Pharmacy Association (NPA), Health Education Foundation Bursary 2012. (£3,000)
2. College of Mental Health Pharmacy (CMHP), Bursary for Postgraduate Studies, November 2012 (£300).
3. Harold and Marjorie Moss Charitable Trust Fund, Pharmacy PhD Research Award 2013 (£5,000)
4. Pharmacy Research UK (PRUK), Leverhulme Pharmacy Research Fellowship 2014 (£18,000)
5. Selected delegate of Institute for Policy Research, the University of Bath for placement with Lord Patel at the House of Parliament on the 29th January 2014.

I have also been fortunate to be supported by a small travel bursary from the Department of Pharmacy and Pharmacology, University of Bath.

Preface- Reflexivity

> *A reflexive researcher does not simply report facts or 'truths' but actively constructs interpretations of his or her experiences in the field, and then questions how those interpretations came about.* (Hertz, 1995).

Here, I have reflected on my journey through this doctoral study focusing on the main reflective considerations. I present this account to give the readers an insight into my role and my standpoint in creating the knowledge.

My background

As an overseas pharmacy graduate from Nepal, my knowledge about Opioid Substitution Therapy (OST) in the UK was primarily gained through work experience or work-based training. At the time of starting the doctorate, I had six years of experience working in English community pharmacy, four years as a pharmacist. While the research area is related to my professional practice, I have maintained objectivity throughout this PhD: I have discussed the validity tools in chapter 2 (methodology), which I have practised as a researcher to maintain rigour and robustness in my work. While I have personally benefitted from the skills I learned during this PhD, I also hope to positively impact pharmacists' professional practice through this doctorate's findings. I am also thoughtful of the unconscious researcher bias that would be applicable in any research field and cannot be ruled out completely.

The direction of my doctorate

This doctoral research's main aim was set based on a preliminary literature review prior to any fieldwork undertaken. While the primary aim remains unchanged, the studies planned within this thesis changed to reflect and accommodate the study's preliminary findings as it progressed.
Initially, the observation study was only planned to be a brief observation of CP practice at two to three sites to outline the interview study's findings. However, the interview study's early findings demonstrated variations in how

OST services were organised within the community pharmacy. Participants also reported how various factors within the pharmacy could influence the individual practice of the CP. Aware that some of the issues identified would be difficult to capture within the quantitative questionnaire survey that was to follow, the scope and the objectives of the observation study were modified to accommodate emerging themes.

The researcher inside me

As a practising community pharmacist, my work involves being precise and accurate in the dealings I have. I, therefore, on reflection, held a positivist approach to work and life in general. Before starting this PhD, I had minimal experience in conducting research. When I started my PhD, I could quickly identify myself with the quantitative elements of the research. The qualitative concepts took a while to get used to. On reflection, I can see why I always found something more important to do than to analyse the interview transcripts. It took a while and a lot of pushing (thank you, Denise!) to get going. It only took a few transcripts to realise the strength of spoken words and the power of qualitative research. I did not necessarily feel the full force of the words while I was interviewing the participants. Reading and listening to the memos I wrote or recorded immediately after the interviews shows that my reflections were mostly related to the overall assessment of how the interview went. This was possibly because I was too focussed on the technicalities and processes of conducting the research. Reading through the transcript, in the honest reflection shared by some of the participants, I could feel a qualitative researcher waking inside me! Now at this later stage of my study, I truly can say that the depth of understanding I have developed of this research area and the new findings I have presented in this thesis would not have been possible without the qualitative work I did. Starting as a novice researcher, I believe I have come a long way, yet this is only the beginning.

Rapport with my participants

The Oxford Dictionary defines rapport as a ‘relationship in which people understand each other very well’. As noted by Prior 2017, when people talk about personal experiences of any great emotional intensity, there is an

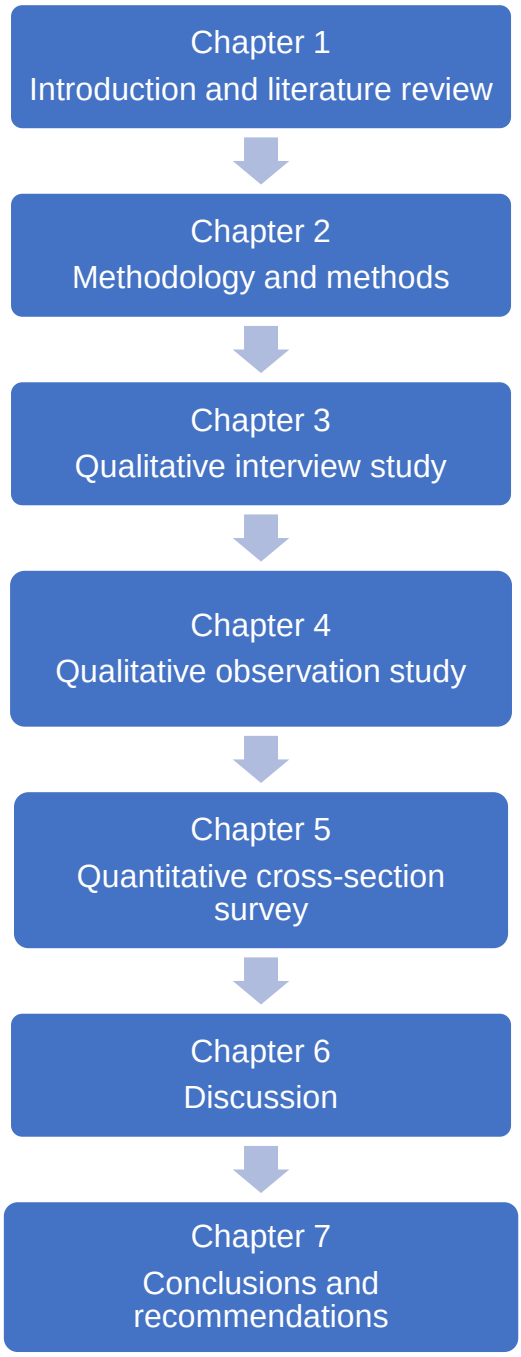
expectation that their recipients show not only their understanding of the content of the talk but also their understanding of the teller's stance toward that talk by displaying affiliation and empathic alignment with the teller. My role as a community pharmacist was known to all research participants beforehand. I believe this helped me to better connect to the experiences shared by the participants of all three studies. In the interview study, I felt the connection with my research participants more strongly. The frank account of their experiences demonstrated in the quotes reflects the strength of the rapport I established with research participants. Conversely, as noted in the experiences of Davis 2018, my insider knowledge of the subject area may also have deterred some of the interview participants from being completely open in expressing their views.

Through this introspection and continual awareness of the research process, I hope to have provided transparency and a tool to validate my work.

Thesis Outline: an alternative format thesis

This PhD thesis is presented as an alternative format thesis. It is divided into seven chapters consisting of a mix of published and publishable papers and chapters written in traditional PhD format. Chapters 3, 4 and 5 presenting the findings of the interview, observation and survey studies consecutively are presented as journal papers, whereas the other chapters are presented in the traditional format.

As a non-native English speaker, I took journal publication as a challenge and this was the primary reason for choosing an alternative format thesis. I was tempted by the opportunity to improve my academic writing skills through the peer review process and to have my work reviewed by experts in the field outside my supervisory team. As a part-time PhD student, it was also a practical decision to have my research published while I still could devote time to do so as I will be returning to full-time practice after completing my doctorate.



Outline of the PhD thesis

Chapter 1

Introduction and Literature Review

Chapter overview

This PhD's focus is to examine community pharmacists' role in preventing opioid overdose deaths in patients receiving opioid substitution therapy (OST) and explore if pharmacists can do more to prevent such deaths. This chapter presents an introduction and literature review to contextualise the research area. This chapter will first give the background of drug treatment services in England and community pharmacists' (CPs) role in delivering relevant services. It will then review the literature around opioid-related deaths with a specific focus on OST-related death and prevention. This chapter will then reflect on the guidance and policy recommendations available, which guide CPs to prevent overdose deaths related to OST and discuss previous evidence of the CP role. Findings from the literature review will be summarised with identified evidence gaps. This will then lead to the overall aims of the thesis and project development.

1.1 Background

Opioid Substitution Therapy (OST) programmes provide illicit drug users with a substitute, most commonly methadone or buprenorphine, as a replacement drug[1]. In the United Kingdom (UK) and Europe, methadone is the most widely prescribed substitute, followed by buprenorphine [1]. What started as a small experimental programme by Dole and Nyswander in Kentucky, United States of America (USA) in 1965, substitution therapy is now well-established in treating opioid addiction internationally [2, 3]. Internationally, this treatment method is also referred to as opioid replacement therapy (ORT), opiate agonist therapy (OAT), methadone maintenance therapy (MMT), or opioid agonist maintenance treatment (OAMT) in the literature [4].

OST has been the predominant intervention in treating opioid addiction in the UK and internationally [5, 6]. In England in 2019/2020, 140,599 people were receiving treatment for opioid addiction of which (94%) received OST[6]. OST interventions are primarily prescribed by either a drug treatment service through community-based settings or the patient's general practitioner as part of the primary care setting[6]. The prescribed interventions are then dispensed in community pharmacies, with an estimated 98% of UK methadone being provided through community pharmacies[7]. Of all the healthcare professionals involved in the primary care of opioid addiction treatment, community pharmacists (CPs) are in most frequent contact with patients, often daily [8]. Since its inception in the UK in the 1990s, CPs have also supervised the consumption of prescribed OST[9]. The UK clinical guidance recommends new OST patients receive supervised consumption for some time to allow monitoring of progress and an ongoing risk assessment[10].

Aside from dispensing and supervising OST consumption, CPs also provide Needle and Syringe Programmes (NSP) and Take-Home Naloxone (THN). A new community pharmacy-based Hepatitis C screening programme for England was announced in the new Community Pharmacy Contractual Framework (CPCF) 2019 and came into effect in 2020[11]. In the UK, the remit of health services lies with the devolved governments of England, Wales, Scotland, and Northern Ireland[12]. The development of OST-related

services, the role, and the extent of pharmacists' involvement within it vary according to the priorities set by national governments.

Receiving OST lowers the risk of death in those dependent on opioids [13-15]; however, death in this treatment population remains higher than in the general population [16, 17]. The overdose death risk is higher in the first four weeks of starting treatment and the four weeks after completion of OST [13]. Opioid-related deaths have dramatically increased in the UK and other developed nations in recent years [1, 18-20]. The UK ranks worst for opioid-related deaths in Europe, accounting for a third of the 9,221 overdose deaths reported in 2018[21].

Most opioid-related deaths result from an accidental overdose [16, 18, 19] and are preventable. While existing guidelines and government reports outline strategies to lower opioid-related deaths, given the scale of the problem faced nationally and internationally, there remains scope for improvement. The essential role of CPs in dispensing OST and their frequent contact with opioid-dependent populations means there could be missed opportunities in addressing the issue. Consequently, this research is interested in exploring what these improvements could be in relation to community pharmacy practice.

1.2 Literature review

The literature search was performed using the following databases; Embase, PubMed, Web of Knowledge, and Google Scholar using the terms described in the table below. Keywords, truncations, combination words, and wild cards were used based on the database's search function.

Table 1.1: Terms used for the literature search

Opioid	Overdose	Methadone	Addiction
Buprenorphine	Suboxone	Naloxone	Take-home naloxone
Community pharmacy	Opioid-related deaths	Intoxication	Needle and syringe programme
Tolerance	Stigma	Privacy	Pharmacist
Supervised consumption	Opioid substitution therapy		

The grey literature held an essential role in understanding the subject area of this research. It allowed access to health policy documents, government strategy documents, and professional guidance, which shaped the professional practice of CPs involved in OST and unpublished conference proceedings. Relevant reports and guidance published by the government, non-government and professional organisations were identified by searching the web and relevant websites. These sources were identified through references of published work, supervisory input, and peer recommendations. Given the influence of the wide variety of grey literature in this research area, a narrative review of the literature was considered to be more suitable for this PhD as it allowed the evidence to be selected judiciously and purposively with an eye for those which held relevance for key policy questions[22]. Unlike conventional systematic reviews which address narrowly focused research questions, the narrative review allows the researcher to interpret and critique a wider variety of literature in gaining a deeper understanding of the research area[22]. The narrative review was chosen to gain a clearer insight into the broad and complex issues associated with OST-related deaths[23]. Nevertheless, a systematic approach, as discussed above, was undertaken in reviewing the literature.

Literature searches were completed at intervals throughout the PhD to ensure important data and publications were not omitted or missed. The last of these searches were undertaken in December 2020. Where appropriate, email alerts were received for any updates in the searched literature content. Given the part-time engagement of the research student in this PhD and the time taken to complete the research, this was particularly important in keeping the study relevant and up to date. The abstracts of the articles and other documents identified in the searches were reviewed and those relevant to the research topic are integrated into this thesis. The presentation of the literature review is structured to inform the readers of the background of OST in England, the different stages of OST, and the role of CPs in delivering the services. This is then followed by reviews of evidence around OST-related deaths and the policy guidances to prevent these deaths.

1.3 The drug treatment service

The then National Treatment Agency for Substance Misuse (NTA) proposed a tiered approach in commissioning drug treatment services in England in 2002 [24]. The NTA ceased, and its essential functions moved to Public Health England in 2013.

1.3.1 Tiers of drug treatment service

The drug treatment service is organised into four different tiers, based on the nature and level of support and services provided to the service user. Community pharmacies provide some aspects of tier 2 and tier 3 of the service.

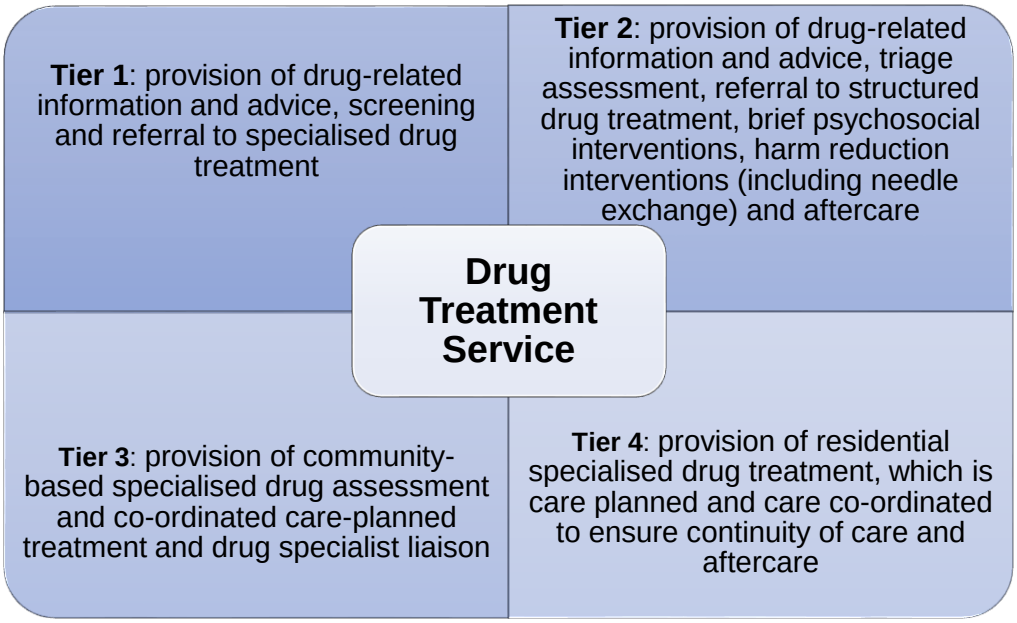


Figure 1.1: Tiers of drug treatment service in the United Kingdom Adapted from; Models of care for treatment of adult drug misusers: Update 2006, National Treatment Agency.

Tier 1 offers the provision of drug-related information and advice, screening, and referral to specialised drug treatment services from settings that are not specific to substance misuse treatment like general practice, social care, and educational settings.

Tier 2 is classed as the open-access tier. It offers drug-related information and advice, triage assessment, referral to structured drug treatment, brief psychosocial interventions, harm reduction interventions (including needle exchange), and aftercare[24]. This tier's main advantage is its accessibility, where the user of the service needs to show little commitment towards the service. Users are not required to be registered with the service provider on an ongoing basis.CPs offer the Needle Syringe Programme (NSP) under this tier.

Tier 3 involves structured drug treatment following a comprehensive assessment of the patient which includes OST services, the prescribing of OST by a specialist prescriber and its dispensing by a CP. It also offers the provision of community-based specialised drug assessment and co-ordinated care-planned treatment and drug specialist liaison.

Tier 4 includes inpatient substance misuse treatment and residential rehabilitation services.

1.3.2 Models of primary care drug treatment services

Different models of primary care drug treatment have evolved across England [10, 24, 25]. These essentially hinge around the general practitioner (GP) or the specialist drug treatment teams, prescribing the OST treatment, which is then dispensed in a community pharmacy. The GP and the local treatment team often work on a shared care basis where they share the care of the patient receiving the treatment [25]. Patients are assigned a care worker who provides support through their treatment journey. Care workers have an essential role in ensuring continuity of treatment by liaising with the pharmacy, GP, and the patient, mainly when there is a transfer of care between the treatment centre and the GP[25].

Alternatively, the prescribing of the OST in primary care is undertaken by a GP with a particular interest in substance misuse. Large numbers of non-medical prescribers (pharmacists and nurses) have acquired training to prescribe OST[10]. The patients are required to attend regular assessments with the prescribing team as part of their treatment plan. Patient progress and their engagement with the treatment are reviewed and altered accordingly at these assessments, as well as the dose and frequency of OST collection, the need for supervised consumption (SC), and the frequency of the assessment itself.

1.3.3 Commissioning of OST services

In England, community pharmacies provide three main groups of services as part of their contract. The current provision of OST and related services fall under the essential and enhanced pharmacy services.

1.3.3.1 Essential services

These are the core services provided by all community pharmacies holding a National Health Service (NHS) pharmacy contract under the NHS Community

Pharmacy Contractual Framework (CPCF). Dispensing of NHS OST prescription falls under essential service and therefore can be provided by all community pharmacies. Examples of other essential services include signposting, support for self-care, promotion of healthy lifestyles, and disposal of unwanted medicines[26].

1.3.3.2 Advanced services

These are additional services commissioned nationally that community pharmacies can choose to provide if they meet the service specification requirements [27]. Services like NHS flu vaccination, New Medicines Service (NMS) and Community Pharmacy Consultation Service (CPCS) fall under this category. The newly commissioned Community Pharmacy Hepatitis C Antibody Testing Service for those using NSP is an advanced service that directly links to the care of people who use drugs (PWUD).

1.3.3.3 Enhanced services

These include services that are commissioned locally by local stakeholders such as local authorities, local NHS teams, and Clinical Commissioning Groups (CCGs). Local authorities commission the SC, NSP, and THN services provided by community pharmacies under their public health obligations. Therefore, the availability and the scope of these OST-related services vary based on local need and commissioning priorities. Also, as these are not core contractual services, CPs can choose to provide some or none of these services. Cuts to local authority funding in England in recent years has seen a reduction of the financing available for drug treatment services locally[28].

1.3.4 Service Level Agreement (SLA)

The service level agreements (SLA) between the commissioner and the provider pharmacy form the legal basis for delivering public health services. Commissioners often contract the service to a single provider, who then

subcontract individual pharmacies in the area to provide the service. The SLAs vary between various local authorities, but nevertheless, they specify the service's scope and purpose, the quality requirements in the delivery of the service, remuneration, and other aspects of the service. These SLA's stipulate the pharmacy staff training requirement and the reporting obligation placed on the provider pharmacy.

A sample of a SLA for delivery of SC is presented in appendix 1.

1.3.5 The three-way contract

The three-way contract refers to the agreement between the patient receiving the treatment, the pharmacy dispensing it, and the prescriber. This is not a compulsory document, but where used, it sets out the service standards to be provided by the pharmacy and expectations regarding patient behaviour and collection times. Typically initiated by the treatment centre, it is signed by the three parties and each holds a copy of the document. A sample of the three-way contract document is included in appendix 2.

1.4 CPs' role in OST and related services

In England, every year, pharmacists provide more than 14 million face-to-face contacts with drug users[25]. Of all the public health services commissioned through community pharmacies, the SC and NSP are the most commonly used services in England [29, 30]. An estimated 98% of methadone is provided through community pharmacies[7]. CPs dispense most of the interventions; they also supervise the consumption of the dose where specified by the prescriber. CPs see the patient on an almost daily basis, thus are in more frequent contact with the patient than any other healthcare professional involved in the patient's care [8].

Subsequent surveys have reported the increased involvement of community pharmacies in offering OST and related services over the last two decades[31-34]. Since the introduction of SC in the 1990s, the role of CPs in opioid addiction treatment has expanded to services like NSP, THN, and more recently, the Hepatitis C Antibody testing service[11, 34, 35]. Many CPs are also becoming independent prescribers and treating addiction.

Public Health England (PHE) identifies community pharmacy as a key player in delivering the nation's public health agenda [35]. Community pharmacies are often located in some of the most deprived and challenging communities[35]. While drug use is prevalent in all communities, there is a strong link between poverty, deprivation, and drug use[36]. The easy accessibility of CPs, particularly in these communities, provides an opportunity for positive intervention by CPs. The 'Pharmacy- A Way Forward' report, published by PHE in 2017, identifies CPs as important and crucial in delivering treatment for drug dependence[35].

1.4.1 Supervised consumption

Supervised consumption (SC) involves the patient consuming the prescribed dose of OST in the pharmacy under suitably qualified staff supervision. The prescribed OST doses should be supervised at the start of the treatment and during periods of instability[10]. The SC should be relaxed only when the patient's compliance with treatment is assured[10].

SC is an enhanced service commissioned locally, depending on need. The SLA between the commissioner and the provider pharmacy sets requirements for reporting and patient monitoring and the quality of service delivery in general. In the absence of national guidance for SC, various service specifications have evolved locally. In 2015 the NHS Forth Valley (Scotland) issued a document entitled 'Recovery Focussed Pharmaceutical Care for Patients Prescribed Opiate Replacement Therapy' [37]. This document provides a template for the standard of SC service in community pharmacies and highlights the need for user-friendly, non-judgemental, patient-centred, and confidential service provision. It also states that CPs should ensure patients are advised on overdose prevention, access to naloxone, and signposted for other helath-related needs as necessary. It also recommends that CPs provide regular feedback to the treatment team regarding patient progress or any OST-related concern about an individual patient.

Availability of a private consultation room is mandatory for offering the service, and also requires the pharmacist to complete additional training to provide the service. Most SLA's need pharmacists to complete the Centre for Pharmacy Postgraduate Education (CPPE) module on substance use and misuse[38]; however, some might require the pharmacist to complete other training or additional face-to-face learning.

SC has a unique role in OST, as supervising the consumption of the dose in the pharmacy guarantees compliance. It also reduces the risk of the medicine being diverted by the patient as cases of overdose deaths have been reported following consumption of opioids intended for other patients[39]. Preventing the diversion of prescribed opioids is another key component in tackling overdose deaths.

Williams et al. 2009, reports that 50% of patients prescribed methadone store them appropriately in the home[39]. This report was based on a self-reported survey of OST patients at a primary health care centre in Edinburgh, Scotland. It also reported just over half (51%) of the participants received information on safe storage of OST medication. Many patients receiving OST have chaotic lifestyles; meaning the safe storage of the prescribed medication can be challenging.

1.4.2 Needle and syringe programme

The Needle and Syringe Programme (NSP) gives access to sterile injection equipment for those who inject drugs [40]. This service is aimed at reducing the transmission of blood-borne viruses and other infections caused by sharing of injecting equipment[40]. Pharmacy-based NSP has also been shown to reduce risky behaviour among people who inject drugs [41].

NSPs operate through various modalities, including fixed sites, outreach, peer networks of People Who Inject Drugs (PWID), vending machines, and pharmacies [42, 43]. These services are commissioned through CPs by local authorities. A systematic review by Platt et al. in 2005 reported there were an estimated 1,700 NSPs in England, 70% of which were provided by community pharmacies, with the rest offered by specialist community-based

services and outreach/mobile services and in custody suites. Given NSPs are often the first point of contact with health services for those injecting drugs, CPs can play an important role in encouraging this group of people to engage in safer options like the OST[40].

1.4.3 Take-home naloxone service

Naloxone is an opioid antagonist which rapidly reverses opiate-induced respiratory depression[44]. The Take-Home Naloxone (THN) service allows for the naloxone to be distributed without the need for a prescription. These are usually provided in an easy-to-use kit with instructions for use in an emergency. It is intended to be used by the drug user themselves or those witnessing the overdose[45], because most overdoses are seen by family members or friends[46]. The World Health Organisation (WHO) guidelines recommend that people likely to witness an opioid overdose should have access to naloxone and be instructed in its administration[45]. It is available without prescription in many developed countries, including Australia, Canada, Italy, and the UK[47].

THN is a relatively new OST-related service to be introduced in the UK. The service was first launched in Scotland in 2011[48], and in 2015 UK-wide regulation was changed to allow anyone working in a drug service to provide THN to promote its distribution [48, 49].

While almost all authorities in England (90%) commission THN as part of their effort to reduce opioid overdose deaths [50, 51], a recently published report on THN service provision found many of these authorities only commission the service through the main drug treatment provider[49]. As only 42% of local authorities commissioned THN service through community pharmacies, England's estimated coverage in 2017/18 was only 11 percent [49]. A survey conducted by the Local Government Association showed a much lower figure, with only 6% of its members commissioning the service through community pharmacies[51].

1.4.4 Hepatitis C antibody testing service

This service was launched in 2020 and aimed to increase the levels of testing for Hepatitis C Virus (HCV) amongst people who inject drugs (PWIDS) who are not otherwise engaged in community drug and alcohol treatment. PWIDs are provided with a point of care testing (POCT) for Hepatitis C (Hep C) antibodies in the pharmacy, and those testing positive for the antibody are referred for a confirmatory test and treatment[11]. PWIDs account for 90% of all new HCV infections in the UK, and pharmacies are most likely to be the more accessible healthcare setting for this cohort, as offering testing in pharmacies is expected to increase early detection of HCV[11].

1.5 Stages of OST

1.5.1 Methadone or buprenorphine

Methadone is a full μ-opioid agonist. Its accumulation can lead to sedation, respiratory depression, respiratory arrest, and even death[52]. Methadone also prolongs the QT interval, which can cause tachycardia leading to syncope or sudden death[52]. However, methadone-related deaths are primarily mediated through its respiratory depression effect[53, 54]. Buprenorphine is a partial agonist; thus, the potency of buprenorphine and its effect is self-limiting. It also has a ceiling effect on respiratory depression [55], which means higher doses do not lead to higher rates/levels of respiratory depression[53]. Despite it greatly reducing the risk of overdose, buprenorphine has failed to overtake methadone in OST management in the UK [18, 19, 53, 56]. Low retention rate on buprenorphine is regarded as a possible explanation for this[57]; however, other factors include inflexibility in dosing, and unwelcomed suppression of illicit drug use by the patient.

Both methadone (24 to 36 hours) and buprenorphine (36 to 48 hours) have a long half-life, which allows single daily dosing for methadone and an alternate day or daily dosing with buprenorphine[53].

Suboxone, a combination of buprenorphine and naloxone, is also prescribed in the UK. Naloxone is an opioid antagonist and therefore blocks the effect of buprenorphine if it is present in plasma. However, when taken orally,

naloxone reaches insignificant plasma concentrations, so it does not inhibit the therapeutic effect of buprenorphine[10]. Naloxone, therefore, can only discourage the misuse of this buprenorphine if administered by injection.

1.5.2 Initiation stage

Because of the long half-life of methadone, it's blood level gradually increases over 3 to 10 days to reach a steady level. This cumulative effect means a dose tolerated on day-one might become toxic on the third day, and hence the increased risk of OST-related death on initiation[10]. Therefore, the dose of methadone is gradually titrated over days and weeks to achieve a stable maintenance dose, which is a balance between preventing withdrawal symptoms (dose too low) and intoxication (dose too high). Patients should be monitored for signs of withdrawal or intoxication and dose adjustments carried out accordingly. CPs, who would see the patient on an almost daily basis during the initiation stage, can help monitor the patients' response to treatment[10]. Significant clinical methadone-drug interactions have been reported in patients receiving OST [58], and patients are at increased risk of overdose during the dose titration stage.

Because of its antagonistic property, buprenorphine can precipitate withdrawal if given to patients who still have an opioid agonist drug in their blood. Typically, it should be started when the patient begins to show signs of withdrawal from the opioid drug they have been using. The CP supervision when dispensing the starting dose of buprenorphine, needs to ensure the risk of precipitated withdrawal is considered and explained to the patient[10].

1.5.3 Maintenance therapy

During the maintenance stage, patients are stable on their substitute's prescribed dose and, therefore, at reduced risk of harm associated with illicit drug use. The risk of death is lower at this stage than in the initiation or detoxification stages. During the maintenance stage,the prescriber completes less frequent reviews of the patient, but this is at least three-monthly[10]. Based on the risk assessment and personal circumstances of the patient,

they can be taken off supervised consumption and collect their medication by instalments instead of a daily collection. CPs are the healthcare professionals who see the patient most frequently during this maintenance stage of treatment.

The duration for which a patient remains in maintenance therapy depends on the patient's circumstances, their preference, and the clinical support available to support them in recovery[10]. The maintenance therapy can often last for an extended period, sometimes lifelong[10].

1.5.4 Detoxification stage

The opioid detoxification process helps patients to become drug-free safely and effectively. The drug dose is reduced gradually, usually every week or two weeks, to minimise the withdrawal symptoms [10, 59]. Although the same drug prescribed in maintenance is often used in detoxification, alternative medicines can also be used [59]. For example, those on methadone maintenance can move on to buprenorphine for detoxification. Patients have been reported to be able to reduce buprenorphine doses more quickly than methadone[10]. Naltrexone, an opioid antagonist, can be prescribed once the patient has been opioid-free to prevent relapse. It blocks the effect of opioids, thus controlling any temptation for illicit opioid consumption. Lofexidine, an alpha-adrenergic agonist, is used to relieve withdrawal symptoms in those who are using small amounts of opioids but is not useful in detoxification for patients with substantial dependence [10].

1.5.5 Tolerance/The three-day rule

If a patient fails to take their OST medication for three days, it is likely their opioid tolerance level would have reduced, and therefore they would be at risk of overdose if they were to carry on taking the same OST dose [10]. UK clinical guidelines recommend the CP contact the prescriber to seek advice on whether the patient can continue on the prescribed dose or whether a re-titration from a lower dose is required. However, if a five-day supply has been missed, the patient would need to be reassessed by the prescriber[10].

1.6 Opioid-related deaths

Almost half (49.2%, n=2,160) of all drug-related deaths in England and Wales recorded in 2019 involved an opiate[60]. Similarly, in 2019, Scotland registered its worst year for opioid-related deaths, where 86% (n=1,092) of drug-related deaths had one or more opiates implicated[61]. A similar trend was also seen globally, where opioid-related deaths accounted for up to half of all drug-related deaths[46]. Opioid-related deaths have increased exponentially in the United States, and the trend is likely to continue[62]. In 2017, opiates were involved in 67.8% (n=47,600) of all drug-related deaths recorded in the United States[20]. Therefore, the burden of opioid overdose deaths is significant.

1.6.1 Death among OST patients

The risk of premature death is ten-fold higher in those dependent on an opioid than the general population[16]. Being in treatment, however, reduces the mortality rate among opioid users [16]. The benefit of structured substitution therapy has been well documented in the scientific literature [63-65]. Methadone treatment has been shown to reduce both overdose and all-cause mortality in treatment populations [14, 15]. The mortality rate is reduced by one-third [13] to one-half [16, 66] among opioid users while on OST than expected in users not receiving OST. A fourfold reduction in methadone overdose death was reported in England and Scotland since the introduction of the supervised consumption scheme in the early 1990s' [9]. According to a PHE report in 2017, in the last ten years, the English public treatment system for opioid use disorder is estimated to prevent an average of 880 deaths annually from opioid-related deaths[67].

While methadone deaths per gram of methadone prescribed have fallen, the overall number of opioid-related deaths has not declined[68]. Claridge and Goodair report nearly a third (32.5%) of methadone-related deaths occurred in those for whom the drug was prescribed[69]. In Scotland, data reported in 2016 shows 46% of opioid-related deaths were people who were being

prescribed OST at the time of their death[70]. This was a sharp increase from 22% in 2009 [70].

While death in the OST population is mostly the result of accidental overdose, several factors underlay the causes of overdose. The substitute being prescribed, treatment stage, co-morbidity, drug-taking behaviours, geographical locations, age, and gender of the patient all can affect the mortality rate among the OST population [16, 17, 19, 71, 72].

1.6.2 Mortality risk and the substitute

Based on the NHS prescription data for methadone and buprenorphine and the mortality data from ONS, Marteu et al. concluded buprenorphine to be six times safer than methadone with regard to overdose risk among the general population[73]. While buprenorphine is associated with low mortality compared to methadone[73, 74], the lower retention rate with buprenorphine[57] means patients go through multiple episodes of 'increased risk period,' i.e., induction and abstinence[13, 72]. Therefore, the potential for the short duration of treatment on buprenorphine means that despite the lower risk, it may not offer greater protection than methadone [68, 72, 74, 75]. The effect of the duration of OST on mortality rate remains to be established.

1.6.3 Mortality risk and treatment stage

The risk of death in OST patients is high during the initiation stage and when and after the patient is detoxifying from the treatment [72, 75]. A systematic review by Sordo et al. reports a high mortality rate among OST patients during the first four weeks (induction phase) and the four weeks after stopping treatment (cessation phase)[13]. They found a mortality rate of 6 per 1000 while on treatment which increased to 30 per 1000 in the four weeks after stopping OST [13]. This pattern of high mortality rate at the two stages of treatment has been reported by many authors, including Hickman et al.[74], Degenhardt et al.[72], Cornish et al.[75]. However, a longitudinal cohort study in Norway reports no increased mortality rate at the initiation and cessation phase of OST[66]. This study suggests the contrasting finding

could be due to how the service is delivered in different countries and the characteristics of the at-risk population[66].

1.6.4 Mortality risk and drug use

The overwhelming majority of methadone and buprenorphine overdose or deaths involve consuming other drugs, most commonly alcohol [10, 18, 19, 54, 76]. Consumption of supplementary opioids, benzodiazepines, and alcohol while receiving OST significantly increases OST patients' mortality risk [2, 77]. The finding of other drugs in methadone-related deaths is not a recent phenomenon and has long been reported[78].

The availability of illicit heroin or its purity has also been linked to the trends of opioid overdose deaths seen in the UK[79]. The sudden increase in drug deaths in 2013, 2014, 2015, and 2016 was partly attributed to the availability of high purity heroin in the illicit drug market[67]. As these spikes in deaths came along after adopting the new drug strategy in 2010, the possible impact of the new drug strategy on drug deaths cannot be overlooked[80].

1.6.5 Mortality risk and demographics

The ageing cohort of heroin users in England and Scotland has also been linked to the recent rise in opioid overdose deaths in these countries [67, 70, 79, 81]. ONS data for 2019 shows drug misuse deaths to be highest in those aged 40 to 49 (n=845), followed by age groups 30 to 39 (n=710) and 50 to 59 (n=705)[60]. Cumulative physical and mental health conditions make this cohort more susceptible to overdose[81]. Given opioids are metabolised in the liver, declining hepatic function in an ageing cohort also increases the risk of opioid overdose[54, 81]. Hepatitis C is prevalent among PWID, increasing the chances of liver damage, therefore, increasing the risk of overdose[82]. PHE identifies 95% of people who use drugs (PWUD) to be smokers[81]. Respiratory depression is the most probable reason for death in opioid overdose[54]; therefore, long-term smoking makes substance misusers more susceptible to overdose[67]. An Irish retrospective case-control study demonstrated OST patients have a higher burden of complex medical

disease[83]. Medication used in treating other medical conditions, particularly those that have the potential for respiratory depression or those affecting metabolism of methadone and buprenorphine, can also increase the risk of overdose in OST patients[54].

There are also differences in death rates between males and females. In 2018 and 2019, males represented two-thirds of drug-related deaths registered in England and Wales (male/female n=2984/1375 in 2018 and n=2968/1425 in 2019)[19, 60]. ONS data of recent years also suggest most opioid-related deaths occur in men. Of the 2,160 opioid-related deaths reported in 2019, 70% (n=1524) were men[60]. In fact, in England and Wales, accidental drug poisoning was the leading cause of death in males aged 35 to 49 years[19]. A PHE analysis in 2016 showed the median age of drug misuse death had increased by nine years in a 13-year period[67].

1.6.6 Underlying causes of deaths

In England and Wales, 87% of drug-related deaths in males and 67% in females result from an accidental overdose. Suicide is the second-largest underlying cause of overdose death, representing 16% of male and 30% of female deaths, respectively[19]. A small number of deaths (3% or less) are attributed to behavioural disorders resulting from drug use or assault involving drugs[19].

Deprivation and socioeconomic inequalities are cited, to some extent, as reasons for the higher drug-related deaths in some areas of England, particularly the North East and North West of England[60, 81]

1.7 Policy and context

The UK Drug Strategy addendum in 2017 emphasised the aim to reduce all illicit and other harmful drug use and increase the rate of individuals recovering from their dependence[84]. Like the 2010 strategy[80], this policy document emphasises 'recovery' orientated approaches. The 2017 strategy is ambitious in defining recovery where it classifies recovery as being free

from dependence for 12 months compared to 6 months in the 2010 strategy. The drug treatment approach of recent years can be seen as a move away from the pre-2010 approach where 'harm reduction' seemed to be its central message[85]. While the harm reduction approach focuses on reducing the negative consequences of drug, the recovery oriented approach focuses on getting the user free from drugs altogether. A 2016 Advisory Council on the Misuse of Drugs (ACMD) report on reducing opioid-related deaths observed this shift of approach in UK drug strategy and points to the possibility of it being a reason for high opioid-related mortality [79]. Other experts in the field have also raised concerns about the negative effect such a recovery-oriented approach might have on drug-related deaths [86, 87].

Internationally, drug treatment policy varies, with some European countries taking a more liberal approach than others. In Sweden, drug policy liberalisation coincided with a decrease in opiate-related deaths, but an increase in methadone and buprenorphine-related deaths[88]. Decriminalisation of personal possession and consumption of drugs in Portugal in 2001 is linked with a two-third reduction in opioid-related deaths. In contrast, it has doubled in the UK in the same time frame[89]. The call to review drug policy in the UK is growing [86, 89].

Drug consumption rooms are supervised facilities where drug users can inject illicit drugs under medical supervision[90, 91]. These facilities have been operational in Europe for three decades and in countries like Canada and Australia[92]. These facilities have been shown to reduce drug-related deaths and other health risks associated with unsafe injection practice. It also reduces drug visibility and related littering on the streets [90, 93]. The UK lags behind many developed countries in adopting this approach to treating addiction and preventing overdose deaths[91].

1.8 Guidelines and strategies to prevent overdose

The management of substance misuse in the four devolved nations is guided by the 'Drug misuse and dependence: UK guidelines on clinical management 2017' [10]. This comprehensive document often referred to as the 'Orange

Guide,' covers different aspects of substance misuse treatment, including pharmacological interventions and CP's role within it. The UK clinical guideline highlights the importance of two-way communication between the prescriber and the CP dispensing/supervising the dose. It also emphasises CP's role in discussing risk management with patients and ensuring all harm reduction options such as overdose awareness and provision of naloxone where available are addressed[10]. Where CPs do not offer the THN service, they should be aware of local provision so as to signpost patients appropriately. [10] It also emphasises ensuring patients' privacy and dignity in the pharmacy, particularly while supervising the consumption.

Community pharmacists and community pharmacy premises in England, Wales, and Scotland operate under the registration and the standards set by the General Pharmaceutical Council (GPhC)[94]. In Northern Ireland, this role is undertaken by the Pharmaceutical Society of Northern Ireland[95]. The GPhC sets out the standards of conduct and performance for professionals providing pharmaceutical services. As in the UK clinical guidelines, it highlights the importance of treating patients with dignity and ensuring patient confidentiality and privacy is always maintained.

The National Instutute for Health and Care Excellence (NICE) has issued the 'Methadone and buprenorphine for the management of opioid dependence (TA114)' guidance for OST and related services[40, 59, 96], and provides evidence-based recommendations for managing opioid dependence in adults. Drug misuse in over 16s: opioid detoxification (CG52) guidance provides recommendations for treating people who are undergoing detoxification for opioid addiction. The Needle and syringe programmes: Public health guideline [PH52] makes specific recommendations for community pharmacy-based needle and syringe programmes[40]. This guidance emphasises discretion and protecting the privacy and confidentiality of users of the service in community pharmacies. It also highlights the role of pharmacists in referring substance misusers to drug treatment services.

The Advisory Council on the Misuse of Drugs (ACMD) report in reducing opioid-related deaths recommends that the OST be provided according to the

national clinical guidelines' recommendations. It also suggests wider availability of naloxone to those using opioids and their family and friends[79].

Public Health England (PHE) recommends making the services easily accessible and attractive to encourage drug users to engage in treatment to reduce substance misuse. It calls for widening of the availability of naloxone and the needle and syringe programme, and identifies flexible opening times and accessible locations of community pharmacies as methods to improve access to OST services[67]. Another 2016 PHE report titled 'Understanding and preventing drug-related deaths' made similar recommendations[81]. It also recommended reflecting on commissioning and clinical practice to avoid poor practice and maintain a balanced approach to risk and ambitions for recovery[81]. While these reports suggest changes to the primary care OST services in general, they remain silent on the role community pharmacy can play.

In response to the growing drug-related death crisis, the Collective Voice and the NHS Substance Misuse Provider Alliance (NHS SMPA) published a summary of best practices and innovations from drug treatment providers in 2017 [77]. It established five practice points in addressing drug-related deaths. This document identifies CPs offering NSP services as important in identifying individuals at risk of overdose and providing information and advice to minimise the risk. Among other barriers, it identifies the lack of pharmacy based NSP as a challenge in implementing guidelines to prevent overdose deaths. This document also calls for broader access to THN in tackling opioid overdose.

1.9 Research chronology

In 1988, Glanz et al. reported on community pharmacies' role in preventing AIDS among misusers of injected drugs [97]. This study was repeated in 1996 by Sheridan et al. [98]. These were the first studies to explore the role of CPs in England and Wales in providing care to those who misuse drugs. Sheridan et al. also reported on the attitude of CPs involved in providing the

service to PWUDs[99]. This study reported a positive attitude of CPs in delivering services to those who misuse drugs.

In a survey of Scottish CPs reported in 1999, Matheson et al. found that CPs who provided services to those who misuse drugs are likely to have a significantly more positive attitude towards this population[100]. It called for improving CPs' attitude by providing training and better remuneration for community pharmacies' services.

In 2001 Fleming et al.[101] reported on Northern Ireland's CP role in providing care to PWUD and compared it to the English CP survey results reported by Sheridan et al. in 1997[99]. This study identified that Northern Ireland's CPs' involvement in illicit drug users' services was lower and less well defined than their counterparts in England and Wales.

In 2007, Sheridan et al.[31] reported another national survey of English CPs and compared it with the findings of a similar study conducted a decade earlier[99]. This comparative study showed a marked increase in CPs involvement in services to PWUD, particularly in SC. In the same year, 2007, coincidentally, Matheson et al. [33] reported on a national survey of Scottish CPs which compared its results with findings from another study reported ten years earlier[100]. As in England, this study showed an increase in Scottish CPs' attitude and involvement in providing services to PWUD, with a noted exception for NSP. The Scottish survey was repeated in 2016 by Matheson et al.[32] which identified training as a critical factor in improving the involvement and attitude of CPs towards PWUDs. A similar national study of English CPs has been lacking. This doctorate attempts to address some of these gaps in the literature in this area.

In 2010, Strang et al. studied the impact of SC on methadone-related deaths in England and Scotland. It reported a four-fold reduction in methadone-related deaths since the introduction of SC in the mid-90s' [9]. This was the first study to link reduction in methadone-related deaths in England with a specific intervention provided by CPs, namely supervised consumption. This study formed the nesting ground from which the author has attempted to explore the role of CPs in preventing OST-related deaths.

1.10 Summary of literature review

Previous research in OST services in community pharmacy has focused on practice and the delivery of the service itself. CP's challenges in delivering the service, the attitude of CPs towards OST, patient perspective of the service have been widely researched and reported. However, there has been limited research exploring the role of CPs in preventing OST-related deaths. CPs practice needs to be better understood to unpick what more they can do to avoid OST-related deaths.

1.11 Aims and Objectives

The overall aim of this research is:

'To investigate the role of English community pharmacists in preventing opioid substitution therapy-related deaths and to explore what more can be done to prevent such deaths.'

This PhD's aim was identified based on a preliminary literature review and was set before conducting any fieldwork. The mixed methods research was conducted in three phases to answer this research question. While this doctorate's broad aim remained unchanged, the aim and objective of the three phases designed to answer the research question evolved and emerged as the research progressed. The direction and the aims of the different phases of the research were guided by the literature review and the research findings as they presented. The context of formulating the aims of each phase of research is discussed in the corresponding chapters. A reflexive account is also presented in the preface about the direction of the research. For clarity of the reader, the aims and objectives of each phase of this doctorate are summarised below.

1.11.1 Phase ONE aims: (qualitative interview study)

This phase of the research aimed to provide an in-depth exploration of CP's practice in relation to OST and preventing OST-related deaths . It explores the challenges and opportunities faced by CPs' providing this service. More specifically, the aims of phase one were;

- To explore the community pharmacists' role in preventing OST-related deaths.
- To explore CPs' understanding of the risks associated with OST.
- To explore what more CPs could do to reduce OST-related deaths.

1.11.2 Phase TWO aims: (qualitative observation study)

The second phase of this research was designed to go beyond the words spoken by the participants to understand the professional context and behaviours of CPs in delivering OST services in practice, using observation methodology. The aims of phase two were:

- To explore the practice of the delivery of OST services in community pharmacy.
- To identify interventions or potential for interventions that may prevent OST-related deaths.

1.11.3 Phase THREE aims: (quantitative cross-sectional survey)

The third stage was designed to see whether the qualitative findings were more generalisable in quantitative results by taking a survey snapshot of CPs' OST related practice using a population sample. The specific aims of phase three were:

- To quantitatively measure CPs' self-reported activity regarding OST-related death prevention.
- To hypothesise interventions to reduce OST-related deaths.

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Chapter 2
Methodology and Methods

Chapter overview

This PhD utilised a mixed method research approach. A qualitative interview study was followed by qualitative observation which together informed a quantitative survey. This chapter describes the research philosophy adopted for this PhD. It starts by explaining different philosophical approaches to research and then explains the methodological considerations and methods used in conducting this research. It briefly describes the strengths and drawbacks of different methodologies and methods and gives justification for those used in this research.

2.1 Introduction

Methodology is the backbone of any research, which determines the philosophical approach to the research. The methodological approach for any research should be based on the research objective/s. This PhD used a mixed-methods approach to answer the research questions. The merit of this approach is argued throughout this chapter.

The ontology, epistemology, methodology and methods are important elements of any research. While they tend to overlap sometimes, they all represent a specific and important element of research. While ontology refers to the nature of the reality, epistemology deals with the knowledge to understand the reality. The epistemological assumptions are guided by the ontological assumption made by a researcher[1]. The epistemological stance undertaken by a researcher modifies the methodological approach, which then goes on to justify, guide and evaluate the methods employed in the creation of knowledge[2].

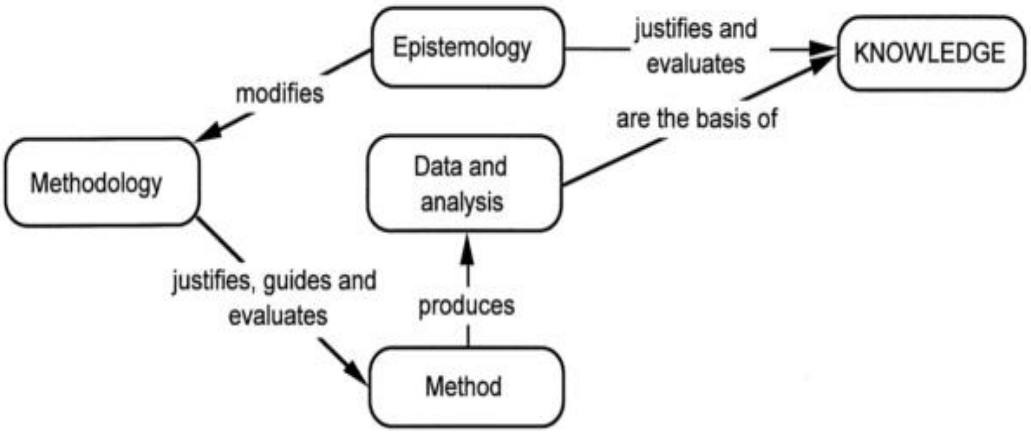

Figure 2.1: The relationship between epistemology, methodology, and method in creating knowledge[2].

Methodology is the philosophical framework within which the research is conducted or the foundation upon which the research is based[3]. It can also be described as a lens through which the researcher looks to find the appropriate method to answer the research questions. The methodology, therefore, is also a determinant of the methods to be used in answering the research questions. Whereas the method is the tool used to answer the research questions.

2.2 The philosophical assumptions

Research philosophy refers to the use of abstract ideas and beliefs that informs the research[4]. Researchers take various approaches to classify their philosophical stance. The value of making these stances explicit in a research study is that it enables the reader to use the appropriate criteria with which to judge the merits of the research[5]. This doctoral study undertook a pragmatic philosophical approach in conducting the research. The philosophical assumptions commonly referred in health literature are discussed below in the context of the researcher's own stance.

2.2.1 Positivism

A positivist approach undertakes that the world is objective and value-free and that the science should restrict its attention only to observable facts[6]. Positivism requires the researcher to distance themselves from the research and not express their biases in the research[4]. Such an approach is usually suitable for those undertaking quantitative research. This doctorate's objectives were to explore community pharmacists' practice in the context of the natural world of community pharmacy. The positivist stance does not allow the flexibility to achieve such objectives; therefore, this approach was considered unsuitable for this research. Moreover, this philosophical approach would not have taken advantage of the researcher's experience as a community pharmacist in interpreting the results.

2.2.2 Constructivism or interpretivism

In contrast to a positivist, the constructivist or an interpretivist sees the world as a layer of multiple realities which is co-constructed between the researcher and those being researched[4, 7]. This approach, therefore, allows the researcher to bring their own personal, cultural and historical experiences in the interpretation of the research[4]. While such a constructivist approach would have been suitable for the interpretative and explorative (qualitative) elements of the doctorate, it would not have been supportive of the more positivist (quantitative) elements of the research.

2.2.3 Pragmatism

Pragmatists believe that the world is not an absolute unity and that the research always occurs in social, historical, political and other contexts[4]. It provides the researcher with the freedom to choose the methods and techniques that best meet the needs and the purpose of the research[4]. It believes that the reality is known through using many tools of research that reflect both objective and subjective evidence. The philosophical flexibility offered by the pragmatist approach was utilised in this thesis to combine the qualitative and quantitative methods in answering the research questions.

As discussed above, the positivist and the constructivist stances on their own fail to encompass the scope of this doctoral study. A pragmatic stance sets the researcher free of the constraints of any one epistemological position thus allowing the selection of methodological approaches that best answer the research question. In this doctoral study, the pragmatist stance allowed the mixing of qualitative and quantitative approaches along with utilising the researcher's experience as a community pharmacist in understanding the reality.

2.3 Qualitative methodology

Qualitative research was born out of a recognition that each individual experiences the world in fundamentally idiosyncratic ways[8]. It is

concerned with the meaning of people's experiences, how people make sense of these experiences and what is it like to have these experiences[9]. Qualitative research answers questions about experience, meaning and perspective, most often from the participant's standpoint. These data are usually not amenable to counting or measuring[10]. This naturistic way of research aims to explore and understand the phenomenon in question rather than testing hypotheses[6]. Qualitative research, therefore, has a constructivist or interpretivist stance[11], and there is an emphasis on the role of the researcher in the construction of the data[12].

There are many different variants, and qualitative researchers may disagree among themselves on fundamental issues[6]. Pistrang and Barker take the stand that there is more similarity than difference among many of the approaches to qualitative research[6]. Ultimately, what should be important is that the research is executed/completed in a systematic way that meets its aims, rather than the particular label that is attached to it.

2.4 Quantitative methodology

The quantitative research methodology has a positivist stand[11, 13]. Quantification of the findings is a dominant feature of any quantitative research. It results in numerical data that are objective and exist independently of any undue influence of the researcher[12]. Causality, generalisability and replicability are other preoccupations of qualitative research[13]. Since qualitative research does not generally seek to enumerate, it is viewed as the antithesis of the quantitative method; indeed, the two approaches are frequently presented as adversaries in a methodological battle[14].

Table 2.1: Comparison of quantitative and qualitative methods (adapted) [11, 15]

	Qualitative	Quantitative
Philosophical foundation	Constructivist or Interpretivist	Positivist, Objectivist
Aim	To explore complex human issue	To test pre-set hypothesis
Study plan	Iterative, flexible	Step-wise, predetermined
Position of researcher	Integral part of research process	Aims to be detached and objective
Assessing quality of outcomes	Indirect quality assurance methods of trustworthiness	Direct tests of validity and reliability using statistics
Measures of utility of results	Transferability	Generalisability

2.5 Mixed methodology

In mixed methods research, the investigator collects and analyses data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or a program of inquiry[16]. While combining qualitative and quantitative methods in a single study is widely practised and accepted in many healthcare research areas, there are critics of this approach[17].

Critics of mixed methodology argue that mixed-methods research is now being adopted uncritically by a new generation of researchers who have overlooked the underlying assumptions behind the qualitative-quantitative debate[17]. The two methods are based on different paradigms of

ontology, epistemology and methodology and their paradigmatic assumptions; the two methods do not study the same phenomena[17]. The proponents of mixed methodology, however, see the two methods as complementary to each other. Both the qualitative and quantitative paradigms have weaknesses which, to a certain extent, are compensated for by the strengths of the other.[18, 19]. The fact that the approaches are incommensurate does not mean that multiple methods cannot be combined in a single study, if it is done for complementary purposes[17]. By using mixed methods, health science investigators can answer new questions and more comprehensively capture complex phenomena, hard-to-measure constructs, and interactions in specific settings and contexts as well as in experimental settings[19]. Methodologically sound mixed methods research can improve our understanding of health services by providing a more comprehensive picture of health services than either method alone[20].

2.5.1 Why mixed methodology?

A researcher could adopt the mixed-method approach for various reasons. Justification for using mixed methods ranges from the complementarity of the two methods, triangulation, credibility, and social justice rational [13, 21, 22]. Bryman has listed 16 reasons as to why a researcher may use mix methods[13]. Those relevant to this research, along with justification, are summarised in the table below.
This doctorate utilises a series of qualitative interview study, qualitative observational study and quantitative postal survey in answering the research question.

Table 2.2 : Ways of combining qualitative and quantitative methods (Adapted from Bryman 2016)[13]

Reasons for a mixed-methods approach	Justification for adopting the mixed methodology
Triangulation or greater validity	The findings of both qualitative and quantitative data are combined to corroborate the findings in the discussion chapter
Offset	The strength of qualitative research to produce highly enriched and contextualised data is utilised to inform the quantitative survey, which in turn make the findings more generalisable than from a qualitative study.
Completeness	The mixing of the methods give a more complete account of the area being researched.
Different research questions	The distinctly different research questions posed in the thesis is answered by the two methods. While the qualitative studies help to explore the research area, the quantitative research quantified the findings.
Explanations	The quantitative survey is used to explore and explain the results of the qualitative study. The results from the two methods are used to explain the overall findings.
Instrument development	The interview study is used to develop the observation tool, and the two qualitative studies' finding then inform the development of the survey tool.
Sampling	The interview cohort is used to recruit the participant for the observations study.
Credibility	The qualitative and quantitative studies are used to enhance the integrity of the findings.

Utility	The usefulness of the findings and the recommendations for practice and policymakers is improved by combing the two methods.
Confirm and discover	The qualitative data is used to generate a hypothesis, which is tested in the survey study.
Enhancement	The findings of the qualitative studies are augmented by exploring it further in a national survey.

The subject area of this doctoral thesis has not been researched in great detail; consequently published literature in the subject area is limited. The qualitative interviews were therefore used to gain a nuanced understanding of CPs' experience of providing OST, their opinion and role in preventing OST-related deaths. The results of the interview study were further explored and expanded upon by conducting an ethnographic observation study. The design and the aim of the observation study were informed by the findings of the interview study. Such detailed, textured and often sensitive data could only have been obtained by qualitative methods. The results of the qualitative studies were then synthesised to develop a research tool (questionnaire) for the quantitative component of the research. The design and the aim of the survey were informed by the findings of the two qualitative studies. This research tool was used to take a snapshot of national practice within the context of the research questions. The results from all three studies were further interpreted in the discussions chapter of this thesis.

2.5.2 Mixed methodology designs

Mixed methods research can take various forms depending on the order in which data are collected, the emphasis given to the different stages of the study and where the mixing occurs[23, 24]. It can broadly be categorised into four different types; the convergent parallel design, the

explanatory sequential design, the exploratory sequential design and the embedded design[23].

In the convergent parallel design, both the qualitative and quantitative components of the research are undertaken at the same time. The results from the two data sets are analysed and compared to see if they converge to produce a meaningful interpretation of the results. In the explanatory sequential design, the quantitative component is followed by a qualitative component. The results of the qualitative study are used to explain the findings of the quantitative study. In the exploratory sequential design, the qualitative component leads to the quantitative phase. In this method, the qualitative phase is often used to develop study materials (e.g. questionnaire), and the quantitative results are used to see if the qualitative data can be generalised. In the embedded design, one component is embedded within the other, and one usually dominates the other.

This study used the exploratory sequential mixed method strategy. Both the qualitative and quantitative component has an equal bearing. The results of the qualitative work (interviews and observations) guided the quantitative phase (survey); thus, fitting the exploratory sequential design scheme.

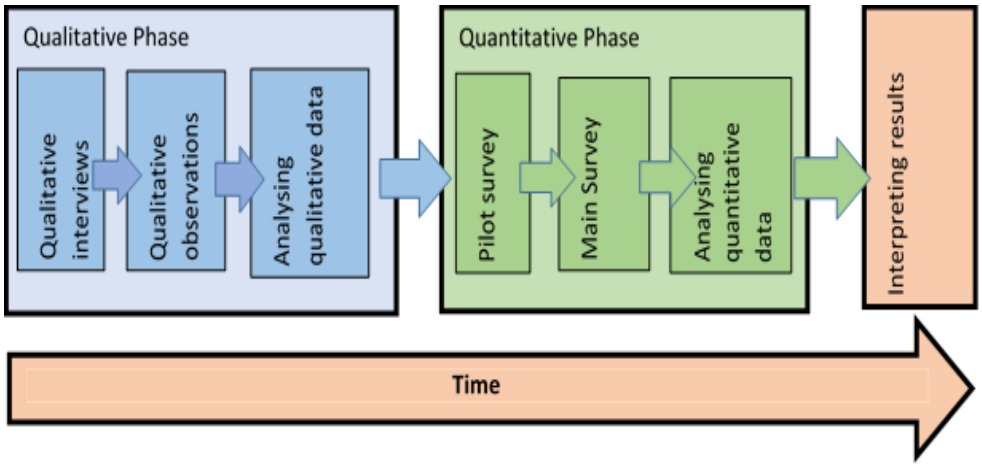

Figure 2.2: The interrelationship between different phases of this mixed-method study

Table 2.3: Methodology and method used to generate and analyse data in the three research stages

Study phase	Methodology	Method of data collection	Analytical approach
Pharmacist Interview	Qualitative	Semi-structured face to face interviews	Interpretative phenomenological analysis (IPA)
Observation Study	Qualitative	Non-participant observation	Combined framework method
Pharmacist survey	Quantitative	Telephone survey	Quantitative descriptive and inferential analysis

2.6 Qualitative Methods

Here an overview of different qualitative research methods and justification for using the specific methods are presented. The detailed development of the data tools and administration of the research are presented in the relevant chapter of the thesis.

2.6.1 Data collection (qualitative)

Data collected through qualitative methods are usually in the form of text or audio-visual recordings. Data collection methods like the interview, focus groups, case studies and observations are commonly deployed in health services research. These data collection methods are usually

deployed to gain in-depth understanding of subject area that are not widely researched.

2.6.2 Interview study

In interview studies, the researcher sets the agenda for the discussion, and the words spoken by the participants become the data[12]. Qualitative interviews can take various forms with varying degrees of flexibility, depending on the objective of the research[13]. In an unstructured interview, the researcher sets the ball rolling by introducing the topic and the interviewee develops their own ideas and follows their own thoughts. In contrast, the structured interview follows a set of usually very specific questions, read out in the same order[12, 13].

The first phase of this PhD study utilised semi-structured face to face interviews as a data collection tool. In semi-structured interviews, the researcher not only has flexibility over the order of the questions; it also allows to ask questions that were not anticipated at the start[25]. Unlike others, the semi-structured interview enables the probing of the participants' views and opinions. Therefore, this method of data collection is useful when the objective of the research is to explore the subjective meaning of events as perceived by the participants[25].

Due to the nature of the subject being researched expressing sensitive views and experiences might have been difficult by another data collection method like a focus group. Crucially, a one-to-one interaction during an interview helps build rapport between the researcher and the participant, facilitating their engagement with the research[25]. This rapport developed between the researcher and the participants during this study was potentially helpful in minimising Hawthorne's effect in the observation phase of the research[26, 27]. Gaining an in-depth highly contextualised perspective of the participant was important to achieve the stated objective of this phase.

2.6.3 Observation study

According to Gray (2008), observation involves the systematic viewing of people's actions and the recordings, analysis and interpretation of their

behaviour[25]. This research method allows the researcher to get beyond people's opinions and self-interpretations of their attitudes and behaviours, towards an evaluation of their actions in practice[25]. This method, therefore, suited the second phase of the PhD study. While the thesis explored the participants' opinion and interpretations of their own practice through interviews, the observational study allowed the researcher to go beyond it and evaluate their practice as it happened. Nonetheless, observational studies have their own criticism. Human memory frailties mean we forget most of what we see and what we recall is affected by recall and perception bias [12]. The researcher's competency, the power of recall, the commitment of an individual researcher will all have an effect on the observational data collected[12]. The reliability of observational studies can be increased by undertaking a more structured recording of what is being observed[25]. This study developed and used an observation schedule to collect data. Depending on the researcher's role, observational studies can take several forms, summarised in the table 2.4

2.6.4 Observation template

The events and behaviour that occur in observation sites can be complex and multifaceted. Thus it is impossible to record every activity that is observed unless it is visually recorded. The observation schedule needs to be selective in the items that are most relevant for the research[12]. A semi-structured observational approach was adopted to keep the focus of the observation on the research questions, yet lending flexibility to identify any new themes emerging[28]. The development of the observation template is described in chapter 4 (observation chapter).

Table 2.4: Four combinations of observational studies

	Participant	Non-participant
Overt	**Overt participant observation** Researcher observes as well as participates in interactions. Participants are aware of being observed.	**Overt non-participant observation** Researcher observes but does not participate in interactions. Participants are aware of being observed.
Covert	**Covert participant observation** Researcher observes as well as participates in interactions. Participants are unaware of being observed.	**Covert non-participant observation** Researcher observes but does not participate in interactions. Participants are unaware of being observed.

2.6.5 Hawthorne effect

The Hawthorne effect is when there is a change in the subject's normal behaviour, attributed to the knowledge that their behaviour is being watched or studied[27]. Such reactivity shown by participants is, therefore, a challenge in observation studies [27, 29]. Measures can be taken in the study design to minimise participant reactivity in observational studies [26, 27, 29]. In this study, these included building good rapport with the participant, using a non-formal approach to communication, flexibility in scheduling the observations, dressing neutrally and a friendly approach towards participants. These measures were adopted as validated strategies to minimise the Hawthorne effect [26, 27].

2.6.6 Sampling (qualitative)

In qualitative studies the sample sizes tend to be small, are studied intensively, and each one typically generates a large amount of

information [30, 31]. Qualitative researchers tend to follow the purposive sampling technique where samples are selected based on their characteristics relevant to answering the research question [13]. Qualitative samples are designed to make possible analytic generalisations (applied to wider theory on the basis of how selected cases 'fit' with general constructs), but not statistical generalisations (applied to wider populations on the basis of representative statistical samples) [30]. Other non-probability sampling technique used in qualitative research is convenience, snowballing or accidental sampling, where participants are selected for being easily available as research participants[32].

2.6.7 Analysing and reporting (qualitative)

Of all the phases of a qualitative study, data analysis is considered the most complex and mysterious phase[33]. Unlike quantitative data analysis, clear-cut rules about how qualitative data analysis should be carried out have not been developed[13]. Qualitative data analysis involves interconnected steps of organising data, reading the database, coding and organising themes, representing the data and presenting an interpretation of the data[4]. Qualitative analysis is the interplay between researchers and data[34]. The analysis, to some extent, begins as the data is being collected, which then informs the process of additional data collection. For this reason, some argue that the qualitative data analysis processes are not entirely distinguishable from the actual data[33].
The underlying theoretical techniques of qualitative analysis and the justification for their use in this thesis are discussed below.

2.6.8 Interpretative phenomenological analysis

Interpretative phenomenological analysis (IPA) was developed as a qualitative analytical approach by Jonathan Smith in 1996. It has been widely used in health research in recent years[35]. IPA is concerned with lived experience and the meaning of those experiences to people[36]. It views participants as the experts of their own personal and social worlds and seeks to establish an equality of voice between the researcher and

the researched[37]. It has three primary theoretical touchstones: phenomenology, hermeneutics, and idiography. While phenomenology is primarily concerned with human lived experience, making sense of these experiences itself requires engagement and interpretation on the part of the researcher. Hermeneutics, the theory of interpretation, allows an IPA researcher to make their own interpretation of the participants' experience. The idiographic element of IPA, unlike other qualitative approaches, allows the researcher to analyse the data by focusing on the particular experience of the individual[35, 36]. This analytical approach was considered appropriate for the interview stage of the doctorate as it allowed the researcher and the participant to relate in terms of their shared professional roles, allowing professional nuances and language to have a shared understanding.

2.6.9 Framework technique

The Framework Method sits within a broad family of analysis methods, often termed thematic analysis or qualitative content analysis[38]. The framework technique is a highly structured approach to qualitative data analysis and is not aligned to any particular epistemological, philosophical or theoretical approach [38, 39]. In this method of analysis, the data is coded into predefined (deductive) and or new emergent codes (inductive), which are then organised into a matrix of codes (column) and cases (rows). The framework, therefore, gives a new, organised easy to follow structure to the dataset.

The combined analytical framework approach was used to analyse the observational data. This approach was adopted primarily because of the flexibility it lent in combining the findings of the interview study with the new themes emerging from the observational study to give a fuller understanding of the research subject. Combining the two studies in this way further demonstrates the mixed methodological approach of this doctoral study.

2.6.10 Other qualitative analytical approaches

Grounded theory is one of the most commonly used approaches in qualitative research [25]. It intends to construct fresh sociological theories through using comparative methods in an iterative process using inductive qualitative data[40]. Therefore, it moves the analysis beyond description into developing new concepts and theories[40].

Another distinct approach to qualitative analysis is narrative analysis. It focuses on exploring the life of an individual with a goal to create generalisations about human processes that hold across individual participants[40].

Case study research, commonly used in medical science[25], is aimed at illustrating the general, by looking at the particular[12]. It focuses on one or a few instances of a particular phenomenon with a view to provide an in-depth account of events, relationships, experiences or processes occurring in that particular instance(s)[12].

2.7 Quantitative methods

Here an overview of different quantitative research methods and justification for using the specific methods are presented. The details of development of the data tools and administration of the research are presented in the relevant chapter of the thesis.

2.7.1 Data collection (quantitative)

Survey and experimental data are the two common methods of data collection in quantitative studies. While experimental methods are used to test the impact of interventions through measurements of the outcomes, surveys explore and describe the phenomenon in real-life situations to determine meanings and frequencies of the phenomenon under investigation at a single point in time (Burns and Grove, 2011). As the aim of this doctorate's quantitative phase was to explore the participants' real-life practice, a survey method was deemed appropriate for data collection. Pharmacy practice researchers have long reported findings based on postal surveys. The response rates of postal surveys among healthcare

professionals are low and declining [41, 42]. A poor response to a survey can limit the survey findings and generalisability of these findings. Telephone surveys were used as a data collection tool to achieve a higher response rate [43, 44]. Bourque and Fielder argue the response rates for telephone surveys are consistently and significantly higher than those for mail surveys[45]. Telephone surveys, however, are more time-consuming and expensive to administer as compared to postal surveys. A telephone survey approach was chosen as an appropriate data collection tool because of the poor response to postal surveys in community pharmacy research.

2.7.2 Samling (quantitative)

In quantitative research, the aim of the sampling strategy is to draw a representative sample from the population so that the results of studying the sample can then be generalised back to the population [15]. Probability sampling, where samples are selected at random, is one of the defining features of quantitative research[25]. In random sampling, the researcher has no influence in sample selection and the selection is based on pure chance. However, when a homogenous representation from a different group within the sample is desired, then the sample can be stratified from which a proportionate number of the sample are picked at random, known as the stratified random sampling[12, 25]. Another commonly used probability sampling technique is cluster sampling, where samples are grouped into clusters and a cluster is selected at random. The drawback of this technique is that the clusters may not be a homogenous representation of the sample[25].

The quantitative phase of this doctorate adopted a stratified random sampling technique to ensure a proportionate representation sample from all geographical areas of the country.

2.7.3 Sample size estimation

The sample size must be a compromise between the competing demands of good science and available resources of time and budget[46]. A study with too many participants is not desirable because it is unethical and a

waste of limited resources to expose more participants to research than necessary[46]. A pilot survey was conducted to estimate the response rate of the telephone survey. The sample size estimation for the main survey was based on the response rate of the pilot survey.
The sample size was calculated using the Surveymonkey online sample size estimation software [47]. The details of sample size calculations are presented within the draft paper in chapter 5 (survey study).

2.7.4 Analysing and reporting (quantitative)

Quantitative data analysis involves statistical tests that are then presented in the form of tables and figures with the written interpretation of the statistical findings[12]. Such findings are then validated through internal consistency or external benchmarks[12]. The quantitative data generated in the survey study was subjected to various descriptive and inferential analysis. Descriptive statistics was used to describe the basic features of the study whereas inferential statistics helped to generate conclusions. Detail of the method is presented in chapter 5 (survey study).

2.8 Rigour and robustness in research

Rigour refers to the extent to which the researchers worked to enhance the quality of the studies[48].

2.8.1 Rigour in qualitative study

While reliability and validity are commonly used to evaluate quantitative work, these criteria are more aligned to the positivist epistemology; therefore, not considered suitable for a more naturalistic approach of qualitative research[13, 49]. Despite the debate in the application of the concept of rigour to qualitative research, conducting qualitative research without sufficient consideration of rigour can be labelled as ‘fictional journalism’, and unable to contribute to knowledge [49]. Several quality criteria have been proposed by researchers over time to evaluate qualitative research[13]. The trustworthiness criteria proposed by Lincoln

and Guba (1985) has four elements which reflect the reliability and validity criteria of quantitative research[50].

2.8.1.1 Credibility

The credibility criteria for assessing qualitative work are comparable to quantitative research's internal validity criteria [13, 49]. As a social reality can have several possible accounts, qualitative researchers may arrive at different conclusions based on their own interpretation of the reality [49-51]. The credibility of a qualitative account can be established through respondent validity where the participants are presented with the findings of the research to confirm that the conclusions drawn are a true representation of the reality[52]. This approach, also known as member checking, puts extra demand on the participants and is also subject to recall bias of the participants[53]. Because of these reasons and the limited resource and time available to the researcher, respondent validity was not undertaken.

The credibility of qualitative work can also be improved by prolonged engagement and persistent observation[50]. The researcher has spent over eleven years working in community pharmacy and therefore has a sound understanding of the research setting. The researcher also spent considerable time engaging and building rapport with participants of the interview and observation studies. Several contacts with the participants leading up to the interviews and conducting the one-to-one interviews in private over a prolonged time meant the researcher had time to build rapport with the participants. Lincoln and Guba state that prolonged engagement provides scope and persistent observation provides depth to qualitative research[50]. This PhD utilised both these techniques in giving credibility to the findings. Nevertheless, as presented under reflexivity, the researcher's insider knowledge of the subject area may also have deterred some of the pariticipants from being completely open in expressing their views.

Triangulation is another technique proposed by Lincoln and Guba in establishing credibility of qualitative work[50] and can be used to address internal validity issues [53]. Triangulation refers to using more than one

method or source of data to study a social phenomenon[13]. It is often presented as a means of addressing qualitative/quantitative differences[49]. The findings of the qualitative interview (chapter 3) and qualitative observation (chapter 4) were compared with the quantitative findings of the cross-sectional survey (chapter 6) to identify similarities and differences in the findings, thus facilitating triangulation of the results.

2.8.1.2 Transferability

The transferability criteria refers to the generalisability of the qualitative findings [49] and is comparable to the external validity criteria of quantitative research [13, 49]. As qualitative findings are based on small sample sizes and are unique to the context and phenomenon being studied, generalisability is usually not an expected attribute of qualitative research[54]. Bryman, Lincoln and Guba encourage qualitative researchers to produce a 'thick description' of the findings which can be used as a database by others to make judgements about the possible transferability of the findings[13]. A thickly described research merges the participants' lived experiences with the researcher's interpretations of these experiences, thus creating thick meaning for the reader as well as for the participants and researcher. This allows the reader to digest the essential elements of the findings and discern whether he or she would have come to the same interpretive conclusions[55].

In the context of this doctorate, the findings of the qualitative studies extend to other community pharmacists in the UK and possibly in other countries operating in a similar context to the participants of this doctoral study. The objectives of the qualitative studies in this PhD were to develop a quantitative research instrument (survey questionnaire) and not necessarily to achieve transferability.

2.8.1.3 Dependability

The dependability criteria for assessing qualitative work is comparable to the reliability criteria of quantitative research and is achieved through auditing[13, 49]. The reliability of the qualitative studies was, therefore, ensured through keeping records of all phases of the research process.

The research was periodically assessed internally by university committees and externally by funding bodies, ethics committees, and editorial boards.

2.8.1.4 Confirmability

The confirmability criteria for assessing qualitative work is comparable to the objectivity or neutrality criteria of quantitative research[13, 49]. While complete objectivity is impossible, the researcher has ensured the personal values and preconceptions have not swayed the conduct or the findings of the research[13]. The researcher has maintained objectivity by constantly reflecting on his viewpoints on different aspects of research design and methodological approaches undertaken. While a brief discussion on reflexivity is presented below, a detailed account of researcher reflexivity is presented in the preface to this thesis.

2.8.2 Robustness in quantitative study

The robustness of quantitative research is demonstrated through reliability and validity. While reliability refers to the reproducibility of the research findings, validity refers to the accuracy of them[48].

2.8.2.1 Reliability

In quantitative research, reliability refers to the exact replicability of the processes and the results[54]. A participant completing an instrument meant to measure motivation should therefore have approximately the same responses each time the test is conducted [48]. The reliability of quantitative research can be assessed through different statistical methods, of which those considered in this doctoral research are discussed here.

a. Test-retest reliability

This is undertaken by repeating the same test (questionnaire) on the same sample (participant) over time. Consistency in the results of these tests indicates a high test-retest reliability. The nature of the test requires multiple responses from the participants, thus placing them under extra

research burden. This would also require the researcher to break the participant's anonymity, which would be against the ethics of the research. This approach would also require considerable resource and time commitment. Therefore, this approach of measuring reliability was not considered for the survey.

b. Internal consistency reliability

The internal consistency test, also known as the Cronbach's alpha test, was performed on factor analysis output. The result of the test meant the findings of the factor analysis were inconclusive.

c. Split half reliability

In this test, the sample is divided into two halves, and correlation is measured between the two halves' items. Because of the lack of statistically interpretable outcome of the factor analysis, this test was not used.

2.8.2.2 Validity

In a quantitative study, validity refers to the extent of accuracy to which a concept is measured[48]. While there are several ways of establishing the validity of quantitative research, for example, face validity, concurrent validity, predictive validity, convergent validity and construct validity [13], this doctorate relied on face validity and content validity technique.
Face validity involves asking for opinion from others who have experience or expertise in the field to determine whether the instrument (questionnaire) measures the intended concepts [13, 48].
Content validity refers to the extent to which the items in a questionnaire are representative of the entire theoretical construct the questionnaire is designed to assess[56].

2.9 Research ethics

Research ethics is the moral principle that guides research[57]. The Economic and Social Research Council (ESRC) has proposed six core principles for conducting ethical research[57].

- Research should aim to maximise the benefit for individuals and society and minimise risk and harm.
- The rights and dignity of individuals and groups should be respected.
- Wherever possible, participation should be voluntary and appropriately informed.
- Research should be conducted with integrity and transparency.
- Lines of responsibility and accountability should be clearly defined.
- Independence of research should be maintained and where conflicts of interest cannot be avoided they should be made explicit.

Throughout this thesis, the discussion of ethical considerations touches on one or more of these principles. This research did not involve any medical intervention or invasive procedure. All research participants were practising health professionals who took part in the research voluntarily. As well as providing written information about the research, participants were given the opportunity to ask questions before giving signed consent. All participants were also aware of their right to withdraw from the research without giving any reason.

According to the University of Bath data management plan, all research data and any supplementary material generated during the research were stored anonymously. Data selected for retention will be preserved for ten years from the end of this thesis or date of research publication as per the University requirement.

All three phases of studies undertaken in this doctorate received ethical approval from appropriate ethics committees, as stated in the corresponding chapters.

2.10 Reflexivity

Reflexivity can be defined as thoughtful, conscious self-awareness. Reflexive analysis in research encompasses continual evaluation of subjective responses, intersubjective dynamics, and the research process itself[58]. In this PhD, reflexivity is used not only as a concept of

qualitative validity[59] but also as an introspection; as a facilitator into one's own personal and social experience[60].
A detailed account of the researcher reflexivity is presented in the preface to this thesis.

2.11 Summary of the chapter

This chapter reviewed the various philosophical approaches to research. It deliberated the strengths and weaknesses of qualitative, quantitative and mixed-method research and presented the argument for selecting the mixed methodology. It also presented the various methods of qualitative and quantitative research and the appropriateness of those selected in answering the objectives of this thesis. While one-to-one semi-structured interviews allowed the exploration of the otherwise under-reported research area, the non-participant observation helped to contextualise the findings. The cross-sectional survey was used to further explore the research question in the community pharmacy practice context and give generalisability to findings. The merits and demerits of different sampling strategies showed the appropriateness of the purposive and stratified random sampling for the qualitative and the quantitative stages of research respectively. The analytical methods discussion demonstrates the suitability of IPA for the interview data and the combined framework method for the observation data.
The section on rigour and robustness in research presents an open account of the quality criteria considered in designing, executing, and presenting this PhD's findings. It also gives an account of limitations in the methods and methodological approach undertaken by the researcher.

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Chapter 3
Interview study

Chapter overview

This chapter presents the qualitative interview study as a research article published in the International Journal of Clinical Pharmacy (IJCP). The presentation of this chapter is centred around the published article and starts with an introductory remark. This article presents the background to this study, the methods, results and a discussion of the findings. The article also highlights the impact of this research on practice and concludes by briefly summarising the findings and how it informs the thesis's next stages.

3.1 Introduction to chapter

As detailed in chapter 1, section 1.9, extensive research in OST has investigated various aspects of OST service delivery in primary care settings. As demonstrated earlier, research is scant in the understanding of the role played by CPs to prevent overdose deaths in those receiving OST. Anecdotal and limited published evidence suggests that community pharmacists may not fully implement clinical actions to prevent OST-related deaths. There is also a lack of evidence as to what more could be done by CPs to reduce OST related deaths. These are some of the fundamental questions which this study intended to explore.

This study's preliminary findings were presented orally at the 2014 Health Service Research and Pharmacy Practice Conference in Aberdeen. The results were written in a journal format and submitted for publication in the peer-reviewed journal 'International Journal of Clinical Pharmacy' on 22nd December 2017. The paper was accepted for publication on 10th January 2019 and first published on 15th February 2019.

3.2 Conference presentation

Peer-reviewed published conference abstract

Yadav R, Scott J, Taylor G, Taylor D. Community pharmacists' role in preventing methadone related deaths: a qualitative exploration. International Journal of Pharmacy Practice. 2014; Volume 22 Issue S1 pages 2-27, April 20014,
(Oral presentation at the Health Service Research and Pharmacy Practice Conference: 3-4 April 2014; Aberdeen) https://doi.org/10.1111/ijpp.12101

3.3 Publication

Yadav, R., Taylor, D., Taylor, G. et al. Community pharmacists' role in preventing opioid substitution therapy-related deaths: a qualitative investigation into current UK practice. Int J Clin Pharm 41, 470–477 (2019). https://doi.org/10.1007/s11096-019-00790-x

3.4 Methods

A concise description of the methods undertaken for this study is included in the published paper. Because of editorial restrictions, not all methods could be detailed within the paper. For transparency and clarity, an additional description of the interview study methods is presented here.

3.4.1 Development of the interview guide

A guide was first drafted based on the initial literature search and reviewed with the supervisory team's input. The interview guide was then tested by conducting two trial interviews with volunteer pharmacists. One of these interviews was observed by a supervisory team member Dr Denise Taylor (DT). Following the test, interviews questions were adapted to make them clear and unambiguous. DT gave feedback on the researcher (RY)'s approach to the interview, tone of voice, body language and probing during the interview.

The interview guide further evolved during the actual interviews to accommodate new and unexpected themes as they emerged.

3.4.2 Geographical sites of recruitment

All community pharmacies in two geographical locations, Worcestershire and Bath and North East Somerset (BANES), were sent an invitation pack by post to participate in the study. These two locations provided a good mix of rural and urban pharmacies.The invitation pack included an invitation letter, an information sheet, an expression of interest form and a free post envelope to return the form. The expression of interest form had seven questions to allow for purposive sampling. Maximal variation sampling was used to gain as broad an understanding as possible based on age, gender, years of experience, experience with substance misuse, role within the pharmacy and other relevant markers. The final number of participants was guided by the principle of data saturation, which was achieved at 24 interviews.

3.4.3 Incentives to encourage participation

No financial incentive was offered for participating in the research. The recommendations of a systematic review on how to increase the response rate to a postal survey was adapted and implemented as appropriate for this research[1]. At the time that this work was being undertaken there were no publications available to support participant engagement in qualitative interview research, therefore the researcher relied on the evidence available at the time, which was only from a quantitative perspective. The invitation pack, a C5 Manila pocket envelope, was addressed to 'The Responsible Pharmacist', all the paperwork held the University of Bath logo, had the contact details of the research team and the invitation letter was signed in ink by RY. The invitation letters were sent on a day to avoid known busy times in community pharmacy, i.e. before public holidays.

3.4.4 Procedure

The interviews, on average, lasted between 35 to 45 minutes, with some extending to an hour. All interviews were conducted at the pharmacy premises. All participants signed the consent form before the interviews were conducted. The participants were given opportunity to ask questions before the interview and were also informed of their right to stop the interview at any stage. The interviews were recorded on an Olympus Dictaphone. Following each interview RY also recorded his own experience of that particular interview which were reflected upon during the analysis. The recordings were transcribed verbatim and each transcript was checked for typographical errors and any missing information.

As noted by Smith et al. qualitative analysis is inevitably a personal process where the researcher may have their way of working with the data. For this study, the researcher used a combination of QSR NVivo 10 software and the traditional paper method to analyse the data. Initially, all transcripts were coded using the software where the data was coded to specific words and phrases. All the codes were reviewed to ensure they represented the experience shared by the participants. The codes were then narrowed down by merging duplicate or similar codes. The use of software allowed the researcher to quickly search for any existing code or rename the codes with

ease. The resultant codes were then grouped into clusters (sub-themes) representing a particular topic within the research area. A manual approach was then adopted to organise these sub-themes into themes. The subthemes were written on individual post-it notes and were stuck on the wall. Based on visual connections and conceptual similarities these subthemes were moved around on the wall to form larger groups (themes) representing a broader aspect of the research area. Further details of the procedure are presented in the published paper (section 3.5).

3.4.5 Confidentiality

All identifiable information in the data were de-identified, and data confidentiality was assured by storing data as per the University of Bath policy on the confidentiality of research data. This includes data only being accessible to the research team members and the destruction of all data 10 years after the project completion.

3.5 Published article

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RESEARCH ARTICLE

Community pharmacists' role in preventing opioid substitution therapy-related deaths: a qualitative investigation into current UK practice

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Abstract

Background Opioid substitution therapy involves prescribing of medical substitutes like methadone and buprenorphine to patients who are addicted to opioids. The majority of opioid substitution therapy dispensing in the UK is done by community pharmacists and they often see the patients on daily basis. It is unknown to what extent community pharmacists implement the policy to prevent overdose in patients receiving such treatment. *Objective* To explore what UK community pharmacists think about their role in preventing opium substitution-related deaths, their understanding of the risks associated with this substitution therapy and their views on what else community pharmacists could do to reduce such deaths. *Setting* Twenty four community pharmacists from two areas in UK (Worcestershire and Bath and North East Somerset). *Method* Between January and March 2013, community pharmacists providing opoin substitution therapy were interviewed in their pharmacy, using semi-structured interviews. Interpretative Phenomenology Analysis was used to analyse the data. *Main outcome measure* Thematically organised description of professional practice as reported by the participants against the clinical/practice guidance for opioid substitution therapy in UK. *Results* While participants felt their role to be essential in providing the service, they did not feel part of an integrated system. Participants' ability to act in risk situations was affected by their knowledge, confidence in intervening in such situation, as well as the support they receive in providing the service. *Conclusion* Participants reported large differences in how 'opioid substitution therapy' services are provided in community pharmacy. Lack of knowledge among some pharmacists and lack of support in providing the service resulted in some patients at high risk not having their risks acted upon.

Keywords Buprenorphine · Community pharmacy · Intoxication · Methadone · Opioid-related death · Opioid substitution therapy · United Kingdom

Impacts on practice

- Pharmacists providing opioid substitution therapy service should receive mandatory standardised training, and mechanisms should be in place to monitor their training and competency; existing mechanism like the 'Centre for Pharmacy Postgraduate Education CPPE self-declaration of competency' can be adopted.
- Practice guidance to pharmacists should be clear and specific to deal with the challenges faced by community pharmacists in providing the service (for example identifying intoxication, dose withholding, out-of-hours referrals, dealing with security concerns).

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s11096-019-00790-x) contains supplementary material, which is available to authorized users.

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- Information sharing between the treatment centres and the community pharmacies should be promt and standardised to ensure clarity and consistency.

Introduction

Opioid substitution therapy (OST) is the mainstay of pharmacological therapy for opioid dependence in the United Kingdom (UK) [1]. The majority of this treatment is provided in the community setting with prescribing being undertaken by either community drug teams or general practitioners. Methadone and buprenorphine are the most commonly prescribed OST treatments [2]. Community pharmacists (CPs) are increasingly involved in providing services related to OST, including dispensing, supervising consumption and giving advice on preventing overdose [1, 3, 4]. Dispensing of OST can be undertaken at a registered pharmacy, but supervised consumption and needle and syringe provision, two other key harm reduction intervention, require a service level agreement (SLA) with local commissioners. While commissioners may require evidence of training in this area, no formal qualification is required.

Opioid-related deaths have received significant attention in both the literature and media in recent years. In 2016 they accounted for over half of the drug related deaths in England and Wales. Mostly these deaths are the result of accidental poisoning and involve multiple drugs (mostly heroin and/or morphine) and alcohol [5]. Methadone was listed as one of the drugs in 691 deaths in UK in 2015 as compared to 565 deaths in 2010 [5–7].

Strang et al. [3] demonstrated that a shift in methadone treatment practice, introduced in the mid-1990s, has prevented methadone-related deaths increasing as prescribing has increased. In brief, this policy involves supervising the consumption of OST doses (which only became common practice in later years [8]), withholding OST dosing of intoxicated patients e.g. with alcohol, re-titrating patients who have missed more than 3 days' OST treatment, and providing overdose prevention advice on completion of detoxification [1]. Most OST treatment in the UK is provided in the community, and the majority of CPs undertake OST dispensing [8, 9]. As they often see patients on a daily basis, they are the main healthcare professionals responsible for ensuring that OST is undertaken in accordance with the guidelines of preventing overdoses i.e. withholding dose from intoxicated patients and those who have missed three or more doses and referring them to the prescriber and giving advice on preventing overdose [1]. According to a study, between 2008 and 2011, the English public treatment system for opioid use disorder prevented an average of 880 deaths each year from opioid-related poisoning [10]. While continuing in OST is associated with reduced risk of death [11], it is unknown whether pharmacists could do any more to reduce OST-related deaths.

A 2015 report by the Advisory Council on the Misuse of Drugs (ACMD) [12] raised concerns about the variable quality of drug treatment services at a local level in England. It identified variations in the quality and skills of staff and the culture of the local treatment system. A 2016 report by Public Health England (PHE) 2016 [13] recommended actions to reduce drug-related deaths, of which opioid-related deaths are a significant component. Among several other measures, it recommended the strengthening of clinical governance and workforce competence to reduce drug related-deaths. While these and other reports suggest changes to the local treatment systems in general, they remain silent on the community pharmacy aspects of the service. There has been very little work done to understand the role of community pharmacy in minimising opioid-related deaths. Based on the limited literature published and anecdotal evidence, it is hypothesised that the policy to prevent OST-related deaths is not being fully implemented by pharmacists, and that more could be done to reduce these deaths.

Aim of the study

To explore what UK community pharmacists think about their role in preventing OST-related deaths, their understanding of the risks associated with OST and their views on what more community pharmacists could do to reduce such deaths.

Ethics approval

Ethical approval was obtained from the Research Ethics Approval Committee for Health (REACH), University of Bath (REACH reference number: EP 12/13 18). All participants were required to give signed consent before the interviews were conducted.

Methods

Qualitative methods were used primarily because of the lack of any significant research in this area of pharmacy service. Semi-structured, face to face interviews were considered appropriate for the study as they allowed for the collection of enriched data on personal experiences, understanding and views. Due to their sensitivity, these experiences and views might be difficult to express during other data collection methods like focus groups. CPs were recruited from two different sites: Bath and North East Somerset (BANES) and Worcestershire. These two

locations provided a good mix of rural and urban pharmacies. All community pharmacies (n = 138) in these two study sites were sent an invitation pack inviting them to take part. The invitation pack was addressed to 'The Responsible Pharmacist'. An expression of interest form included seven demographic questions to allow for purposive sampling. These markers were adapted from the analysis of GPhC pharmacist register 2011 [14]. From the responses received (n = 31) participants were selected using maximal variation sampling to gain a broad sample based on age, gender, years of experience and role within the pharmacy. All had experience with substance misuse service provision. The final number of participants was guided by the principle of data saturation, which was achieved at 24 interviews. No financial incentive was offered for participating in the research.

An interview guide was first drafted based on an initial literature search and was reviewed following two pilot interviews. The interviews were digitally audio-recorded and transcribed verbatim. Each transcript was de-identified, anonymised and checked for typographical errors and any missing information.

RY undertook the interviews. All transcripts were coded by RY and a sample by DT to confirm the coding process, using interpretative phenomenology analysis (IPA). IPA allows researchers' interpretation of the experiences lived by the participants. RY is a part time community pharmacist, which was made known to participants. IPA was chosen as it allowed the participant to relate to the researcher in terms of their shared professional roles, allowing professional nuances and language to have a shared understanding. It also allowed the experience of the researcher to be used in the interpretation of data to understand the lived experience of participants [15]. The analytical process started with listening, reading and rereading of the transcripts. The transcripts were then coded to specific words or phrases that reflected the lived experience of the participants. The emergent codes were discussed among research team members (RY, DAT and JS) to reaffirm rigour and consistency, allowing convergence and divergence to be identified. A pattern started to emerge as the coding progressed. When a new code emerged, previously coded transcripts were reviewed to check if such views were expressed by other participants. The process was one of constant iteration to ensure consistency in coding. The codes were then organised into themes and subthemes representing a particular participant experience of OST provision. QSR NVivo 10 software was used as a data management tool. For the purposes of reporting, participant pharmacists have been assigned a pseudonym, with actual job role, gender and years of practice experience stated.

Results

Participants ranged from newly qualified (less than 1 year) to those with experience of greater than 30 years. Participants all provided OST service, but had varied amounts of experience of this service. They had varied roles within the pharmacy. There were 14 female and 10 male participants. While most participants were UK graduates, two were from Europe and a further two from India. All graduates are required to register with General Pharmaceutical Council (GPhC) before they can practise in the UK.

The interviews were conducted in the consultation room of the participants' pharmacy and lasted between 35 to 60 min.

Three key overarching themes emerged from the analysis in relation to the aims of the study:

1. Organisational challenges of providing OST service.
2. Managing risk in practice.
3. Behavioural and environmental impact on patient care.

Organisational challenges in providing OST service

Though participants, in general, felt their role was essential in providing OST services within the existing model, most did not feel part of a co-ordinated system. While they realised the importance of their frequent interaction with the patients (almost daily to once a week) there were also concerns and frustration that the potential of such high frequency interaction were not capitalised upon because of this lack of coordinated working. These views of detachment were underpinned by personal experiences of inability to contribute to clinical decision making; difficulty in prompt communication and lack of support in providing OST. This is illustrated in the quote below by Jill when she describes the lack of communication prior to receiving a prescription.

> We do try as much as I could to get involved in the patient care but I am not given much scope, so we only get told what dose to give, when and where, sometimes we even are not updated about the dose change until we get the script.
>
> Jill, Pharmacy manager, F, 1.5 yrs experience

Sharing of information between treatment teams (prescribers) and pharmacies can be crucial in clinical decision making; thus delay in communication and problem solving caused frustration for many participants. They also expressed concerns about the support available to them when making clinical decisions (for example dose withholding from an intoxicated patient), particularly during out of hours.

> I think we have a much prompter response if it is a green [non-OST general practice] prescription from a doctor, we would get a call within 15 min or the next half an hour… so I don't understand why we can't get to speak to a professional about the blue one [blue refers to two weekly OST prescriptions] and very unlikely that we can get a doctor on the phone, very, very unlikely it takes ages to get a doctor on the phone, you get a worker [support worker] all the time in the [drug] clinic.
>
> Josephine, Locum, F, 8 yrs experience

Participants expressed views about variation in the service delivered to OST patients, some were concerned about non-equitable services to OST patients, as expressed in the example below.

> There are different ways of looking at it but I don't think it's a standardised service for everyone, I think it's hit and miss as to which pharmacy you go into, which pharmacist is on duty you know so yeah I think it could do with some sort of work across the board really.
>
> Amanda, Second pharmacist, F, 24 yrs experience

One aspect of the variations in practice experienced by the participants was in the way the OST service was commissioned and organised in primary care. Different service providers have different working practices (for example the requirement for community pharmacists to report back on any missed dose by patients) thus leading to regional variations. For Lee, the commissioning of the service through different providers meant different expected outcomes leading to provider variations.

> I suspect that different providers would want maybe different things, but if there was a sort of a national framework that they understood this was what was happening…
>
> Lee, Pharmacy manager, M, 20 + yrs experience

Managing risk in practice

Participants expressed a varying degree of awareness about the prescription-related factors that have potential to harm or kill a patient receiving OST.

> …clients who are showing signs of withdrawal possibly needs referring back because they are not getting adequate treatment and the risk of them using additional substance is going to be high.
>
> Amy, Pharmacy manager, F, 1.5 yrs experience

While most participants identified the innate overdose danger associated with OST, others showed little recognition of risk factors. Where participants recognised potential risk situations they did not necessarily act to mitigate the risk. Such actions or inactions were underpinned by lack of confidence and knowledge in dealing with the issues, misinformation, training gaps and no awareness of clinical guidance.

Some participants reported that they had not taken any remedial action in cases where there were threats to the wellbeing of the patient, for example; intoxication of patients receiving their OST treatment. Generally, this non-intervention was explained by participants perceiving that the patient would not be harmed as they were used to risky drug taking habits.

> To me the danger is, 'is this dose going to cause him harm if he takes it?' and I have always thought well that's pretty unlikely. I think if he can manage to get here and he can get down the stairs (pharmacy located downstairs) and he isn't falling over then he can probably take this without harming himself, whether his treatment is of any benefit to him is another issue obviously.
>
> Joseph, Pharmacy manager, M, 32 yrs experience

Joseph, as many others, also reflected on the complexity faced by pharmacists in ascertaining the clinical appropriateness of OST prescriptions and suggested how lack of professional confidence could lead to inaction by pharmacists in risky situations. Largely, participants acknowledged that pharmacists failed to undertake a clinical assessment of OST prescriptions.

> …we're supplying them with daily or almost daily medication. We theoretically have a duty to question the prescribing or the treatment if we thought it was in effect more dangerous or counter-productive or whatever, but that requires us to have the confidence to suggest something to the people we perceive to be experts in this field and that's quite difficult.
>
> Joseph, Pharmacy manager, M, 32 yrs experience

The issues of professional confidence were reflected equally among newly qualified and those with several years of pharmacy experience. While some were more forthcoming in accepting their professional shortcomings others were hesitant and reverted to using plural nouns ('we' rather and 'I') to reflect a collective approach in adopting such practices. The switching between singular and plural noun is evident in the two statements above.

Amanda in her quote below, also uses 'We' to reflect a collective responsibility in not performing clinical checks on OST prescriptions which she puts down to lack of information.

> We can look at them (OST prescription forms) and think gosh this is high (dose) but then we don't know their drug history, we are not told of their drug his-

tory, often we can't do clinical checks because they might come and collect their methadone from us but they might get their other prescriptions from another pharmacy and they're not always willing to tell us what they are taking so in that respect no there's not (clinical check) but then unless we have access to their clinical records I don't see that we can do much more.

Amanda, Second pharmacist, F, 24 yrs experience

Participants often shared their experience of OST in comparison to non-OST prescriptions, thus giving an insight into differences in professional thinking that happens while caring for OST and non-OST patients. Despite giving more time and attention to process an OST prescription, pharmacists omitted the critical step of clinical checking, as legal and dispensing accuracy was their priority. The views expressed by the two participants below encapsulated this attitude among participants.

To be honest, I mean this is really being honest. I know what the correct answer is; that you would check against what they take and then you make sure that it is clinically appropriate and you check that the dose is not overdose that kind of thing, I don't think that happens in practice…

Rachel, Relief Pharmacist, F, 3.5 yrs experience

I think pharmacists unfortunately, tend to think more of the accuracy. I don't think you probably have sometimes too much time to go further than that and probably it is quite sad but it is how it is…. You are making me reflect on my practice which is quite important and interesting.

Jasmine, Pharmacy manager, F, 12 yrs experience

The perceived lack of training and guidance on OST were referred to by many of the participants. While most of the participants seemed unaware of the existence of clinical guidance relevant to OST, those who knew of the guidelines expressed concern over the lack of clarity within existing guidance. Training and guidance on dealing with more challenging aspects of OST in community pharmacy, such as dealing with intoxicated patients, missed doses and dose withholding, were identified by participants as necessary to improve their role in minimising OST-related deaths. Peter, who had been qualified for 2 years, found the guidance to be 'a grey area' when deciding on dispensing to patients under the influence and made decisions based on personal experience rather than on any guidelines.

I don't think we have been provided [with] enough training with how do deal with if an addict was under the influence, it is a bit of a grey area really. You are not told what the protocol is. You don't really know, I mean it's, you are using your sort of clinical judgement really your benefits against the risks aren't you? You are just going to decide for yourself whether or not to supply it.

Peter, Second Pharmacist, M, 2 yrs experience

Behavioural and environmental impact

Participants related their decision making around OST with the work environment they operated in. Many participants shared examples of specific situations where, at the least, their approach towards an OST patient would be different, and more critically, their clinical decision making might be compromised when compared to a non-OST patient, in the management of risk. Workload was cited as a factor that could compromise participants' clinical input in the care of OST patient. Some participants gave examples of situations when they might provide diminished care with potential to harm the patient.

To be honest the workload so if I'm very very busy I'll be more inclined to just give it (dispense to an intoxicated patient) and give them a word of caution ah for me it's probably workload how many things I've got to do at that moment in time, if I'm very stressed that's what I would do… I just think there's so many pressures that pharmacists come across and I think this probably does happen in general. I don't think I'd be alone in admitting it.

Rita, Pharmacy manager, F, 4.5 yrs experience

The statement above confers to the idea of a collective approach, as referred to under risk management, among the participants on otherwise professional shortcomings.

Stigma or stigmatised behaviour by participants, patients and others involved in OST services were evident in many of the participants' narratives. Most participants acknowledged the stigma associated with this aspect of healthcare and sought to avoid stigmatised behaviour in their own practice. However, a minority of the participants admitted how their individual negative preconceptions about OST affected their service provision.

I know some people see a methadone patient as a different sector of patients, that they're ones that you try to get out of the shop as fast as possible, they're ones you don't want to have any interaction with.

Tracey, Pharmacy manager, F, less than 1 yr experience

In the quote below, Joseph is keen to point out the importance of treating his patients equally; nevertheless, he is also aware how his underlying beliefs might not necessarily lead him to do so.

> I think it's extremely important for me to treat everybody with the same respect and in a way that's not in any way prejudicial, not always that easy and we do have hidden underlying prejudices and there are all kinds of things that we can often not avoid which make us behave in a different way to one person than to another.
>
> Joseph, Pharmacy manager, M, 32 yrs experience

The unavoidability of the effect of preconceptions about people who use drugs was expressed more bluntly by other participant, Matt, when he said; 'It is a stereotype, but a stereotype is a stereotype for a reason.'

The comfort of familiarity among pharmacist, patients and others involved in OST was referred to by the participants as one of the reasons for some of the deaths related to OST. Frequent exposure in dealing with opioid substitutes can lead to a false sense of security and diminished responsiveness in identifying and acting on risky situations. Such actions put patients and others who might gain access to the drugs at increased risk and was highlighted, for example in relation to cases where children have been the victim.

> I think part of the problem is maybe it is because when you have been on methadone so long you fail to see it a potentially dangerous drug because it is something you have every day and you sort of get familiarity for its content sort of thing and it is like 'it is alright for us it will be alright for the baby
>
> Chris, Owner, M, 23 yrs experience

While participants reflected positively on the good relationship they develop with their OST patients over time, there were also concerns of security of the pharmacy and its staff. Participants shared personal experiences and examples where such security concerns affected their professional decision making thus compromising patient safety. While some female participants shared how their gender and personal security concerns affected professional decision making, such concern, however, were not limited to female participants. This is illustrated by Susan, who describes how her decision to withhold an OST dose from an intoxicated patient may be influenced by her perceived risk of aggression and her perception of her own vulnerability.

> It is one of the hardest to be honest (dose withholding in intoxicated patients) because quite often umm those who are the heavy drinkers are also quite often the most aggressive so being a young small female the last thing I particularly want is to put myself at risk (by withholding the dose) umm so it is a case by case scenario
>
> Susan, Pharmacy manager, F, 5.5 yrs experience

Discussion

This study demonstrates that while CPs can identify the innate overdose danger associated with OST there are variations in their understanding of risk and their willingness and ability to take remedial actions where concerns exist. It also demonstrates the variability in the provision of services provided by community pharmacists to OST patients. More importantly, it highlights how some patients might be at greater risk of OST-related deaths due to the action (supplying dose to an intoxicated patient) or inaction (missing clinical check of OST prescriptions) of CPs.

While critical to the delivery of OST services in community based care, participants considered that they are seen as the supplier of the medication and not part of the integrated treatment team. Input by pharmacists in OST services seems dependent on the interest and proactive initiative of individual pharmacists. While successive reports and guidance [16, 17] have recommended better integration of CPs in the treatment service to minimise OST-related deaths, the experience of the pharmacists participating in this research suggests that in their localities, this has not happened.

In the absence of standardised communication and feedback mechanisms between the treatment teams and CPs, current information sharing is patchy, with different working practices emerging locally. The ACMD report 2015 [12] highlighted the variability of the service due to different providers. While this report does not comment on the provision of OST services in community pharmacies, the findings of this research nevertheless, are in line with that of ACMD findings.

In the absence of mandatory professional training, and the variable extent to which OST is taught at undergraduate level in UK universities [18] a situation exists where the service is provided by pharmacists with little or no exposure and understanding of the service. Some pharmacists did not use the same in-depth clinical checking to establish prescription safety as is completed for non-OST dispensing (for example, not checking patient medication record for possible interactions, not talking to the patient about side effects and outcomes). CPs' decision to dispense to intoxicated patients has also been reported by other researchers [9]. CPs' professional decision-making was influenced by workload, safety concerns and the stigma attached to OST. The negative effect of aggressive or inappropriate patient behaviour on pharmacists' decision-making has also been reported by other researchers [19, 20]. This is one area where practice urgently needs appropriate guidance and education to enable change.

Part of the aim of this study was to identify what more could be done to reduce OST-related deaths. Familiarity about the risks associated with OST and a misguided

comfort of other pharmacists adopting a similarly compromised practice, prevented participants from intervening in risky situations. Hesitations, use of pronoun 'We' and reference to experiences of some other pharmacists in expressing difficult situations were noted among some participants in distancing themselves from challenging situations. Lack of training and confidence in dealing with OST-related issues, misinformation, training gaps and lack of guidance were identified by the participants as reasons for not intervening in situations where a patient could be at risk of harm. Recent developments in practice include the provision of take home naloxone by drug treatment services and pharmacies to people who use drugs and their families and carers to treat overdose. This study implies that the opportunities for proactive take home naloxone supply may not be fully utilised until issues of confidence and training are addressed. More work is needed to establish if this is indeed the case around naloxone supply.

Implications for policy

While drug policies have evolved to reflect the political will of the incumbent government [21, 22] the involvement of CPs in OST has also greatly increased in recent years [9]. Policy makers should be aware of the challenges faced by community pharmacists in providing OST services at the frontline of service provision. Drug policy should become more inclusive to harness the strategic position of CP in monitoring and supporting patients to minimise OST-related deaths. Local commissioning of the OST service and the involvement of different service providers makes it difficult to have consistency at local and national level. A 'National Commissioning Framework for OST Services' should be adopted to streamline service delivery across all localities. As stated in the introduction, while local commissioners may require evidence of continued professional development, there is no national certification of pharmacist who are suitably trained to provide this service. National certification mechanism currently exists for other pharmacy services like flu vaccination and it would seem prudent that this gap in OST service provision is addressed.

Limitations and suggestions for further research

This is the first published qualitative research to describe community pharmacists' opinion on OST-related deaths. While the data generated are rich in content it only involved participants from two localities thereby only reflecting the OST practice in these areas. A national study, a quantitative survey, to test if the issues identified in this research are more widespread would add significantly towards optimising the role of the CP in preventing OST-related death.

Conclusion

Participants reported large differences in how OST services are provided in community pharmacy. Local commissioning of the service and the involvement of different service providers makes it difficult to have consistency at local and national level. A lack of standardised service protocol, training requirements and differences in policies from different commissioners and service providers exaggerated these variations. Lack of knowledge among some pharmacists and lack of clear guidance and support in providing the service resulted in some patients at high risk of OST-related deaths not having their risks acted upon. Thus, a national standard of mandatory training for pharmacist, harmonisations of local policies, better integration of CPs in the service provision and support to CPs providing the service could improve the role of community pharmacists in preventing OST-related deaths.

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Conflicts of interest None.

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3.6 Commentary on the publication

This research paper presents an in-depth insight into the role of CPs in OST and their awareness or lack of awareness of the risk associated with OST. This chapter also gives a rich and varied understanding of the challenges faced by CP in delivering the service in a manner that minimised the risk to patients.

One of the important findings of this study is the normative approach taken by CPs in dealing with situations that could pose a risk to OST patients. CP lack of knowledge, support and clarity of guidance implied that the risks for some patients at high risk of OST-related death were not acted upon.
The interview study results highlighted areas of pharmacy practice that will require further research to answer the main aims of this doctoral research. The findings of this study informed the design and aims of the observational study and the questionnaire for community pharmacists.

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Chapter 4

Observation study

Chapter overview

This chapter presents the results of the qualitative observational study in the format of a research article. The article is in draft form and is intended for submission to the peer-reviewed journal BMJ Open. This chapter starts with an introductory remark, followed by the background, methods, results, discussions and the strengths and limitations of this study, which are presented in the draft paper.

4.1 Introduction to chapter

This study was conducted to observe the professional, personal and clinical behaviours demonstrated by CPs providing OST-related services. While this study aimed to gain some meaningful supporting data to understand the findings of the interview study, it was equally open to identifying any new themes that might not have been captured in the previous study.

There is a paucity of qualitative ethnographic studies based in the community pharmacy setting. While some of the findings of this study are new, the design of this study lends methodological uniqueness in OST research. There have been growing calls to move addiction treatment towards more patient-centred care to improve outcome and reduce mortality [1-3]. Patient-centred care requires healthcare providers to empower patients to become active participants in their own care [4, 5]. The findings of the interview study, published literature and anecdotal evidence suggest the current service provided to people who use drugs (PUWD) in community pharmacy is not patient-centred. This methodology allowed the researcher to go beyond the self-reported practice of CPs in the interview study and allowed the analysis and interpretation of the actual current practise of community pharmacists in delivering OST-related services.

4.2 Publication

Draft article intended for peer-reviewed journal.

Yadav R, Scott J, Taylor D. Can community pharmacy teams do more to prevent opioid substitution therapy (OST)-related deaths? An observational study of pharmacy OST services.

Can community pharmacy teams do more to prevent opioid substitution therapy (OST)-related deaths? An observational study of pharmacy OST services.

Introduction

Community pharmacies play a central role in delivering Opioid Substitution Therapy (OST) services in the United Kingdom (UK). Since the introduction of supervised consumption of methadone from the mid-1990's, both the range of OST-related services and the number of CPs providing the service has increased [6-9]. Community Pharmacists (CPs) are involved in dispensing substitute opioid medication (mostly methadone and buprenorphine), supervising consumption (SC), Needle and syringe exchange programmes (NSP) and Take-home naloxone (THN). Naloxone, a synthetic blocker to opioid, is used in an emergency to reverse an opioid overdose and thus can be lifesaving[10]. Substitution therapy is the most common intervention in treating heroin addiction in the UK, and most of this intervention is dispensed by CPs[11]. SC allows the prescribed dose to be consumed in the pharmacy under the pharmacist's supervision to ensure adherence and reduce medication diversion risk [12]. NSP gives access to clean injecting paraphernalia to those who inject drugs, and the THN programme allows CPs to supply naloxone to patients without prescription[13]. The range of services currently offered by UK community pharmacies to those addicted to opioids is broad, and the CPs scope of practice includes ensuring compliance to treatment, harm reduction, and overdose prevention.

NHS dispensing of OST medication is deemed an essential service under the Community Pharmacy Contractual Framework (CPCF) and can be provided by any community pharmacy[14]. Other OST services are classed as enhanced services and fall under Public Health England's remit [15]. The enhanced services are commissioned locally by local authorities, dependent on local need. However, this local need may be unknown and result in inequitable geographical access. A service level agreement (SLA) agreed

between the provider (pharmacy) and the commissioner (local authority) forms the basis of delivery of these services. The SLA defines the requirements of the service, standard expected in the delivery of the service, CP training requirements, remuneration and other aspects of the service[16]. With 1.2 million people in England visiting community pharmacy every day, CPs are increasingly seen as key in delivering the national public health agenda[17]. Every year, pharmacists provide more than 14 million face-to-face contacts with people who use drugs (PWUD) [18]. Of all the public health services commissioned through community pharmacies, the SC and NSP are the most commonly used service in England [19, 20].

OST has been shown to reduce opioid overdose mortality and overall mortality in the treatment population [21, 22]. An ecological study of the impact of SC demonstrated that its introduction in UK community pharmacies was followed by a four-fold reduction in methadone-related deaths[23]. This study by Strang et al. used defined daily doses of methadone to come to the conclusion and did not take account of other changes like the improvement in care and support available to PWUD; thus needs to be interpreted within context. Other studies have reported OST to reduce the mortality rate by a third [24] to one-half [25, 26]. Nevertheless, opioid-related deaths have seen significant increases in the UK and internationally in recent years. Almost half; 49.2% (n=2160) of all drug poisoning deaths recorded in England and Wales are opioid related[27]. Whereas in Scotland, one or more opioid is implicated in 86% (n=1021) of drug-related deaths [28].

As CPs collectively undertake most of the OST dispensing in the UK; and probably see most people on OST more frequently than their drug treatment service or GP, they may be well-positioned to prevent OST-related deaths. For example, many deaths are associated with polydrug use, such as heroin, benzodiazepines, alcohol and methadone. CPs may identify when a person presents for methadone consumption that they are intoxicated and potentially intervene. They may also notice when a person appears to be unwell or declining in physical appearance. This study was informed by an interview study[29] with pharmacists, which identified self-reported variability in the provision of OST services in community pharmacies. It also highlighted the

concern of how the actions (for example, dispensing a methadone dose to a visibly intoxicated patient) or inactions (for example, not checking for drug interactions with other prescribed medication) of some CPs may pose overdose risk to those receiving OST[29]. While there are clear positive benefits of OST, patient retention on OST can be negatively impacted by the stigma associated with OST provision. [30, 31]. PWUD find supervised consumption to be a stigmatising experience but accept this as a necessary evil to receive OST therapy. [32-34]. But should stigma be a necessary evil in OST?

This study was designed to go beyond the self-reported practice, experience and opinions of CPs and evaluate their observed practice in OST provision. No previous ethnographic work on OST services within community pharmacy could be found in the literature.

Aims

This research aimed to explore the practice of delivering OST services in community pharmacy and identify interventions or potential for interventions that may prevent OST-related deaths.

Methods

This study utilised non-participant ethnographic observation as a data collection method. This method was used as it allowed the researchers to go beyond pharmacists' self-interpretations of their attitudes and behaviours in evaluating their practice[35]. This method also allowed to identify any unreported OST-related practice. Participants were recruited using an opt-in approach from the cohort who participated in the previous research [29]. Aside from convenience, this sampling approach minimised the Hawthorne effect by utilising the rapport developed between the researcher (RY) and the participants during the previous study[36, 37]. Approval was gained from the owner or the head office of each community pharmacy where potential participants worked before inviting individuals to participate. Not receiving appropriate permission from some community pharmacies owners negatively

affected the potential participant population and the final sample size. Observation episodes were arranged at the pharmacist's convenience and a non-formal approach was adopted in communicating with the participants to mitigate the observer effect [37]. A poster was displayed at the pharmacy window stating a researcher was on-site to observe the pharmacy staff's practice and their interactions with customers and outlined they could ask to be excluded from this observation if they wished.

An information sheet was sent by post in advance and was addressed to the ‘Responsible Pharmacist’ who also acted as a gatekeeper in disseminating the information to other pharmacy staff. Potential participants were given the opportunity to ask questions about the research and were also made aware of their right to end the observation episode at any time. Written consent was obtained from all staff members present during the observation period. No patient-specific information was collected, and where required, only a general description of those presenting in the pharmacy was recorded.

An observation template was developed with the research team's input and was based on the team's previously published work [29]. It was designed for completion by hand during the observation episode, which lasted four hours. The template was piloted in one community pharmacy and subsequently modified and structured to add items most relevant to the research aims[35, 38]. The template captured data on the pharmacy's general description, provisions for OST services, the role of pharmacy counter and dispensary staff, and the dispensing of OST, including SC. A detailed description of the interaction between the patient and the pharmacy team and the actions/inactions of staff members was written. While the observer took a non-participatory role, any impromptu information provided by participants, or information sought by the observer to understand the context of the activity happening in the pharmacy were also noted. Any information sought was after completion of the observation period. Participant comments were not recorded verbatim but were noted with sufficient detail to ensure they reflected the participant's opinion. The researcher’s own reflection of the observation was recorded separately from the observation template in a reflexive journal after the observation event and used to aid the interpretation

during analysis. This created an implicit narrative along with the explicit completed observation template of each CPs practice. All observation was conducted by RY between January and July 2017.

Analytical method

A combined analytical framework utilising inductive and deductive codes was used for analysing the data. Deductive codes were derived from our previous study[29]. The descriptive observation data was then coded into either these predefined (deductive) codes or new (inductive) codes representing the data. This approach was adopted primarily because of the flexibility it lent in combining the previous study's findings with the new codes and themes emerging from the observational study. The codes were then grouped into themes and overarching themes, which are presented in the results section. QSR NVivo 10 software was used as a data organising tool.

Ethical approval

This study received ethical approval from the NHS Health Research Authority, NRES Committee South West - Central Bristol in August 2014 (REC reference 14/SW/0140).

Results

The result includes observational data from nine community pharmacies in England's two geographical areas (Worcestershire and Bath and North East Somerset). A total of 24 pharmacists were invited to take part in the research, of which nine participated. Periods of observation at each site lasted four hours (half a day) which were undertaken either in the morning or in the afternoon. This resulted in the collection of 36 hours of observational data. There was a change of one pharmacist during the observation period at one site; therefore, the results of this study are informed by the practice of 10 CPs at 9 different pharmacies. The practice of other 24-pharmacy staff members, which included dispensary and counter staff, was also observed

during the data collection period. A total of 31 OST-related interactions were recorded in detail.

Demographic results

Demographic data was collected for the pharmacists participating in the observation. Out of the 10 CP participants, six were female and four were male. Pharmacists' post-registration experience ranged from 6 months to 27 years (Mean 6 years, Median 4.5 years). The pharmacies reported having low (less than 5), medium (16 to 25) and high (over 25) numbers of OST patients during the observation period. While five participants were pharmacy managers, one was a locum pharmacist, one a relief pharmacist and two were the pharmacy owner. Demographic data were not collected for a pharmacist who joined the observation midway. Two pharmacies were in suburban areas, whereas the rest were in urban locations.

Pharmacy settings

While each observation site was unique in its own way, commonality existed. The researcher (RY) took a position to maintain the view of the dispensary and the shop floor without coming in the way. Most pharmacies were located among other shops in the area. All observation sites had distinctive dispensaries and shop floor and also had private consultation rooms. The number of staff at each location varied depending on the pharmacy workload. The flow of customers and the activity in each pharmacy varied between the pharmacies and often changed within the observation period in the same pharmacy. The arrangement of OST service provision and the involvement of different pharmacy staff in delivering the service is detailed below in the results.

	Pharmacist's Gender	Age Range	Experience (Yrs)	Employment status	Location	Regular OST patients	Number of OST/NSP transactions observed	Support staff	Region
Pharmacy 1 (Ph1)	Male	30-39 Yrs	6	Owner	Urban	More than 25	6	2	Banes
Pharmacy 2 (Ph2)	Female	29 Yrs and under	3	Pharmacy Manager	Urban	5 or less	1	2	Worcestershire
Pharmacy 3 (Ph3)	Male	29 Yrs and under	1.5	Pharmacy Manager	Urban	16-25	7	3	Worcestershire
Pharmacy 4 (Ph4)	Female	29 Yrs and under	5	Pharmacy Manager	Urban	16-25	5	2	Worcestershire
Pharmacy 5 (Ph5)	Female	30-39 Yrs	4.5	Pharmacy Manager/ Lecturer	Urban	6--15	1	2	Worcestershire
Pharmacy 6 (Ph6)	Male	50-59 Yrs	27	Owner	Urban	16-25	4	2	Banes
Pharmacy 7 (Ph7)	Male	29 Yrs and under	0.5	Relief Pharmacist	Suburban	5 or less	2	3	Banes
Pharmacy 8 (Ph8)	Female	29 Yrs and under	5	Pharmacy Manager	Suburban	6--15	4	5	Worcestershire
Pharmacy 9 (Ph9)	Female	29 Yrs and under	1	Locum	Urban	5 or less	1	3	Worcestershire
TOTAL			53.5				31	24	

Table 4.1: Participant demographics

Themes

Patient confidentiality and stigma

All observation sites in this study had a consultation room accessible from the pharmacy shop floor. One observation site (Ph8) had two consultation rooms. At observation site Ph6, all observed SC transactions were undertaken in the consultation room. At site Ph4 some but not all SC were conducted in the consultation room. At sites Ph1, Ph2, Ph3, and Ph7 all SC transactions took place on the pharmacy shop floor, meaning that the pharmacist and the OST patient were in full view of other customers and pharmacy staff. No SC transactions were observed at sites Ph5, Ph8 and Ph9. At Ph1, the consumption of a buprenorphine dose was supervised with both the pharmacist and patient standing on the shop floor in full view of other customers and pharmacy staff. Consultation rooms were not used by all CPs at all times. Drinking water was offered to the patients following the consumption of methadone solution or before buprenorphine tablets at only one site. The researcher also observed practice where take-home doses of methadone were handed out un-bagged and a takeaway dose of buprenorphine tablets were handed out loose (un-boxed) to the patient. When asked about the practice of SC in open space, some CPs reported this to be the choice of the patient, whereas others reported they would use the consultation room for SC only if patients asked for it.

Inadvertent disclosure

Where OST services were being delivered in the consultation room, patient confidentiality was still inadvertently breached as interactions between the CPs and OST patient could still be observed by other staff members. At site Ph6 where all SC was undertaken in the consultation room, the consultation room door was left open during the transactions. It was observed that even when consultation rooms were being used to deliver OST, actions such as walking in and out of the room with the distinct (blue) OST prescription or the dispensed and empty bottle of dispensed methadone visible compromised patient confidentiality. Furthermore, the counter staff's calling out of ‘methadone’ or ‘buprenorphine’, to notify OST patients' presence, also

breached the confidentiality of those accessing OST services at the research sites.

Patient-centred care

Most patient interactions, especially those undertaken outside the consultation rooms, were brief and lasted only a few seconds. In most interactions observed, there were very little to no verbal interactions between the pharmacy team and the OST patient. Most CPs-patient interactions did not appear to provide the environment or the time to encourage engagement with the patient in any other way than to receive their medication. Mostly OST medications were ready to be handed out to the patient. It was common to see OST patients being served first by dispensary staff while those before them were waiting for their turn to be served. While most of the transactions seemed to be focused on getting the patient out of the pharmacy as quickly as possible, some good person-centred care practice was also observed. Most OST patients were known to the pharmacy staff and were often addressed by their first name. Pharmacy staff members appeared keen to help when OST patients sought help. For example, at Ph3, pharmacy staff advised a patient on rearranging a missed appointment with the treatment team and at Ph6 the CPs expressed concern and kept a close eye on a patient who had informed staff they had not been feeling well.

Patient education and counselling

Most pharmacies had a separate or semi-separate area for the display of posters and information leaflets. These leaflets covered various aspects such as diabetes, asthma, stroke, smoking cessation, alcohol-scratch cards, and other public health campaigns offered in the pharmacy. However, there was no OST-related or overdose prevention information for patients at the participant pharmacies. At one site, a copy of guidance to reduce opioid overdose risk was displayed in the dispensary, only visible to staff. No counselling on overdose prevention was observed and no patient information leaflets were seen to be given with OST dispensing. These two practices were in sharp contrast to those seen with non-OST patients.

Differences between OST and non-OST patient interactions

There was a visible and identifiable difference in the way in which OST and non-OST patients were treated. OST patients' presence in the pharmacy triggered an almost hurried chain of events not observed with non-OST patients. The OST patients generally did not approach the counter as other patients did; they instead stood aside in the shop waiting to be served. The pharmacy team appeared to have a better acquaintance of the OST patient and would call them by their first name. However, the non-OST patient appeared to receive more attention; their conversations were longer and often involved multiple members of the team. Unlike non-OST patients, the OST patients were not always asked to confirm their identity before the handing out or supervision of consumption of prescribed medications was completed.

Dispensary arrangements

There were also observable differences in the organisation of dispensing of OST and non-OST prescriptions. At almost all sites, OST prescriptions were usually pre-prepared and ready to be collected or consumed before the patient presented for their medication. Being controlled drugs (CD), methadone and buprenorphine were stored in CD cabinets. Most OST dispensing was reported to be completed by the pharmacist themselves, who would then self-check their own dispensing. This practice was in sharp contrast to how non-OST prescriptions, including other controlled drugs, were dispensed. Where observed, the dispensing of OST items often occurred in a different dispensing space. The CPs at Ph1 and Ph5 sites reported this was to minimise interruption or disturbance. Most CPs used plastic bottles, intended for solid dosage forms, to dispense methadone oral solution in. Where the dose was supervised, some CPs kept the plastic bottles for future use for the same patient. While the CPs undertook most dispensing and SC, the NSP, where observed, was delivered or reported to be delivered by counter staff. At one site, a non-pharmacist provided SC. The involvement of non-pharmacist staff members was primarily limited to the delivery of NSP services.

Communication with the treatment team

Difficulty in contacting the prescriber was observed at Ph1 site, but other participants also reported this. At Ph1 the pharmacy staff failed to contact the prescriber on the telephone after trying for 20 minutes to clarify and correct a technical error on the OST prescription. The CP at site Ph4 reported concerns about OST prescriptions going missing in the post and the risk of these being presented at a different pharmacy. The researcher also observed a telephone call from the treatment centre to site Ph6, trying to locate a missing prescription. The CP at the pharmacy notified the treatment centre that the particular patient had not used the pharmacy in the previous 6 months.

Discussion

Principal findings

The results of this study demonstrate that the practice of CPs participating in this study did not always offer adequate privacy and dignity to those receiving OST. Delivery of the service outside of the consulting room and the rushed nature of the interaction between CPs and OST patients did not provide a conducive environment for patients to engage in their treatment. While the pharmacist and pharmacy team were responsive to OST patients' expressed needs, they did not exhibit proactive behaviour in engaging patients with their treatment.

While concerns around patient confidentiality and privacy in community pharmacies are not new, the stigma associated with OST makes this more challenging. The stigma associated with OST among CPs, patients and users of pharmacy services have been widely recognised in practice and reported over the years [30, 32, 33, 39-43]. Stigmatised behaviour (not ensuring patient privacy) and perceptions (the OST patient not wanting privacy) were exhibited by pharmacist and pharmacy staff members. Notley et al. reports that the pharmacists' own attitude can be critical in influencing a sense of privacy and contributing towards stigma[40]. Our work reported elsewhere found stigmatising beliefs about PWUD among CPs can limit their

engagement with OST patients [29]. This study adds observational evidence of stigmatised behaviour towards those receiving OST. PWUD can often perceive themselves based on their stigmatisation, which simply reflects the prejudices of others[44]. Therefore, a situation exists where stigma might be being normalised and internalised, leading to its perpetuation. Where patients have shown a preference not to use a consultation room in the past, such consent should be reassessed at every opportunity with the view to encourage the use of private space. This also fosters feelings of self-worth in the individual and the understanding they should be treated like non-OST patients. The good rapport between the OST patients and the pharmacists and the authority figure of CP in the pharmacist-patient interaction can be utilised to encourage positive patient engagement [29, 43, 45]. As Harris et al. noted, recovery cannot be achieved if individuals are devalued by the treatment system itself [43]. CPs need to reflect on, and where needed, change their practice and environment to ensure dignity and privacy of those receiving OST is protected.

OST patients' presence in the pharmacy appeared to create a sense of urgency among CPs and other pharmacy staff alike. The quick and hurried interaction between CPs and OST-patients were in sharp contrast to those with non-OST patients. Stigma, perceived risk of aggression and shoplifting from OST patients as reported by different researchers may, to some extent, explain this approach [29, 43, 45]. There is, however, a lack of substantiating evidence for this interpretation. Very little or no interaction between CPs and OST patients, as observed in some sites, are in contradiction to the existing guidelines and practice standards[12, 46]. One of the aims of supervised consumption of OST is to allow the opportunity to build a therapeutic relationship between the pharmacist and the patient to promote health and harm reduction[12]. This objective can be better achieved by engaging OST patients in a more meaningful way than the transactional interaction observed among participants of this study. Anstice et al suggest that the transactional interaction may be the personal preference of some OST patients [31]; however, where such a situation exists, CPs should work

towards fostering the development of supportive relationships with these patients.

There were differences in how the OST and non-OST services were organised in the pharmacy. As noted by Harris et al., OST might be the most regulated and controlled intervention that operates under the guise of treatment[43].The focus on the accuracy of OST dispensing, as we have reported elsewhere, may underline the different approach adopted by CPs in delivering OST services. While the support staff mostly dispensed non-OST prescriptions, including controlled drug prescriptions, the pharmacist mostly dispensed or reported to dispense and self-check OST prescriptions. Conversely, support staff provided or reported to provide NSP. This working arrangement, where CPs undertook dispensing of OST and support staff provided NSP, has also been reported by Scott and Mackridge in a national survey of pharmacy support staff providing OST-related services[47]. Given NSPs are often the first point of contact with health services for those injecting drugs, those delivering the service need to be suitably trained to encourage this group of patients to engage in safer options like OST[48].

The practice of re-using bottles to dispense the supervised consumption dose poses hygiene and contamination risk, particularly if the intended patient does not collect the dispensed dose and the medication must be returned to pharmacy stock.

The findings also demonstrate that the role of CPs in OST services is mostly that of supply with minimal engagement beyond the dispensing of what has been prescribed. This finding is in stark contrast to service provision to non-OST patients where clinical checks are completed, the patient receives counselling in a relaxed environment, and medication is handed over in an appropriately confidential manner. The lack of proactive engagement of CPs in delivering the OST service was also demonstrated in the non-availability of any OST-related patient information resources or promotion of OST services in the pharmacy. Increasing access to OST and patient education about overdose have been identified as key approaches to reducing the risk of opioid overdose[10, 49]. Because of the high-frequency interaction (often

daily) between the pharmacist and the OST patient, reinforcing overdose prevention advice at every patient interaction is debatable. Nonetheless, no overdose prevention counselling or handing out of ‘patient information leaflet’ were observed during this study. A patient-centred practice based on the recommendations to reduce opioid overdose should be adopted to deliver OST services in community pharmacy. The opportunity of improving patient outcome by creating an environment for patient-centred care, better patient monitoring, improving patient engagement and reducing the risk of overdose by patient education/counselling is going largely unutilised.

Strengths and Limitations

To the best of our knowledge, this is the first qualitative ethnographic study of the English community pharmacists' practice in relation to OST services. The strengths of this study are the strong relationship between the researcher and the study participants which supported the participants to behave in their usual manner when responding to OST and non-OST patients.

The researcher did not observe the pharmacist-patient interaction in the consultation room, so conversations in the private context would have been missed, nor did they speak to the patient to seek their opinion on the pharmaceutical care they received. This can be seen as not hearing the voice of the patient. On reflection, after the transaction, OST patients could have been asked to opt in to an interview or provide information for a telephone interview later. In the absence of a validated observation tool for the research subject, the research team developed its own tool tested through face validity and a pilot observation. As discussed in the methods, the research team took practical measures to minimise the Hawthorne effect during observations; nevertheless, its impact on this study's results cannot be completely ruled out. The results of the study demonstrate little impact or unfamiliarity of good practice.

Conclusion

This study's findings demonstrate that the privacy and dignity of patients receiving OST-related services are not given due consideration. The actions of the pharmacy team, knowingly and unknowingly, are compromising the confidentiality of those accessing OST-related services in community pharmacies. This non-rigorous approach to confidentiality needs to be addressed through a change in the professional practice of CPs individually and collectively. The non-conducive way of delivering the OST service means the true advantage that could be achieved through frequent contact, and the good rapport between CPs and OST patients remains unexploited. Providing a confidential and dignified service, creating conducive environments for patient engagement and monitoring are elements of existing guidance and standards that need to form the core of OST service delivery in community pharmacy. Addressing the stigma among pharmacists and other pharmacy staff, encouraging proactive interactions with OST patients can reduce the barrier to patient engagement, improve compliance to the service and counselling patients on overdose prevention can potentially reduce OST-related deaths.

Future research

This was a small ethnographic study presenting great insight into OST services delivery in community pharmacies in England. It would be important to know if the themes found in this ethnographic work apply more broadly, and therefore a quantitative study of self-report, such as a survey, is advocated.

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The research team would like to thank all the pharmacists and pharmacy staff who consented to participate in this research and the patients who were unknowingly part of the findings/research.

4.3 Commentary on the publication

This paper presents the findings of what the authors believe to be the first qualitative ethnographic study of OST practice in English community pharmacy.

Lack of due consideration to the privacy and dignity of those accessing OST services in community pharmacy is one of the main findings of this study. Despite evidence of apparent good relationships between the pharmacy team and the OST patient group, delivering the service in a non-conducive environment means a patient-centred approach is not being achieved.

The results of this study, along with the interview study's findings, informed the design and development of the survey questionnaire, which is explained in the following chapter.

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Chapter 5
Survey study

Chapter overview

This chapter presents the findings of the cross-sectional national survey of community pharmacists providing OST services. This chapter is presented in a research manuscript format, intended for publication in a peer-reviewed journal. The chapter begins with an introductory remark and ends with a brief commentary. Introduction to the study, methods, results and discussions of the results are presented within the manuscript.

5.1 Introduction to chapter

This study represents the quantitative element of the mixed-method research adopted for the doctoral thesis. It is the final study in the three-phased sequential exploratory research design.

The survey questionnaire was informed by the literature review and the findings of the previous two studies. The survey explored wide-ranging aspects of OST services focusing on CPs' practice in preventing OST-related deaths.

5.2 Conference presentation

Oral presentation

Preliminary work for this study was selected for oral presentation at the Health Services Research and Pharmacy Practice Conference: 16-17 April 2020 Cardiff.

Peer-reviewed conference abstract

Yadav R, Scott J, Taylor D, Rogers P. Community pharmacists' role in preventing Opioid Substitution Therapy-related deaths: A national survey of English community pharmacists. International Journal of Pharmacy Practice. 2020; Volume 28 Issue S1, pages 1-89, April 2020, https://onlinelibrary.wiley.com/toc/20427174/2020/28/S1

5.3 Methods

5.3.1 Respondent stimulus

There were no foreseen significant changes in community pharmacy practice and in particular, in OST-related services provision during the course of administering the survey. Consequently, all participants were expected to have a similar stimulus as far as this survey's scope is concerned.

5.3.2 Strategies to improve telephone survey response

Recommendations from the literature to increase response rates to telephone surveys, where practical, were adapted and applied in this research [1-3].

Table 5.1: Strategies to improve telephone survey response rate (adapted)

Recommendations to improve telephone survey response rate	Strategy adopted for this research
Advance letters	All potential participants were sent information about the research in the post in advance. The post was addressed to the 'Responsible Pharmacist'.
Researcher credentials	The University of Bath logo appeared on all correspondence sent to the participants. The information materials also shared the name and contact details of the research team. The survey administrator introduced themselves and referred to the research group in their introduction.
Targeted call times	The calls were avoided during the times when community pharmacies are likely to be busy, for example, at the opening and closing times. The expected duration of the telephone survey was mentioned in the printed information.
Call scheduling	All participants were given the opportunity to ask for a call back at a more suitable time if they requested this. Where such scheduling coincided with another scheduled call, then a different member of the research team made the call at the agreed time.
Interviewer training	All researchers administering the survey practised it on the phone several times to ensure they became comfortable and adept in using the survey format. Each researcher had a transcript to read from to keep the consistency of the information provided to the participants.

Incentives	No incentives were offered to participants.

5.4 Publication

Draft article intended for peer-reviewed journal.

Can community pharmacists do more to prevent opiate-related deaths in people who use drugs? A national survey of community pharmacists in England.

Introduction

Opioid overdose deaths have increased in high-income countries. In England, opiates are implicated in around half of all drug poisoning deaths (49.2%, n=2,160, 2019)[4]. A high proportion of these deaths occur in those who are currently in treatment for their addiction. Of the 2,929 recorded deaths in treatment in 2019, 69% (n=2,010) were people with opioid problems[5]. The UK has one of the largest opioid treatment population in Europe[6, 7]. In 2019/20, England had 140,599 people on treatment for opioid use and the majority of this cohort (94%) received opioid substitution therapy (OST) [5]. Community pharmacists (CPs) deliver OST services, seeing patients at least weekly and often daily, more frequently than most others involved in the care of people who use drugs (PWUD). As such, CPs are well placed to intervene to reduce opiate-related deaths. This research investigates the role of CPs in OST-related death prevention to identify whether their contribution is optimal or whether they can do more.

In the UK, CPs are involved in dispensing OST (mostly methadone and buprenorphine), supervised consumption of OST dose (SC)[8, 9], needle and syringe programmes (NSP)[9-11], take-home naloxone (THN) service[12, 13]. A new national pharmacy hepatitis C screening service was launched in 2020[14]. CPs are also expected to advise patients on the safe use and possible side effects of the medication prescribed[15], especially if patients are at higher risk of harm as in OST[16]. OST reduces both overdose and overall mortality in the treatment population [17, 18]. Supervised consumption of OST aims to ensure compliance with the treatment and reduces the risk of drug-related overdose[19, 20]. NSP gives access to sterile injection equipment for those who inject drugs [21] and has been shown to reduce risky behaviour[10]. THN schemes allow CPs to supply naloxone, a first aid treatment for overdose, which has demonstrated efficacy in reducing mortality [22]. In England, dispensing services are classed as essential services; thus, OST dispensing can be provided by all community

pharmacies[15]. However, SC, NSP and THN are locally commissioned by the local authorities (LAs), so their scope and availability vary between different geographical areas as well as availability in pharmacies within the same area. This results in inequity of services for OST-users and frequently poor correlation with potential benefits to the local community [23].

Most deaths involving opioids are accidental overdoses [4, 6, 24]. Since the introduction of supervised consumption in community pharmacy in England, methadone-related deaths have not increased in the same proportion as its prescribing [19]. However, methadone deaths have been persistently high in recent years. The England and Wales data shows methadone-related deaths at 434 in 2015, 413 in 2016, 367 in 2017, 419 in 2018 and 407 in 2019[4].

CPs practice in the UK is guided by professional guidance and service specifications[25]. These guidelines recommend that healthcare professionals supervise the consumption of methadone until the patient is stable to ensure the patient has taken the correct dose. It also recommends withholding the dose if a patient presents intoxicated, and where three or more consecutive doses have been missed, the patient must be referred to the prescriber for possible retitration [16]. The UK guidelines also highlight CPs' role in ensuring that patients have access to naloxone, particularly if they are suspected of being involved in risky drug-taking behaviours[16]. Those involved in providing OST should take all reasonable actions organisationally and within individual care plans to address overdose risks[16, 26]. Several aspects of OST service in community pharmacy has been reported nationally and internationally, highlighting the attitudes, skills, experiences and challenges of providing OST services [9, 27-38]. While some aspects of overdose prevention interventions are reported, there remains a paucity of literature exploring English CPs role in preventing opioid overdose deaths. A 2015 survey reported increased awareness of potential overdose situations among Scottish CPs [9]. This report concluded that the role of Scottish CPs has evolved from the supply of OST to a broader, more clinical one. However, a survey of English pharmacists in 2005 reported 20% of CPs never withheld a dose from an intoxicated patient, with the same proportion stating they always withheld a dose from intoxicated patients[8]. Our previously reported qualitative study [39] and ethnographic work[40]

suggest the above guidance to prevent opioid overdose deaths is not being fully implemented in community pharmacy. We reported that the lack of knowledge among some pharmacists and lack of clear guidance and support in providing the service resulted in some patients at high risk, not having their risks acted upon[39]. We have also reported evidence of stigmatised practise and a non-rigorous approach to confidentiality when delivering OST services, thus hindering a patient-centred approach[40]. This qualitative exploratory work shone a light on the issue but now requires investigation to see if findings are generalisable.

This study aimed to measure CPs' self-reported activity regarding OST-related death prevention quantitatively and to use this data, alongside the previous studies, to hypothesise whether there is more CPs' can do to prevent deaths.

Method

A telephone survey primarily using closed questions and Likert scale attitude measurements was undertaken. Telephone contact was chosen over postal because of the team's recent experience in another study where the postal response was low. Online methods were rejected as there is no available list of pharmacists' email addresses to create a sampling frame.

Participants

A list of registered pharmacy premises was obtained from the General Pharmaceutical Council (GPhC). The list was cleaned, and used to create the sample. A random sampling of community pharmacies stratified by location was adopted. Pharmacists working as the 'responsible pharmacist' in a community pharmacy were taken as the sample unit. Registered community pharmacies in England were divided into nine geographical clusters to mirror the then NHS England regions, and a proportionate number of pharmacies were randomly stratified into each cluster. To reassure CPs working in large multiples, consent was sought from the pharmacy head office before sending the research invitation. Participants were sent an information pack by post with an option to opt-out from being contacted by telephone. It was addressed to the 'responsible pharmacist' and contained

an invitation letter, participant information sheet, an opt-out slip and freepost envelop. Eligibility criteria were set as those CPs providing any drug misuse service.

Questionnaire

The literature and our previous work informed the development of the questionnaire. Recommendations in the UK clinical guidelines were used as the markers of good practice. JS held special expertise in the field and had significant input in the development of the tool. The survey was pre-piloted with six practising community pharmacists recruited purposively to conduct the questionnaire's face validity. The research team then reviewed the survey questionnaire before it was tested in a formal pilot study to predict the response rate and test the survey instrument. The responses were examined to develop the final version. The survey contained questions on participant and pharmacy demographics, self-reported practice and a 24 item Likert scale to explore attitude and beliefs about pharmacy addiction services and PWUD.

Pilot study

A 0.5% sample of total registered community pharmacies (n=60) in England were randomly selected from the stratified geographical cohorts. They were sent the invitation pack with the option to opt-out from any contact from the research team by returning the opt-out slip in the free post envelope. A total of 30 pharmacists completed the survey giving a response rate of 50%. Of the remaining 30 potential participants, six opted out, one could not be contacted, 11 were ineligible, and 12 did not participate after contact by the research team. RY administered the pilot survey.

Sample size estimation

The sample size was estimated to ensure enough responses were recorded to give the survey findings statistical significance without wasting resources in conducting unnecessary surveys. The sample size was calculated using an online sample size estimation software [41]. Based on the total number of registered community pharmacies of 11,699 (31st March 2017), 95%

confidence level and 5% margin of error, the required sample size was estimated to be 372. Given the 50% response rate in the pilot survey, the required sample size was calculated to be 744 (2x372). The calculated sample size was then rounded up to 750 to allow for pharmacy closures or contact information changes.

Data collection and analysis

The survey was administered between January and May 2019. IBM SPSS Statistics 25 software was used for data management and analysis. RY mainly administered the survey with the support of two research assistants, who were trained to be conversant on the topic, and administer the survey. Data entry accuracy was checked on 10% of the survey sample. The data were subjected to descriptive and inferential analysis. Frequency and cross-tabulation were initially used to describe the data. Chi-squared test was used to detect any difference in response within the categorical data, for example, gender and experience of training. Relationships between independent and dependent variables were tested using Mann–Whitney U-test (two independent variables) and the Kruskal-Wallis test (more than two independent variables) as appropriate. P-values ≤0.05 were considered statistically significant. Responses to the Likert statements were scored between 1 and 5 (1= strongly agree, 5= strongly disagree), where lower score indicated positive and higher score indicated negative attitude. Scoring was reversed for negative statements. Each participant was given an aggregate score and the scores were subjected to inferential analysis. Ten questions within the Likert scale were included as attitude statements and were used to measure CPs attitudes to OST.

Ethics

This study received ethical approval from The Research Ethics Approval Committee for Health (REACH), University of Bath. (EP 17/18 220, 09/10/2018)

Patient and public involvement

Practising pharmacists were involved in the design of this study. The lead author is a practising community pharmacist. JS is a prescribing pharmacist in an addiction service. Patients were not involved in the design or administration of this study as it was exploring pharmacist perspectives.

Results

Sample and response statistics

A total of 750 CPs were invited to participate in the survey, of which 253 completed the questionnaire (33.7%). A further 12.4% (n=93) of participants on telephone contact stated they did not provide OST services and were counted as ineligible. We do not know the eligibility status of 404 participants who did not participate in the survey. The participants' experience as a pharmacist ranged from newly qualified to 46 years in community pharmacy practice (mean 11.12, SD 10.69). Pharmacy managers (43.5%, n=110) were the largest group of participants, followed by locum pharmacists (27.7%, n=70) and owner pharmacists (10.3%, n=26). Those working in independent pharmacies (39.92%, n=101) and large multiples (40.71%, n=103) formed the majority of the participants with small multiples (10.28%, n=26) and medium-sized multiples (9.1%, n=23) also represented. The majority of pharmacies were in urban locations (58.9%, n=149), followed by suburban (31.6%, n=80) and rural locations (9.5%, n=24). The number of patients receiving OST from pharmacies ranged from 0 to 210 (mean 11.3, median 6, SD 17.94). Table 5.2 and Table 5.3 presents the descriptive statistics of the survey.

Table 5.2: Geographical breakdown of survey response

Geographical region	Potential participants (n)	Participants invited %(n)	Survey respondents % (n)
London	1118	18.9 (142)	18.6 (47)
South West	414	7 (53)	9.1 (23)
South East	729	12.3 (92)	13.4 (34)
East of England	577	9.7 (73)	9.5 (24)
West Midlands	836	14.1 (106)	13.8 (35)
East Midlands	491	8.3 (62)	6.7 (17)
Yorkshire and Humber	583	9.9 (74)	10.7 (27)
North East	277	4.7 (35)	7.1 (18)
North West	892	15.1 (113)	11.1 (28)
Total	5917	100 (750)	100 (253)

Table 5.3: Participant demographics

	Demographic Data	**Number of Participants**	**Percentage**
OST related services offered *	Dispensing FP10MDA (instalment) prescriptions	253	100
	Supervised consumption	236	93.3
	Needle & syringe programme	45	17.8
	Take home naloxone service	4	1.6
	Others	0	0
Employment status *	Owner	26	10.3
	Pharmacy Manager	110	43.5
	Locum	70	27.7
	Second Pharmacists	8	3.2
	Relief Pharmacist	14	5.5
	Others	31	12.3
Pharmacy category	Independent (1 store)	101	39.92
	Small multiple (2-4 stores)	26	10.28
	Medium sized multiple (5-25 stores)	23	9.09
	Large multiple (0ver 25 stores)	103	40.71
Location of the pharmacy	Urban	149	58.89
	Suburban	80	31.62
	Rural	24	9.49
Gender	Male	142	56.13
	Female	110	43.48
	Prefer not to say	1	0.40
	Other	0	0
Age range **	29 years and under	91	36.25
	30 to 39 years	77	30.68
	40 to 49 years	38	15.14
	50 to 59 years	30	11.95
	60 years and over	15	5.98
Supervised consumption *	Shop floor/ counter	71	28.1
	Consultation room	204	80.6
	Screened area	10	4
	Other	14	5.5
	Not applicable	14	5.5
Formal training to provide OST services	Yes	194	76.68
	No	59	23.32
CPD related to OST in the last 12 months.	Yes	102	40.32
	No	151	59.68

*****Total exceeds 100% as participants could choose multiple answers
******Two participants did not want to answer this question

Service provision

While all participants provided dispensing services, the majority (93.3%, n=236) also offered supervised consumption. NSP was provided by 17.8% (n=45) of the pharmacies, and 1.6% (n=4) participants provided THN. Except for NSP, there were no significant differences in the availability of addiction-related services in different regions of the country or between independent pharmacies and those belonging to multiple pharmacy groups. NSP service was exclusive to urban and suburban pharmacies (χ^2=7.1, df =2, p=0.028) and was more common in London, South East and South West regions (χ^2=15.7, df =8, p=0.046). Those who had received formal training on substance misuse were more likely to be providing NSP (χ^2=4.5, df =1, p=0.033) than those without formal training. One fifth (20.2%, n=51) of respondents said they never offered feedback to the prescriber on the patient's treatment progress.

Guidelines and practice outcomes

Twenty-one per cent (n=54) reported they never counselled patients about overdose risks, whereas 50% (n=126) counselled at the OST initiation stage and one-third (32%, n=81) did so when there was a change in dose/circumstances. Kruskal Wallis Test highlighted a significant relationship between providing overdose counselling and believing that CPs input reduces overdose deaths (χ^2=18.25, df= 2, p<0.001). While all pharmacists (100%, n=253) checked prescriptions for legal correctness, one-fifth (19%, n=48) did not always establish clinical appropriateness. Almost all CPs consulted the prescriber (97%, n=245) when three or more consecutive doses were missed. A significant majority (87.4%, n=221) suspected patients used drugs whilst receiving OST. Nearly a third (32.8%, n=83) indicated that on occasions, they dispensed doses to patients appearing to be intoxicated. 40% (n=101) of CPs reported being aware of patients diverting their prescribed medication. Though most participants (80.6%, n=204) said they supervised consumption in the consultation room, over a quarter reported (28.1%, n=71) to supervise the dose on the shop floor. The majority of CPs (63.2%, n=160) did not ensure patients had access to naloxone. A

statistically significant relationship existed between receiving training on OST and ensuring patient have access to naloxone (χ^2= 6.5, df =2, p=0.038).

Training and practice outcomes

Over three-quarters of participants (76.7%, n=194) reported they had received formal training to deliver OST services, but only 40.3% (n=102) had been asked by the service commissioner or their employer to provide evidence of that training. 40.3%, n=102 also reported having undertaken OST-related CPD in the last 12 months. A strong association was detected between those who had received training on OST and those who had been asked to provide evidence of training (χ^2=29.06, df =1, p<0.001). Those with training were more likely to see OST as an important service (χ^2= 8.6, df =3, p = 0.034) and be aware of the working of their local drug treatment teams (χ^2= 11.90, df= 3, p=0.008). They were also more likely to challenge a prescriber when they had a concern about their OST prescribing (χ^2= 9.8, df= 4, p=0.042) and withhold dose from intoxicated patients (χ^2= 6.4, df=2, p=0.039).

Gender and practice

Being male was a significant determinant in several aspects of CPs practice. Male pharmacists were more like to feel confident about their ability to provide OST service (χ^2=23.38, df=3, p<0.001) and to identify patients who presented intoxicated for their dose (χ^2= 7.8, df= 3, p=0.049). Male and female pharmacists also held differing perspectives when asked if reporting suspected drug misuse to the prescriber breached patient confidentiality, with male pharmacists more likely to agree with the statement (χ2=11.8, df= 4, p=0.018). While pharmacists' decision to withhold dose from an intoxicated patient was affected by the behaviour of the patient (χ^2=149.78, df= 4, p<0.001), no association was found between gender of the participants and the effect of patient behaviour on withholding dose (χ^2=4.8, df= 4, p=0.303).

Integration and attitude

CPs were more likely to provide feedback to the prescriber about the treatment progress if they felt the prescriber valued their opinions (χ2=26.5, df= 8, p=0.001) or that their feedback affected future treatment plans for the patient (χ2=32.3, df= 8, p<0.001).

The overall attitude of participants towards OST service was positive, as shown in Figure 1. The mean score for attitude-based statements was 2.30 (SD 0.349). CPs perceived OST as an important service they provide to patients (Mean 1.45, SD 0.644, n=253) and that their input helped prevent opioid overdose among those receiving OST (Mean 1.79, SD 0.821, n=253).

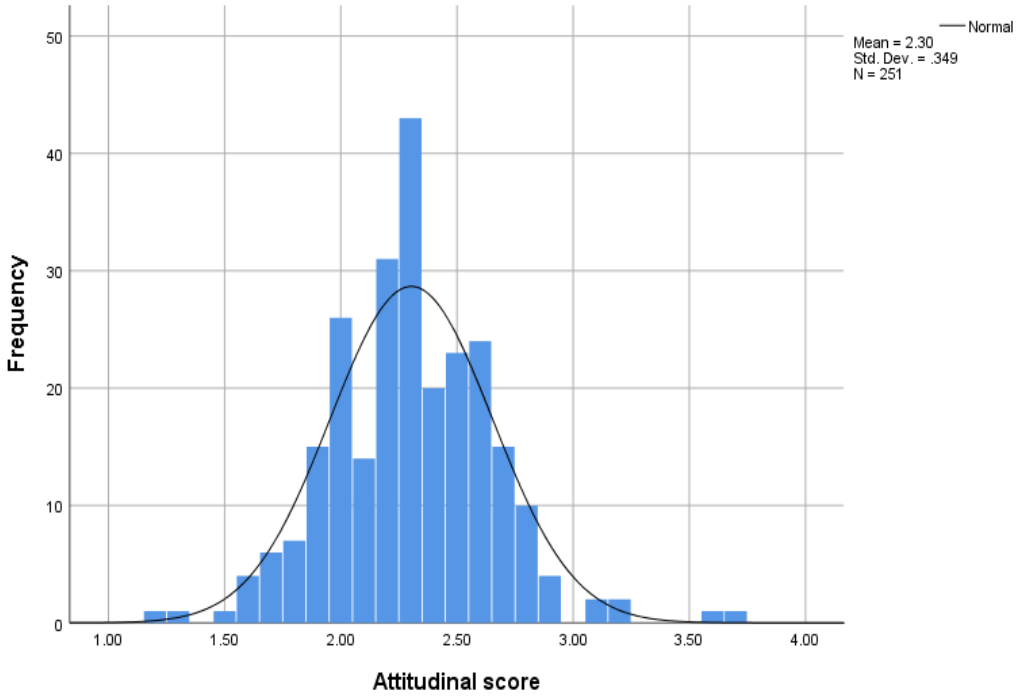

Figure 5.1: Attitudinal score of participants providing OST services. Lower score representing a positive attitude and a higher score representing a negative attitude.

Though participants responded positively to receiving professional advice and support in delivering the service (Mean 1.97, SD 0.859, n=253) during the regular working hours, the response was contrasting when receiving support during out-of-hours (Mean 3.30, SD 1.003, n=253). The National

Health Service (NHS) defines the out-of-hours period to be from 6.30 pm to 8 am on weekdays and all day at weekends and on Bank Holidays[42].

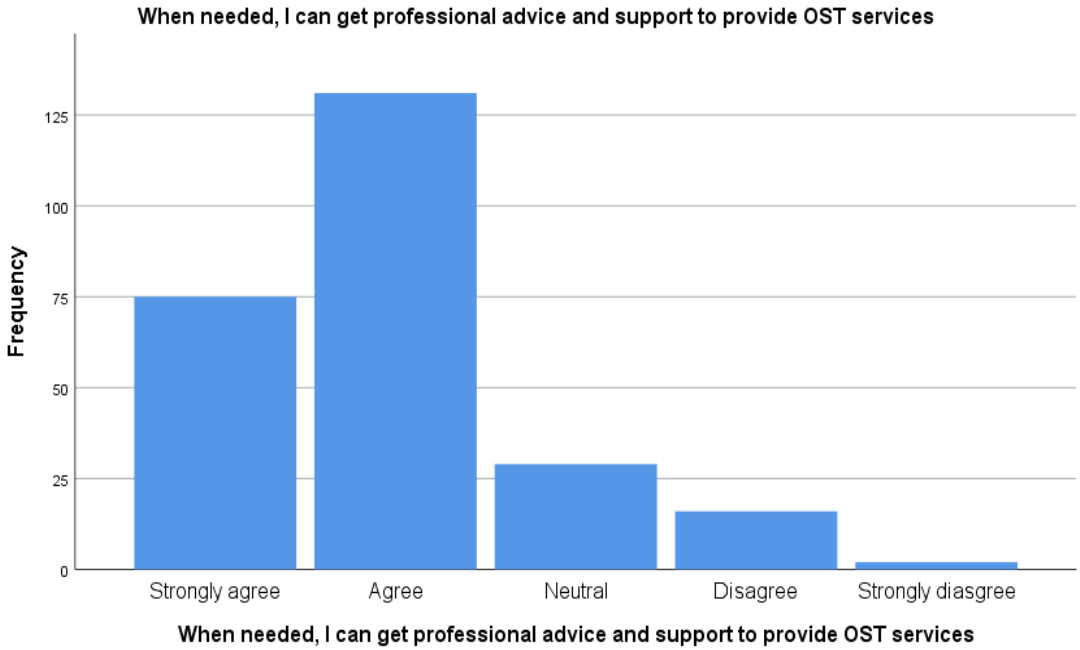

Figure 5.2: Response to support received by CPs in providing OST services.

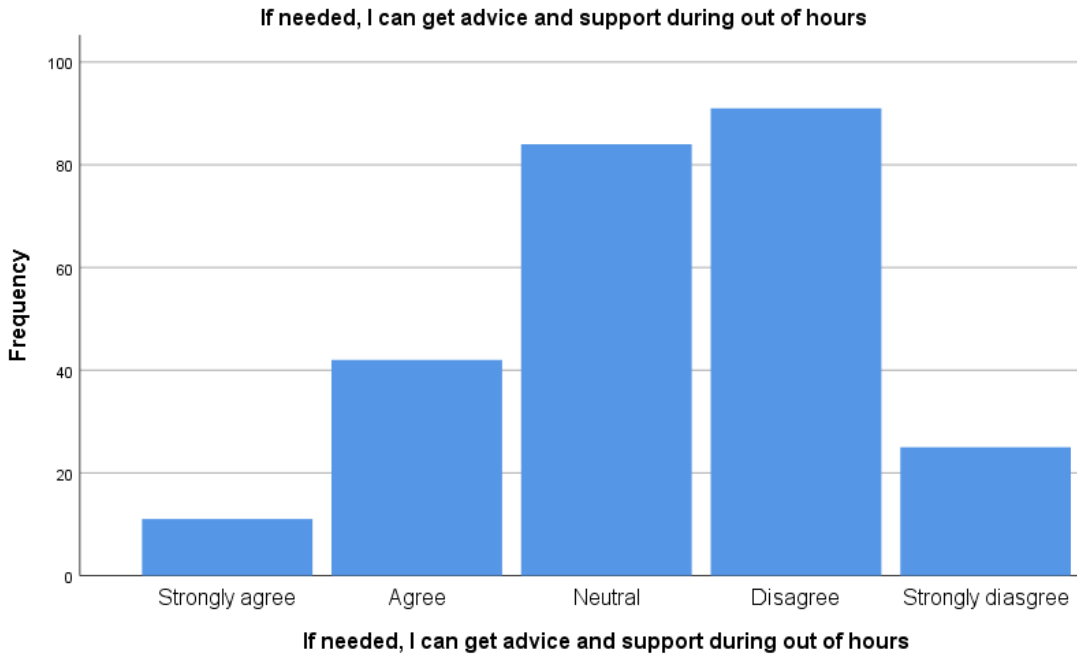

Figure 5.3: Response to support received by CPs during out of hours.

Discussion

This paper presents a survey of community pharmacists in England to explore their self-reported practice in relation to the provision of addiction services and their attitudes towards these services.

The findings of this study suggest community pharmacists could modify their practice to incorporate greater intervention to potentially reduce opiate overdose. This study reports very high self-reported adherence (97%, n=245) to the three-day rule, where patients who miss three consecutive doses are referred back to the prescriber. Likewise, 100% of respondents said they check prescriptions to ensure it meets the controlled drugs legal requirements. However, assessing the prescription's clinical appropriateness, withholding a dose from an intoxicated patient, counselling patients, checking access to naloxone or providing feedback to the prescriber were less adhered to.

One-third of CPs did not feel able to withhold doses from those presenting intoxicated in the pharmacy. There is no contraindication in dispensing OST to a patient who has been drinking alcohol[16]. It is, however, critical to be aware that in most overdose deaths where methadone is implicated, the use of other CNS depressants, commonly alcohol and benzodiazepines, is also a factor [4, 43, 44]. It is likely that non-clinical factors (for example, patient behaviour, workload) may influence CPs decision to dispense a dose to an intoxicated patient. Intoxication with both alcohol and benzodiazepines produces signs that can be visibly observed. While alcohol consumption can sometimes be detected by smell or use of breath alcohol monitoring, benzodiazepines intoxication can be hard to spot, especially to untrained eyes. Although we did not ask our respondents which substances they felt patients were intoxicated with, it is likely that alcohol and benzodiazepines feature. A Scottish pharmacist survey reported that almost half (47.9%) of CPs withheld dose from an intoxicated patient[27], whereas in this study, 32.8% said they sometimes supplied, suggesting 67.2% withheld doses or had not faced this problem. Although not directly comparable due to phraseology, this implies that this is an area of OST practice where CPs practice can be improved.

Only half of the pharmacists counselled the patient on overdose risk at the start of the treatment, and about a third did so when there was a change in dose or circumstances. Opioid tolerance changes during the induction and detoxification stages of OST treatment when patients are at heightened overdose risk [45]. The absence of overdose counselling by CPs at these stages, and in general, is of concern and, therefore, a clear area for improving practice.

UK Guidelines[16] recommend supervised consumption is undertaken in a consultation room or discreet area to protect patient confidentiality and foster a therapeutic relationship between the pharmacist and the patient. The practice of supervising OST consumption on the shopfloor was identified, with 28.1% (n=71) CPs reporting this practice. This supports the findings of our observation study reported elsewhere[40]. While such practice creates a barrier for patient engagement[46], it also internalises the stigma associated with OST[47, 48]. Vogel et al. argue that public stigma can be internalised as self-stigma by those seeking mental health help [47]. Wakeman et al. argue that deeply entrenched stigma, embedded within our language, our policies, and our systems of care, limits access to OST and can be a matter of life and death[49]. The stigma associated with OST is societal; community pharmacy team members can play their role by providing confidential and patient-centred practice. While it is to be acknowledged that some OST patients may refuse privacy while using the pharmacy, there remains a broader argument of whether patients perceive pharmacy as a place for a transaction or a space for clinical intervention. Inadequate privacy in pharmacies could result in patients' lack of appreciation for the clinical role of CPs[46], and CPs own attitude can be critical in influencing a sense of privacy and contributing towards stigma[50].

The finding of this study suggests the provision of NSP (17.8%, n=45) and THN (1.6%, n=4) in English community pharmacies is inadequate. A survey of the local authorities (LAs) by Mackridge et al. reported only 20% of the English community pharmacy offered NSP despite 98% of the LAs commissioning the service through pharmacy [23]. The Mackridge study was based on the Freedom of Information (FOI) request to the LAs and, therefore, likely to overestimate the number of pharmacies offering the

service. Anecdotally, the number of NSP pharmacies does not reflect the number who provide the service as some pharmacies have since stopped delivering the service. The National Institute for Health and Care Excellence (NICE) guidelines on NSP [21] recommend that services be available through CPs, particularly those already offering OST services and those who open longer hours. The insufficient financial incentive, workload pressures and stigma associated with the service may, to some extent, explain the inadequate provision of NSP in pharmacies, but this needs further investigation. Another freedom of Information (FOI) report (2017-2018) demonstrates that 58% of LAs did not provide THN through community pharmacies[12]. The same report also estimated inadequate THN coverage among OST patients (11%) and those not receiving treatment for their opioid dependence (28%). The wide availability of THN, as first aid in opioid overdose, is now being called upon by researchers and government authorities alike [51-54]. Therefore, it would appear prudent to improve the access of THN through pharmacies, particularly for those who are not receiving treatment. Because of their accessibility, the pharmacy setting is more likely to be used by those not in treatment than the more structured treatment centres.

This study highlights that CPs are more likely to engage and provide feedback on patient progress if they perceive their feedback is valued and makes a difference to patient care. This finding is new. Thus, a more inclusive communication, beyond transactional information sharing, needs to exist between CPs and the treatment team. Matheson et al., in a survey of Scottish pharmacies, also identified scope for better communication and integration of CPs with the wider addiction treatment team[27]. The provision of late-night and weekend opening pharmacies has increased access to pharmaceutical care; however, the support mechanism relied upon by CPs to deliver OST services ceases beyond regular working hours.
While strong correlations between formal training and good practice indicators (withholding dose from an intoxicated patient, ensuring access to naloxone, challenging concerning prescriptions, and understanding of the local drug treatment arrangements) were identified in the results, the

direction of the correlation cannot be ascertained from the available data. Therefore, while it could be argued that CPs trained in OST provision potentially reduces risk to OST patients, it can also be argued that those engaged in providing OST are more likely to attend training. The results also demonstrated that the professional decision making of CPs is affected by the patient's behaviour. This finding is supported by our previous work in this area[39]. CPs training and the support available to CPs in providing the service should be nuanced to address the challenges faced by CPs and more targeted to promote risk-reducing interventions. Matheson et al. argue that training improves CPs confidence to provide the service, facilitating experience, enabling attitudes to improve[27]. An online training delivered to CPs in New Zealand demonstrated that training improved the clinical skills of CPs in providing OST[55]. The difference in reported confidence of male and female CPs to provide OST service and identify an intoxicated patient is supported by our previous work in this area[39].

Strengths and weaknesses of the study

This is the first English national survey, specifically looking at the practice of CPs in activities that can prevent OST-related deaths. Data on adherence to the 3-day rule, level of naloxone supply in English community pharmacies, CPs dealings with intoxicated patients, the correlation between CPs gender and OST-related practice have not been reported before.

The main survey response rate was lower than the pilot survey (33.7 vs 50%); however, it remains in line with those reported by other researchers in recent years. (Barrett et al. 2020 postal survey 20.44% [56], Paudyal et al. 2019 postal survey 16.1%[57], Aston et al. 2018 postal survey 21.5%[58], Barnes et al. 2018 postal survey 10%[59], Weiss et al. 2016 postal survey 39%[60]). The research team is not aware of any significant change in external stimuli, which could have affected the response rate; however, the use of two non-pharmacist personnel administering the main survey could be one possible reason. Non-participation of two large multiple chains in the survey is another limitation of this research. As with any self-reported survey, social desirability bias in the findings of this research must be considered. While the results suggest little impact of social desirability bias,

the fear of reporting non-compliance to legal requirements of OST cannot be overruled.

While this survey has identified scope for improvement in the current practice of some CPs providing OST, by the very nature of the survey study, it could not establish the reason for the practice reported. For example, we could not explore why pharmacists chose not to counsel OST patients on overdose risks or ensure they had access to naloxone to treat an overdose. Our previous work in this area [39, 40] and those reported by others [30, 49, 61-64] suggest the stigma associated with OST, such as fear of violence or shoplifting, may contribute to CPs reluctance in engaging with OST patient.

Strengths and weaknesses in relation to other studies

This study is the first to report on CPs practice intended to prevent OST overdose and investigate their attitudes in relation to preventing overdose. The positive attitude of pharmacists towards OST services has also been reported by other researchers [27, 32, 65, 66]. Our findings demonstrate that CPs perceive OST to be an important service and that their input helps prevent overdose in OST patients. The inadequate provision of THN [12, 27] and NSP [23, 27] is widely reported. The need to uphold privacy standards in community pharmacy has also been reported by other researchers investigating the patient experience of OST services in pharmacy [48, 50, 62].

We have previously reported the negative effects of patient behaviour on CPs clinical decision making[39]. This study further supports the argument that the inaction by CPs in risk situations (for example, dispensing doses to an intoxicated patient) could be influenced by non-clinical factors (behaviour of the patient). However, in contrast to our previous reported qualitative work, this survey found no association between CPs gender and the effect of patient behaviour on CPs decision to withhold a dose.

Implications for clinicians and policymakers

It appears guidance pertinent to legal aspects and generally clear to follow (for example, the three-day rule) is more closely adhered to than those where professional judgement or clinical skills are required (for example,

withholding dose from an intoxicated patient). Therefore, policymakers and service commissioners need to be mindful of this while formulating OST-related policies and guidance/SLAs for CPs. Watkins et al. conclude that while guidelines can influence community pharmacy practice, there is little evidence to suggest they positively affect patient outcomes[67].

Lessons must be learned from the generally inadequate provision of NSP and THN services in community pharmacy to ensure the new Hepatitis C screening service launched in 2020 is more accessible. We have previously called for national certification of pharmacists trained to provide OST services[39], comparable to flu vaccination requirements. Declaration of competence should become mandatory for all pharmacist providing OST-related services[68].

The UK guidelines[16] emphasise the importance of good relationship and communication between CP and the prescriber. CPs are more likely to engage in the service provision if they felt their feedback was valued; thus, a robust feedback and support mechanism between CPs and OST prescribers must be established. The positive effect of regular feedback on improving adherence to guidance has also been reported by other researchers [69].

Conclusion

This study's findings demonstrate CPs are more adherent to certain aspects of delivering OST service than others. The current practice is well versed in the mechanics of delivering the OST service. The critical elements in preventing opioid overdose and requiring knowledge, professional judgement, skills and motivation are less evident in practice. Pharmacists' education on overdose prevention, patient confidentiality, their motivation to intervene in risk situations, improving access to NSP and THN in pharmacies, and better-integrating pharmacists in the treatment network all need attention.

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5.5 Commentary on the publication

This study presents a snapshot of the OST-related practice of CPs in England.

The results confirm the hypothesis that there remains a gap between the current practice and the recommended good practice in preventing overdose deaths in patients accessing OST and related services through community pharmacy. It also highlights various factors that contributed towards this imparity.

The findings of this study and that of the two previous studies are further discussed in relation to each other and in the context of published literature in the discussion chapter 6.

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Chapter 6

Discussion

Chapter overview

This chapter triangulates the findings presented in chapters three, four and five and presents an overarching discussion of those findings. This chapter also highlights this doctorate's originality and its contribution to knowledge, along with its potential impact on practice and policy. Finally, this chapter identifies the strengths and limitations of this doctoral study and future research areas.

6.1 Introduction to chapter

The first aim of this study was to investigate the role of UK community pharmacists in preventing opioid substitution therapy-related deaths. The second aim was to explore what more can be done to avoid such deaths. To achieve these two aims, a series of three studies were conducted. The three phases of study each had their own aims and objectives and designed to answer the thesis's main aims. The discussion of the three phases presented as published or publishable journal articles in chapters 3, 4 and 5 is limited to individual study scope. Here, the author presents an overarching discussion on the findings and the interconnectedness of the three studies' findings.

6.2 Originality and contribution to the knowledge

This study's originality lies in exploring the CPs perception of risk associated with OST and their perceived role in preventing overdose deaths. Secondly, this study presents observational evidence of stigmatised practice in delivering OST service in English community pharmacies. This study is also novel in utilising mixed methods research in exploring CPs role in providing OST services in English community pharmacy. On the one hand, the study findings contribute to understanding the professional practice of CPs in delivering OST services. On the other hand, the recommendations generated from this research's findings will help improve the input of CPs in preventing OST-related deaths. The findings and recommendations are also likely useful in improving existing or implementing new community pharmacy services. The new community pharmacy-based Hepatitis C screening programme for PWID, implemented in England in 2020, can benefit from this thesis's recommendations [1].

6.3 Triangulation

The triangulation protocol proposed by Farmer et al. [2] was adapted to suit the scope and need of this thesis. Firstly, the key themes discussed in each study were identified. Through careful considerations and reflection, the themes were consolidated into a unified list of key themes. A total of 17 key themes were identified across the three studies. A comparison matrix was then used to see if and to what extent; these themes converged or diverged between the three studies. This was achieved by organising the themes and the studies in rows and columns. Each theme was then given one of the four possible categorisations of either agreement, partial agreement, disagreement or silence, depending on the strength of the evidence presented in each study. Through reflection and careful deliberation, the author deduced connections between the important, distinct, and sometimes overlapping findings of the three studies. This approach has helped to highlight the strength of evidence in my recommendations. The discussion was completed by corroborating the findings with other published literature in this research area.

Table 6.1: Overview of key findings and how they triangulate across the three studies

Key Findings	Interview study	Observation study	Survey study
OST services are not delivered in an equitable way	Agreement	Agreement	Agreement
CPs do not feel to be integrated into the treatment team	Agreement	Silence	Partial agreement
Lack of mandatory training requirements	Agreement	Silence	Agreement
Practice guidance not always adhered to	Agreement	Agreement	Agreement
CPs exhibits positive attitude to OST	Partial agreement	Disagreement	Agreement
Patients' privacy and dignity not adequately protected	Silence	Agreement	Agreement
Evidence of stigmatised practice	Agreement	Agreement	Agreement
Inadvertent disclosure of patient confidentiality	Silence	Agreement	Partial agreement
Non-rigorous approach to patient confidentiality	Silence	Agreement	Agreement
Practice well versed in the mechanics of delivering OST service	Agreement	Agreement	Partial agreement
Gap in CPs perceived confidence and their knowledge and skills	Agreement	Silence	Partial agreement
CPs role largely limited to supply and supervision function	Agreement	Agreement	Partial agreement
CPs aware of the diversion of prescribed OST	Silence	Silence	Agreement
CPs assessment of intoxication is subjective	Agreement	Silence	Agreement
Clinical decision making influenced by non-clinical considerations	Agreement	Partial agreement	Agreement
Gender is a factor of CPs professional practice	Agreement	Silence	Partial Agreement
CPs limited involvement in providing feedback to the prescriber	Agreement	Silence	Agreement

6.4 Discussions of key findings

The key findings in table 6.1 maps against the socio-ecological model (SEM) framework, first proposed by Bronfenbrenner in the 1970s[3]. The SEM argues that a dynamic relationship exists between an individual and the environment in which it operates. Its surrounding influences the actions and inactions of the individuals; therefore, to understand an individual's behaviour, the whole ecological system it operated needs to be considered[4, 5]. The SEM framework was not used as a guiding framework in designing the study. The author attempts to better understand the findings of this research from a theoretical perspective by utilising it at the later stage of this research. While this can be seen as a criticism of the study, the author believes that the use of a theoretical framework, even at this later stage, has helped to strengthen the recommendations made in this thesis. While the findings of this research conveniently mapped against the SEM framework, the author is mindful that there might be other theories that could be used to explain the findings.

The themes presented in table 6.1 broadly map against the three layers of SEM; the societal or organisational factors, individual or personal factors and the community or professional factors. Accordingly, for ease of presentation and readerships, the discussion of the findings is organised under three overarching headings and subheadings within it. The discussion under each heading leads into recommendations for policymakers, academics, and practitioners to improve care and reduce the risk of opioid overdose deaths. The author has tried to make the arguments without being too repetitive of the discussions presented in the previous chapters. Therefore, this chapter should be read in light of the discussions presented in chapter 3, 4 and 5.

6.4.1 Organisational factors

6.4.1.1 Accessibility to OST services

While all participating pharmacies provided OST dispensing and the majority also offered SC, it was evident in the survey findings that there is significant variation in the availability of other services related to opioid addiction in

English community pharmacy. The availability of NSP and THN services throu community pharmacy is poor across all geographical regions in England. NSP services are more common in the London and the South region than Midlands or the North. NSP is also more likely to be available through pharmacies located in urban or suburban areas. This finding of the inadequate provision of NSP and THN is in line with those reported by others [6, 7]. These services are commissioned locally by the local authority as per local requirements; therefore, it could be argued the current provision reflects the local need for these services. This argument, however, does not hold ground given the high opioid-related deaths of recent years. Mackridge et al. argue the commissioning of services can be influenced by a range of factors other than identified need. They reported a poor correlation between the need and commissioning of service in community pharmacy [6]. NSP is often the first point of contact between those who inject drugs and the health care system. This cohort of the population has a higher mortality rate than those in treatment [8]. Community pharmacists and the pharmacy team can play an important role in engaging and referring these patients to the safer practice of OST. Scott notes that while some signposting to specialist services occurs, there is potential for more to be done and for the outcomes of such to be established[9].

The NICE guideline recommends the NSP service is commissioned through community pharmacies, particularly those also offering OST. Therefore, it is prudent that the local authorities review the provision of NSP and its availability in community pharmacies. Particular attention is required to ensure these services are available in areas with known drug problems and through those pharmacies providing extended opening hours.

The provision of THN in England has been described as ‘finding a needle in a haystack’ in a recent survey report published by Release[7]. The survey study finding supports these findings as only a small minority (1.6%, n=4) of community pharmacies in the survey provide the service. Despite being the most accessible health care facility, the provision of THN in community pharmacy is generally poor, with only 6% of local authorities[10] (but noted as 42% by the Release report[7]) commissioning the service via community

pharmacy. THN programmes combined with educational and training interventions reduce overdose-related mortality and have been proposed as a key approach for reducing opioid overdose death in the recent European Drug Report 2019[11]. The PHE guidance on preventing drug misuse deaths calls for widening access to naloxone[12]. It recommends making naloxone available to those on OST and those currently using illicit opiates or who have been known to use opioids in the past. With the patient's consent, it should also be supplied to family members, friends and peers[12, 13].

The ACMD, in its report on reducing opioid-related deaths, identifies the changes in the drug treatment and the commissioning practice as a possible cause of the increase in opioid-related deaths seen in the UK in recent years [14]. It notes that the frequent recommissioning of drug treatment services has diminished the quality of services, with providers implementing arbitrary changes to the conditions attached to individual patients' treatment. It is the author's observation that while the drug service provider may change, the pharmacy can stay the same. Therefore the pharmacy team can provide continuity and long term support to OST patients.

The resilience of the English community pharmacy network is being demonstrated during the Covid-19 pandemic. The adaptability of this healthcare setup has been reported both here and internationally[15-17]. Nonetheless, the ongoing pandemic is a challenge in caring for PWUDs. The EMCDDA identifies PWUDs to be at heightened risk of catching coronavirus because of activity associated with drug-taking like the sharing of preparation equipment, cannabis joints or cocaine straws[18]. Whitfield et al. report a 36% reduction in the number of people using the NSP in Chesire and Merseyside (North West of England) during the Covid-19 pandemic[19].

In light of the ongoing pandemic, the PHE issued guidance for commissioners and providers providing services to PWUDs. It recommends practical measures to reduce dispensing frequency, allowing take-home doses and collection by a third person where suitable[20].

6.4.1.2 Variability in service

The equity of OST and related services delivered in English community pharmacy is questioned by this research. The three studies demonstrate variability in the types of drug-related services commissioned through community pharmacy and the way these services are provided. The interview study showed variation could range from how the service is commissioned (commissioning variation) to how individual CPs deliver it. The observation study showed variations in the consideration given to the privacy and confidentiality of those accessing the service. The survey study showed variability in the availability of services in different areas of the country. While some good practice is reported in these research findings, scope remains for improving the delivery of the service. Variation in OST service delivery in different geographical areas, or even within different pharmacies in the same geographical area, can arise from many factors. The ACMD report in 2015 raised concerns about the variable quality of drug treatment services at a local level in England[21]. While the findings presented in the report were not specific to community pharmacy, this study's findings suggest that the concerns reported by ACMD extend to pharmacy practice.

Conclusion 1

OST services are not delivered equitably. Local commissioning of the service and various service providers' involvement makes it difficult to have consistency at the local and national level. The provision of NSP and THN in the English community pharmacy is poor.

Recommendation 1

A national framework of addiction care service delivery in community pharmacy primary care is needed to standardise service availability and service standards.

6.4.1.3 Integration and support

Integration is a means to improve services in relation to access, quality, user satisfaction and efficiency[22]. Despite feeling their role to be essential in delivering OST services, CPs did not feel part of an integrated system.

Communication barriers, inability to contribute to clinical decision-making and lack of professional support were identified as possible reasons for this perceived detachment.

The interview study demonstrates the current information sharing between the treatment teams and CPs is patchy. The survey study supported this. Although two-thirds of CPs could promptly contact the prescriber when needed (65.9%, n=166), and 81.4%, (n=206) get the professional advice and support they need, this figure changed for out-of-prescriber-hours service provision, where only one-fifth (20.9%, n=53) felt they could access necessary support and advice. NHS defines the out-of-hours period to be from 6.30 pm to 8 am on weekdays and all day at weekends and on Bank Holidays[23]. Given many community pharmacies are open during these hours, the provision of support in delivering OST services out-of-hours needs to be strengthened. The UK clinical guidelines recognise the advantage these long opening pharmacies can provide in managing OST patients, particularly in those in employment or where a seven-day SC is desired, so access to support should be part of this recognition[24].

In the absence of standardised communication and feedback mechanisms, different working practices have emerged locally. The survey results show that one-fifth (20.2%, n=51) of the respondents never provide feedback to the prescriber on the patient's treatment progress. It also adds that CPs are more likely to engage and give the treatment teams feedback if they feel the prescriber values their feedback. Therefore, the communication between CPs and the treatment teams should be standardised and extended beyond the transactional information sharing to incorporate mechanisms that support feedback in both directions. The current UK guidelines[24] envisage the collaborative working between the OST prescriber and the pharmacist dispensing the intervention. It calls for two-way communication to facilitate feedback and raising concern where it exists. A study in Australia explored the impact of a collaborative (co-prescribing) model of OST on patient, pharmacist and prescriber relationships [25]. Recognising the barrier posed by the impact of workload, changes in professional relationships and training

this study, highlighted co-prescribing may enhance the relationship between pharmacist and patient and improve continuity of care and treatment access.

This finding was further explored in the survey study in this thesis and highlighted that three-quarters of CPs (75.5%, n=191) believed they were integrated into the OST services, and a similar proportion (77.1%, n=195) was also aware of the local drug treatment team in their area. The survey findings suggest that while most CPs felt they were professionally integrated into drug treatment services, a significant minority did not feel that way.

Bond and Hopf note that despite the inalienable right to be represented in the core health care team delivering integrated care, most of the initiatives related to integrated care centre on physicians' roles and practices. The involvement of members of the broader health care team is commonly limited to nursing[26]. Thus it would appear the issue of integration is not limited to CP practice but a reflection of the current healthcare landscape.

Robertson et al. (2015) surveyed the community pharmacy provision of services to drug misusers and compared it to previous surveys [27]. This Scotland-based study reported that drug users' pharmaceutical care has evolved from OST supply to a more clinical approach. It also noted that CPs actively monitor OST patients, manage their minor ailments and are increasingly engaged with the wider care team. The studies in this thesis suggest that while there is evidence of clinical interventions by pharmacists, there is scope for furthering it. Knowledge and confidence in providing the service and non-clinical factors like workload, patient behaviour may impact CPs clinical decision-making in delivering OST. An earlier study by Hobson et al. (2010) concluded that while patients acknowledge pharmacists' expert drug knowledge, doubt exists around privacy and governance concerns for prescribing services to be offered in community pharmacies [28]. In England, there are anecdotal reports of OST prescribers co-located with pharmacies; however, the feasibility and benefit of OST prescribing services being offered in community pharmacy remain to be explored.

Conclusion 2

CPs do not see themselves as a part of an integrated treatment team. Communication and feedback mechanism between the prescriber and the CPs are not standard and largely dependent on local practices.

Recommendation 2

Community pharmacy should be part of the OST teams, with closer working between CPs and prescribers. A shared feedback mechanism, beyond the transactional information sharing, should exist between the prescriber and CPs to improve patient care.

6.4.1.4 Guidance and training

The current UK clinical guidance on the management of drug misuse highlights the issues of opioid-related deaths and recommends steps to prevent such deaths. These recommendations are not specific to pharmacy practice. Participants of the interview study also identified the lack of clarity in guidance to CP. Any guidance to CP should make clear the goal of OST and related services and specify how these goals are to be achieved. Guidance pertaining to dealing with difficult situations in delivering OST, for example, identifying intoxication and withholding a dose, needs to be specific in recommendations. The literature review and the results of this study demonstrate that there are no benchmark or guidance specific to pharmacy practice on preventing overdose-related deaths. In the absence of clear guidance, critical clinical decisions like identifying intoxication, withholding of a dose, patient counselling on risks, and feedback to the treatment team are being made based on CPs personal interest and experience. Notably, this research demonstrates that clinical decision-making is influenced by non-clinical factors, including patient behaviour/aggression, workload, and stigma.

While clinical practice guidance is important in healthcare practice and can be a valuable educational and clinical tool, it is not without criticism. Brown argues that over-reliance on practice guidance can limit critical thinking, and as a drug expert, pharmacists should be able to function beyond the

cookbook recommendations of guidelines [29]. Therefore, consideration should be on the content of the guidance and its implementation [30].

In the survey study, a significant proportion (76.7%, n=194) reported having received formal training to provide OST services, with 34.4% (n=87) of respondents also saying they had completed Continuing Professional Development (CPD) related to OST in the last 12 months. Robertson et al. reported a similar finding in a survey of Scottish pharmacists, where they found three-quarters of participants had received training in drug misuse [27]. The survey (chapter 5) demonstrates a positive correlation between training and good practice indicators, such as withholding a dose from intoxicated patients, ensuring patients have access to naloxone, challenging concerning prescriptions and understanding local drug treatment arrangements. Matheson et al. argue that training improves CPs confidence to provide the service, facilitates experience, enables attitudes to improve, and encourages CPs to provide services like NSP and THN [31]. Likewise, online training provided to CPs in New Zealand demonstrated that training improved the clinical skills of CPs in providing OST[32].

A pilot study of the English community pharmacists assessing the effectiveness of a tailored training programme in behaviour change counselling (BCC) found training pharmacists enabled them to deliver BCC competently and confidently [33]. This study also suggests that ongoing support is needed to maintain CP competence in the long term. Likewise, Gheewala et al. report a web-based training programme positively enhanced Australian community pharmacists' knowledge and skills associated with chronic kidney disease screening [34]. While there is evidence to support a positive patient outcome with pharmacists' training on a given subject, one must be careful in extrapolating such findings, especially to a service with high levels of stigma attached to it.

The content and nature of training are critical in influencing the practice of CPs. As discussed in the interview and survey study, CPs training on OST should be nuanced to address the challenges faced by CPs and more targeted to promote risk-reducing interventions. As argued in the interview

study discussions (chapter 3), lack of knowledge among some pharmacists and lack of clear guidance and support in providing the service resulted in some patients at high risk of OST-related deaths not having their risks acted upon. Awareness of the local drug treatment service, clinical knowledge of OST, identifying intoxication, withholding dose, raising concerns when one exits, challenging concerning prescribing should all form part of CPs training. Stigma has been a common thread running through the results of all three studies. CPs' training should include training on recognising stigmatising behaviours/practice in themselves, their staff and users of the service and reducing it.

Currently, there is no national certification to demonstrate a pharmacist is competent to provide OST services. Therefore, a national certification mechanism, in line with those that exist for other pharmacy-based services, should be the way forward. To provide other pharmacy services like the flu vaccination and emergency hormonal contraceptive, CPs are required to complete recommended learning and provide 'declaration of competence' on the CPPE portal, which then can be verified by the commissioners[35]. This existing mechanism of training and its verification can be adapted nationally.

Conclusion 3

Clinical guidance intended to reduce OST-related deaths are not always adhered to. It appears guidance that is pertinent to legal aspects and generally clear to follow (for example, the three-day rule) is more closely adhered to than those where professional judgement or clinical skills are required (for example, withholding dose from an intoxicated patient).

Conclusion 4

Variability in practice identified in the research suggests a need to improve practice and set national standards for OST service delivery. Education and training to deliver practice to these standards, as used in other service delivery models, e.g. flu vaccination, is advocated.

Recommendation 3

Practice guidance to pharmacists should be clear and specific to deal with the challenges faced by community pharmacists in providing the service (for example identifying intoxication, dose withholding, out-of-hours referrals, dealing with security concerns).

Recommendation 4

Pharmacists providing opioid substitution therapy service should engage in mandatory standardised training, and mechanisms should be in place to monitor their training and competency. An existing mechanism like the 'Centre for Pharmacy Postgraduate Education CPPE self-declaration of competency' can be adopted.

6.4.2 Personal factors

The findings from the three studies demonstrate variability in the approach and attitude of CPs providing OST and related service.

6.4.2.1 Therapeutic Relationships

The three studies' results identify a positive relationship between OST patients and CPs as a strong and positive aspect of OST service provision in community pharmacy. Participants of the interview study alluded how a good relationship develops between patient and CPs with time. Radley et al.[36] report that OST patients valued their positive relationship with the pharmacy team despite experiencing stigma and discrimination. The good rapport between the OST patients and the pharmacists and the authority figure of CP in the pharmacist-patient interaction can be utilised in encouraging positive patient engagement [37-39]. Positive relationships between CPs and OST patients help to minimise the impact of patient aggression on pharmacy practice [38]. As Harris et al. noted, recovery cannot be achieved if individuals are devalued by the treatment system itself[39]. CPs need to reflect on and, where needed, change their practice and environment to ensure the dignity and privacy of those receiving OST is protected.

6.4.2.2 Stigma

Stigma kills. According to Wakeman et al., the stigma associated with OST service provision can literally be a matter of life or death [40]. They conclude that the deeply entrenched stigma embedded within our language, our policies, and our care systems is currently limiting access to OST. The fact OST is possibly the most regulated and controlled intervention in primary care health services is indicative of the stigma associated with it[39]. While OST interventions' controlled drug status necessitates some of the regulations, the apparent lack of interventions in risky situations (interview study, chapter 3) and the apparent disregard for patient confidentiality (observation study, chapter 4) are laden with stigmatised practice. Further evidence of stigmatised practice are reported in the results of the interview and the observation study. Stigmatised practice was observed first-hand in the observation study and by the use of stigmatised language by participants in the interview study. While some participants showed awareness of the intricacy of stigma and how that might affect their practice, others were more confident in their ability to avoid stigma in their practice. Stigma associated with opioid dependence and its treatment is societal and not just limited to pharmacy environment. Vogel et al. argues public stigma can be internalised as self-stigma by those seeking mental health help [41]. Stigmatised behaviour among CPs (not ensuring patient privacy) and the patients (not wanting privacy; as reported by CPs) has created a cycle where the stigmatised practice is normalised, which in turn reinforces the stigma[41]. Notley et al. report that the pharmacists' own attitude can be critical in influencing a sense of privacy and contributing towards stigma[42]. Reducing stigmatising experiences decreases not only the barrier to treatment but also improves patient outcomes[43], by increasing retention in treatment. CPs can help to interrupt the internalisation of stigma among OST patients[41]. Countey et al. report that educating pharmacy students about opioid addiction and its treatment reduces its stigma [44].

Conclusion 5

Community pharmacists providing OST services generally have a positive attitude towards it and the pharmacy team generally have a good rapport with the patient group. However, exceptions to this have been observed and reported in this work.

Conclusion 6

The privacy and dignity of those receiving OST and related services in pharmacy are not adequately protected. Even when caution is practised, inadvertent disclosure of patient confidentiality occurs in the delivery of the service.

Conclusion 7

Stigmatised behaviour among CPs (not ensuring patient privacy) and the patients (not wanting privacy; as reported by CPs) has created a cycle where the stigmatised practice is normalised, which in turn reinforces the stigma.

Recommendation 5

The non-rigorous approach to patient confidentiality needs to be addressed through a change in the professional practice of CPs individually and collectively. And also, by education and addressing and acknowledging what stigmatised behaviours for both CP and patient are.

6.4.2.3 Patient-centred approach

A patient-centred approach requires a practitioner to remain clearly focused on the individual patient's well-being [45]. In pharmaceutical care, as noted by Sanchez, this goes beyond meeting a patient's drug-related needs and includes resolving drug therapy problems and understanding the meanings patients ascribe to their illness as well as to their medications[46]. The UK clinical guidelines recognise pharmacists' opportunity to build a therapeutic relationship with the OST-patient to promote health and harm reduction[24]. Supervised consumption is an opportunity for CPs to build the therapeutic

relationship with patients further by increasing their time together. Such patient-centred practice can be achieved by providing the service in a private and confidential space that allows the time and environment to gain the patient's confidence.

It is evident in the results of the three studies that CPs are not utilising the opportunity to provide a confidential and patient-centred service. The observational study results also demonstrate that body language and verbal and non-verbal interactions between the patient and the pharmacy team are not reflective of a patient-centred approach. The role of CPs in OST services is mostly that of supply with minimal engagement beyond the dispensing of what has been prescribed. The current CPs' practice is well versed around the mechanics of delivering the OST service. The important aspects of preventing opioid overdose which require knowledge, professional judgment, skills, and motivation are less evident in practice. The intrinsic focus of CPs OST practice needs to move away from being solely transactional, i.e. handing out the prescribed OST, to improving health outcomes by reducing risk and improving access to care.

It is to be noted that it might be the personal preference of some clients to be treated in a transactional way, as reported by Anstice et.al.[43] Such choices could result from self-stigma among the users of the service; CPs, therefore, should attempt to address it by promoting self-respect and dignity.

Conclusion 8

The 'mechanics of delivering the OST service' forms the central premise of the English community pharmacist's current practice, and the notion of 'preventing opioid overdose' is peripheral.

Recommendation 6

A patient-centred approach by providing confidential and dignified service, creating conducive environments for patient engagement and monitoring should form the core of OST service.

6.4.3 Professional factors

6.4.3.1 Knowledge and confidence

One of UK pharmacists' fundamental roles is to ensure the clinical appropriateness of the medication prescribed to the patient [47]. CPs require appropriate pharmacological knowledge and confidence to perform this critical role as it involves liaising with the prescriber where necessary. The interview study results demonstrate that some pharmacists do not use the same in-depth clinical checking to establish prescription safety as would be done for non-OST prescriptions.

In contrast to the interview study findings, the great majority of survey participants (96.4%, n=244) felt confident in their ability to provide OST services. The confidence to challenge a prescriber, however, was lower at 84.2% (n=213) participants. When explicitly asked about counselling a patient on overdose risk, one-fifth of participants (21.3%, n=54) stated they never did. A similar proportion (20.2%, n=51) never provided feedback to the prescriber on the patient's treatment progress. It therefore appears, even though CP might feel confident in their ability to deliver the service, they might not be adhering to the practice guidance. From the results and discussions of the studies presented in Chapters 3, 4 and 5 and the argument presented here, it could be concluded that there remains a gap between the perceived confidence of CPs and their knowledge and skills to provide OST service.

Suboptimal dosing of OST in the UK and internationally has been reported by several researchers and government reports [24, 48-50]. Suboptimal dosing has been associated with a low retention rate in treatment [49, 51], thus exposing the patient to high-risk stages of starting and stopping treatment [52, 53]. Suboptimal doses of OST also increases risky drug-taking 'top-up' behaviour in patients. CPs should be able to identify signs of opioid withdrawal, particularly at the initiation and detoxification stages. Their frequent contact with OST patients puts them in a uniquely advantageous position to pick up on physical signs of opioid withdrawal. CPs should

discuss their concern with the patient and provide feedback to the prescriber if appropriate.

Conclusion 9

There remains a gap between the perceived confidence of CPs and their knowledge and skills to provide OST service. Lack of knowledge and confidence in delivering the service means some OST patients at high risk may not have their risk acted upon by some CPs.

Recommendations 7

The knowledge and confidence gap in providing OST should be addressed through appropriate coverage of this subject area in the undergraduate course and during the pre-registration training year and standardised training requirements post-registration.

6.4.3.2 Supervised consumption and patient monitoring

The results of the three studies demonstrate SC of OST medication in a non-private space is prevalent in community pharmacies. The observation study demonstrates that good practice guidance, such as providing drinking water after SC of methadone or before SC of sublingual buprenorphine or having a brief conversation to ensure swallowing of the medication, is not always adhered to. The interview study's findings offer stigma, security concerns, and workload as a possible explanation for such practice.

Lack of privacy during SC has also been reported by other researchers [39, 42, 54]. SC consumption should be delivered confidentially with due regards to the dignity of the patient accessing the service. CPs should ensure the dose of prescribed medication is completely swallowed before the patient leaves the premises, and drinking water following SC should be offered to prevent dental caries.

While NICE guidelines recommend SC for the first three months of starting OST[55], this recommendation has been removed from the 2017 UK clinical guideline[24]. The duration of SC should be based on the ongoing risk

assessment and the patient's progress. A Scottish study of OST prescribers suggests an individualised approach in determining the duration of time patients are maintained on SC[56]. Notley et al., reporting on the patient experience of SC, also called for less rigid adherence to the three-month time frame [42]. This flexibility offered by the non-rigid SC regimen places more emphasis on patient monitoring, which CPs can provide through their observation and frequent interaction with patients. They can also pick up on certain clues which might be indicative of potential risk situations. For example, sudden changes in patient behaviour and outlook, missing doses when they previously did not, being accompanied by other known drug users or children, or collecting NSP packs can all indicate potential risk situations and therefore critical in determining the duration of SC. The new flexible SC regimen recommended in the UK clinical guideline[24] makes the CPs role more critical. Good communication and feedback mechanisms between the CP and prescriber are crucial in ensuring the SC flexibility offered in the guidance is used for the benefit of the patient without increasing risk [57]. Often CPs would be the last healthcare professional to have been in contact with the patient before an episode of overdose.

Conclusion 10

SC offers an opportunity to monitor patients' progress and well-being on a more or less daily basis. This frequent contact by a healthcare professional is largely limited to the supply and physical supervision of the prescribed dose. The opportunity of improving outcomes by feeding back the first-hand information on patient progress, any concern or recommendation by the CPs remains mostly unutilised.

Recommendation 8

OST guidelines should become more inclusive to harness CP's strategic position in monitoring and supporting patients to minimise OST-related deaths.

6.4.3.3 Diversion

Diversion of prescribed opioid substitutes increases the risk to the patient and the general public[58]. In addition to failure to progress, suboptimal dosing in those diverting their medication can lead to risky street drug use[58]. Two-thirds of methadone-related deaths occurred in those who were not prescribed the medicine at the time of their death[59]. The UK government strategies to reduce the supply of illegal drugs by targeting the illicit drug market [60]. To minimise the risk to the general public, CPs need to be aware and skilled to identify the risks of diversion of prescribed medication and accidental poisoning risks.

The interview study results demonstrate the CPs awareness of OST diversion, and the survey results highlighted that 40% (n=101) of CPs stated they were aware of their patients diverting their prescribed medication.

A Swedish study placed self-reported diversion of OST at 24.1% (n=99)[61]. An analysis of UK border agency data on methadone and buprenorphine by Marteau et al. found negligible amounts of methadone and buprenorphine entering the UK illegally. They conclude diversion of the prescribed methadone and buprenorphine, particularly the take-home dose, as a source for these drugs' illegal availability [62]. Winstock et al. explored the methods and motivations behind diversion and sought patients' feedback on strategies to reduce diversion[63]. The study suggests practical measures, including a mouth rinse and checks after consumption to reduce diversion risk. The results of the observation study demonstrate that CPs do not consistently implement these practical measures. Findings from the three studies also establish routine SC on the shop floor. This practice does not offer the appropriate environment for mouth rinsing or checking without further stigmatising the patient.

A report by Adfam researching cases where children have died or been harmed by ingesting OST medication found the risks to children posed by OST medications are not sufficiently managed or minimised in practice[64]. It also reports that service users and professionals are sometimes unaware of the dangers that OST drugs can pose to children when not managed

correctly. This report calls for a more prominent role for pharmacists, health visitors, social workers and the police in safeguarding children from the risks of OST ingestion. In phase one, study participants also shared knowledge of local or media reported incidents of accidental ingestion deaths in children. CPs should reduce the risk of diversion of OST medication by ensuring practical measures like rinsing or checking of the mouth are done after SC. Where take-home doses are dispensed, message for safe storage of the drug should be emphasised.

Conclusion 11

CPs are aware of the potential for diversion of prescribed OST and the risk it poses for others, particularly children and opioid naïve. The measures intended to reduce diversion risk, such as rinsing or looking into the mouth after consumption or a brief conversation to ensure the dose is swallowed, are not regularly observed. SC undertaken on the shop floor is not conducive to perform these interventions without further stigmatising.

Recommendation 9

SC needs to be undertaken in private space to allow for consumption to be observed in a confidential and non-stigmatising way. This practice will also be conducive to forging a therapeutic relationship between the patient and CP.

6.4.3.4 Intoxication and dose withholding

The survey result demonstrates a significant majority (87.4%, n=245) of CPs suspected patients to use drugs while receiving OST. Likewise, interview participants shared their awareness of drug misuse among OST patients. The survey also reports that a third of CPs (32.8%, n=83) on occasions also dispensed doses to patients appearing to be intoxicated. Dispensing OST dose to intoxicated patients by CPs have been reported in the literature [27].

Withholding a dose in patients who present intoxicated in the pharmacy is a critical intervention to reduce the patient's risk of harm. Taking the regular

dose of OST while under the influence of alcohol or other drugs can increase overdose risk. It is not uncommon for OST patients to present intoxicated in the pharmacy[65, 66]; therefore, a balance needs to be struck in dispensing or withholding doses to these patients. Almost always, deaths related to methadone or buprenorphine treatment include another drug implicated as a contributing cause of death[67]. Alcohol is most commonly implicated in methadone-related deaths [68, 69]. In addition to the patient's physical appearance, breath odour could be an obvious indicator of alcohol consumption. However, it can be difficult to tell if a patient is under the influence of drugs, let alone what it might be. The UK clinical guidance[24] requires CPs to notify the prescriber if a patient repeatedly presents in a state of intoxication or unusually presents intoxicated for the first time. It notes that assessing whether a patient is too intoxicated to receive a prescription is a clinical one and can reflect a very high-risk patient. While these observations are made in the context of reviewing the patient in drug treatment clinics, they can be equally applied to dispensing of OST dose to an intoxicated patient. An intoxicated patient collecting their prescription from the clinic might not necessarily access the medication immediately. In contrast, someone presenting intoxicated to the pharmacy is more likely to access their OST dose. So, in a way, the risk of overdose to an intoxicated patient is more imminent when they present in the pharmacy than at their clinical review. If a patient has SC, then the chance to delay taking OST is removed, increasing the risk. Also, withholding a dose from a patient has its own risks as it might prompt the patient to use an illicit drug. Therefore, it is prudent that robust mechanisms are established to deal with intoxicated patients in community pharmacy with the same awareness and urgency as reflected during the clinical review. In the absence of robust training and guidance, the assessment of intoxication by the CP is subjective. It could be even more challenging to make a practical assessment for a locum pharmacist who might not know the patient's usual presentation.

Conclusion 12

Withholding a dose from an intoxicated patient can be a critical intervention in preventing overdose. CPs assessment of intoxication in OST patients is subjective depending on experience, knowledge of patient drug-taking behaviours and any training they might have.

Recommendation 10

CPs providing OST services should have training on identifying intoxication and dealing with patients who present intoxicated for their dose.

6.4.3.5 Risk awareness and intervention

The result of the interview and the survey study demonstrates that as an expert in medication, CPs recognise the inherent risk associated with OST. Their ability or willingness to act where there is a potential risk to OST patients' health and well-being is questionable.

As discussed above and in the result of the three studies, the action or inaction of CPs in risk situations can be affected by both clinical and non-clinical factors. Knowledge and confidence to deliver the service, training and experiences of dealing with OST, clarity of clinical guidance and professional support in providing the service can determine whether a pharmacist intervenes in what they perceive to be a potential risk situation. Non-clinical factors like the CPs perception and stigma towards OST, workload, security concerns, and relationship with the treatment centre can also affect a CPs clinical decision making.

While female participants of the interview study shared their concerns about OST patients' aggressive behaviour, no significant relationship could be established between male and female pharmacists fear of potential aggressive OST-patient behaviour from the survey. However, a study looking into optimising OST in an Irish primary care setting reported that male colleagues' absence in practice posed a problem for female staff supervising male OST patients[70]. It is to be noted that the OST services in Ireland are predominantly provided by general practitioners (GPs). While the study's

setting was different, the finding nevertheless corroborates those presented by female CPs in the interview study.

When the influence of gender and security concern was further explored in the survey study, no significant association was found. Though the gender of the CP was a significant factor relating to several aspects of OST practice, withholding a dose from an intoxicated patient remain unaffected by it. As with any survey, the results represent the participants' perception and self-report, not an objective assessment. Therefore, the author recommends that further work is needed to understand how gender may or may not affect male and female CPs' professional practice while dealing with an aggressive OST patient.

Conclusion 13

While CPs can identify the innate overdose danger associated with OST, there are variations in their understanding of risk and their willingness and ability to take remedial actions where concerns exist. The action or inaction of CPs in risk situations can be affected by both clinical and non-clinical factors.

Recommendation 11

Non-clinical factors like workload, support in delivering the service, security concerns, stigma need to be considered while formulating OST guidance and policy.

6.5 The central premise of OST service

Findings from the three studies suggest that the current practice of OST and the related community pharmacy services are focussed on the mechanics of service delivery, and the notion of preventing opioid overdose deaths is peripheral. The dispensing of opioid substitutes is often seen as a distinct and separate practice with a great focus on the legality of the prescription and the accuracy of dispensing. The use of words like 'methadone mode' and 'compartmentalisation' by the interview participants when describing

their practice supports this point of view. As demonstrated in the three studies, the practice of overdose counselling, feedback to the prescriber or any necessary interventions to minimise risk to the patients is not always practised in delivering OST services. The potential for reducing the risk of harm to OST patients does not appear to be the main concern among the participants of this research.

Practice guidance that is clear and specific, such as withholding a dose following three missed doses, is well adhered to in practice. The survey study results also demonstrated that the controlled drug prescription requirements, which are clear and specific, are said to be always adhered to by CPs. However, tasks like assessing the prescription's clinical appropriateness, withholding doses from intoxicated patients, counselling patients, checking access to naloxone or providing feedback to the prescriber on treatment progress require an element of knowledge, professional judgement, skills and motivation were less adhered to. The author recommends that the guidance related to OST services needs to be clear in its aims and specific to CP's practice. Elements of practice where ambiguity exists, such as identifying intoxication and information sharing, need to be addressed within the guidance.

Where offered, the NSP and THN services are not being delivered from the premise of reducing harm or preventing deaths among opioid dependents. It is the assessment of the author that these services are delivered in isolation and not necessarily seen as part of the overall aim of reducing opioid-related deaths. Services related to the management of opioid dependence should be delivered from the central premise of preventing deaths among opioid dependents. These services should be delivered in conjunction as a supplementary service in achieving the overall aim of reducing opioid-related deaths.

Stigmatised practice hinders patient engagement in their treatment. This entrenches the perceived stigma of the patient creating a cycle that perpetuates OST-related stigma. CPs should use their professional position,

their relationship with the patient and their influence at the workplace to foster a conducive environment.

Some OST-related practice reported among CPs is acquired through anecdote and hearsay rather than based on evidence. Dispensing OST doses to intoxicated patients is one example of this. In the absence of regular training and sharing of good practice, CPs rely on what they perceive to be a shared practice among the wider CP community. The justification for adopting what would be a less than good practice is found in the belief that others are doing the same.

6.6 Survey response rate

Poor response rates have been reported by researchers conducting community pharmacy-based surveys. The most recent survey of pharmacists commissioned by the General Pharmaceutical Council (GPhC) achieved a response rate of 22% for pharmacists and 26.9% for pharmacists registered as prescribers[71]. A postal survey of all English community pharmacy staff (n=11,816) on skill-mix and delegation in 2018 achieved a response rate of 10%[72]. The researchers opted for the postal survey following a poorer response to an online survey. Another survey in 2017 of selected community pharmacies (n=800) on the volume of service delivered by English community pharmacy, achieved a response rate of 34.6% [73].

In 2007 Sheridan et al. reported a response rate of 95% while researching the provision of opioid substitution services in English community pharmacy[74]. A cross-sectional survey of all community pharmacy in Scotland, exploring harm reduction services conducted in 1995, 2000 and 2005, reported response rates of 79%, 82% and 68%, respectively[31]. While historically, researchers have reported high response rates, recent researchers have failed to achieve such high response rates. The trend of decline in community pharmacy-based surveys can be for several reasons. Given the volume of community pharmacy-based research published in peer-reviewed journals in recent years, it can be postulated that participant fatigue affects the response rate in community pharmacy-based research. CPs are

much busier in recent years, and staffing levels are low, which might negatively impact the response rate. Academics and researchers need to be mindful of this factor along with other factors discussed in the methodology chapter in designing survey study.

The phase three pilot survey response rate was 50% (n=30/60); however, the main survey's response rate was lower at 33.7%. When non-eligible CPs are eliminated from the total, the overall response rate rises to 38.5%. As participants could opt-out of the survey without giving a reason, the eligibility of all non-participants was not known.

The author administered the pilot survey, whereas the author administered the main survey with the assistance of two MSc in health psychology research assistants. One of the research assistants spent half-a-day in a community pharmacy to familiarise herself with a community pharmacy's general working and setting. The other research assistant was already aware of the community pharmacy setting. To maintain consistency, all survey administrators followed the same transcript during the survey. The main survey was administered within three months of completing the pilot study. Both the pilot and the main survey was planned to avoid known busy periods in community pharmacy. As far as the author is aware, there was no significant change in external stimuli, which could have affected the participation of CPs in the survey. The change of personnel administering the main survey could be one possible reason for a lower response rate in the main survey.

6.7 Use of IPA

The justification for the use of IPA as the analytical method has been presented in the methodology chapter. The discussion of IPA here is presented as a self-critique of the suitability of this methodology. With the growing use of IPA, particularly in health and psychology, there is an increased focus on the quality criteria in the IPA application. IPA seeks to achieve a comprehensive and in-depth analysis of the participant's experience, and it suits studies involving a small number of participants[75].

Generating a general account on a group or specific population becomes challenging with IPA. Using IPA as an analytical method in exploring 24 research participants' experiences, therefore, can be a criticism of this study. However, research publications based on one or a few participants' experience is not the norm in pharmacy practice research. The publication of the interview study's findings in a peer-reviewed journal demonstrates the merit of the argument. This author utilised IPA as a tool to add his interpretation to the experiences shared by the participants, thus expressing double hermeneutics[75]. The author was interested in exploiting the flexibility and the versatility offered by IPA in understanding the intricacy of CPs OST-related practice [76].

6.8 Strengths and limitations

Each phase of the studies' strengths and limitations has been reflected in the individual monograph presented in chapters 3, 4 and 5. Here, the author covers the ground not covered in the monographs and presents the thesis's strengths and limitations.

6.8.1 Strengths

While various aspects of OST service in community pharmacy have been researched and reported upon, as evident in the references used throughout the thesis, this study is unique in its approach as it explores CPs' practice in relation to OST-related deaths, through the lens of a practising pharmacist. The qualitative studies provide a nuanced understanding of the CPs' perception of OST's risk and their perceived role in providing the service. The observation study was original and added further evidence to the barriers in providing a patient-centred OST service. Qualitative observation studies in community pharmacy are not common, and this study is the first to report qualitative observational data on CPs OST-related practice. More importantly, this observation study allowed the researcher to go beyond the participant's reported practice to understand the professional context and the

participants' behaviour in delivering OST services. The interview study was also the first to describe CPs' opinion on OST-related deaths.

The exploratory sequential mixed method approach adopted for the thesis meant each study explored areas identified as relevant in the preceding study. The author's experiences and assumptions as a practising community pharmacist were balanced through the interview study where CPs of varying experiences and opinions helped shape the study's direction. This approach ensured pharmacists' national survey was based on the issues raised by practising pharmacists and a reflection of their day-to-day practice.

6.8.2 Limitations

The findings of this doctorate are based on the experiences and opinion of those who were providing OST services at the time of the research. Therefore, it does not encompass the view of CPs who were not providing this service. The author believes this was the right approach as it focused the research on exploring CPs practice in relation to overdose prevention. While the author believes his professional role as a pharmacist helped him connect effectively with interview participants and consequently the participants to be honest and open in expressing their experience, the possibility of social desirability bias in response cannot be overruled.

Non-participation of two large pharmacy chains and the poorer than expected response rate in the survey are other research limitations. Existing primary care OST arrangement in England involves other important stakeholders like the drug treatment teams, service commissioners, charities and most importantly, the patients. Restricted by the study's aims, this thesis only presents one of the stakeholders' perspectives on what is rather a complex and challenging area of health service. The results and recommendations of this thesis should, therefore, be interpreted in that light.

The validity issue in using a non-validated scale for the survey has been addressed by pre-pilot testing and piloting the survey. Other consideration used to manage the question of validity has been discussed in the methodology chapter.

6.9 Future research

Based on this thesis's findings and the limitations identified, the following domains are identified for further research. The author believes a wider perspective of OST stakeholder viewpoints would provide better understanding and lead to a more holistic approach to dealing with OST-related deaths.

1. How other stakeholders in OST services perceive the role of CPs? Such investigation will further help illuminate the reasons behind the perceived lack of integration of CPs within the wider service.
   Potential methods: In-depth qualitative interviews and focus groups.

2. Clarity of clinical guidance and their adoption in practice by CPs.
   The results of the survey study suggest a hypothesis where CPs tend to adhere to practice guidelines and regulations that are clear and specific (for example, the CD regulations and 3-day rule for withholding dose) and that the implementation of guidance can be poor where an element of personal judgement is involved (for example, withholding dose in intoxicated patients). Therefore, it would be interesting to explore the awareness of guidance and their implementation in CPs' practice.
   Potential method: Prospective mixed-method study.

3. What are the possibilities of co-prescribing of OST by CPs?
   Independent prescriber (IP) pharmacists are becoming a common feature of primary care services in England, and in future, all graduates will be IPs. Some IP pharmacists are involved in prescribing OST. It would be prudent to explore the feasibility of bringing the prescribing expertise near the patient to reduce the barrier to accessing OST services.
   Potential method: A mixture of qualitative and quantitative studies.

4. How users of OST service see the role of CPs in promoting health and minimising risk and their perception of risk associated with OST? The focus of this PhD was to explore the role of CPs in preventing OST-

related deaths. It would be interesting to explore the risk as perceived by OST users and how they see CPs role in managing that risk.
Potential method: In-depth qualitative interviews and focus groups with OST patients.

5. A national competency framework for CPs and framework for pharmacy premises to provide OST-related services; what may it look like? Such a study will help address service variability, which is one of the major findings of this thesis.
   Potential methods: Delphi studies involving stakeholders, including patients.

6. Comparative study of the quality of OST service provision and opioid overdose deaths at local authority level. The survey data demonstrated significant variability in the provision of OST services in community pharmacies in different geographical regions. Therefore, it would be interesting to study if a correlation exists between service provision and drug-overdose deaths. Such findings will help address some of the underlying reasons for increased OST-related deaths in certain geographical locations.
   Potential methods: Quantitative surveys and statistical analysis of ONS data at local levels.

7. Provision of OST specific education and training to pharmacy students and practising pharmacists. As one of the main issues identified in this research, the author would be interested in benchmarking the training requirements for newly qualified pharmacists and ongoing training requirements for those involved in providing OST and related services in community pharmacy. Such a benchmark can then feed into the national service framework as advocated in this thesis.
   Potential method: Prospective mixed method study involving a survey of current training providers and academic institutes and focus groups.

6.10 Conclusion

This chapter has brought together the findings of the different studies undertaken as part of this PhD. It highlighted the originality of the research and its contribution to knowledge. Through triangulation, it further synthesised the results of the three studies. It has given context to the research's main findings by discussing it in light of other published literature. Discussion of the thesis's strengths and limitations and a retrospective critique of the methodological decisions were also presented. Finally, the chapter identified the proposed areas for future research.

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Chapter 7
Conclusions and recommendations

Overview of chapter

This final chapter draws together and summarises the main findings of this doctoral research. This chapter's presentation is based on the results and recommendations of the three phases of the study and further deliberations presented in the discussion chapter. It also makes recommendations for policymakers, service commissioners and practice to improve community pharmacists' involvement in preventing OST-related deaths.

7.1 Conclusions

1. OST services are not delivered equitably. Local commissioning of the service and various service providers' involvement makes it difficult to have consistency at the local and national level. The provision of NSP and THN in the English community pharmacy is poor.

2. CPs do not see themselves as a part of an integrated treatment team. Communication and feedback mechanism between the prescriber and the CPs are not standard and largely dependent on local practices.

3. Clinical guidance intended to reduce OST-related deaths are not always adhered to. It appears guidance that is pertinent to legal aspects and generally clear to follow (for example, the three-day rule) is more closely adhered to than those where a professional judgement or clinical skills are required (for example, withholding dose from an intoxicated patient).

4. Variability in practice identified in the research suggests a need to improve practice and set national standards for OST service delivery. Education and training to deliver practice to these standards, as used in other service delivery models, e.g. flu vaccination, is advocated.

5. Community pharmacists providing OST services generally have a positive attitude towards it, and the pharmacy team generally have a good rapport with the patient group. However, exceptions to this have been observed and reported in this work.

6. The privacy and dignity of those receiving OST and related services in pharmacy are not adequately protected. Even when caution is practised, inadvertent disclosure of patient confidentiality occurs in the delivery of the service.

7. Stigmatised behaviour among CPs (not ensuring patient privacy) and the patients (not wanting privacy; as reported by CPs) has created a cycle where the stigmatised practice is normalised, which in turn reinforces the stigma.

8. The ‘mechanics of delivering the OST service’ forms the central premise of the English community pharmacist's current practice, and the notion of ‘preventing opioid overdose’ is peripheral.

9. There remains a gap between the perceived confidence of CPs and their knowledge and skills to provide OST service. Lack of knowledge and confidence in delivering the service means some OST patients at high risk may not have their risk acted upon by some CPs.

10. SC offers an opportunity to monitor patients’ progress and well-being on a more or less daily basis. This frequent contact by a healthcare professional is largely limited to the supply and physical supervision of the prescribed dose. The opportunity of improving outcomes by feeding back the first-hand information on patient progress, any concern or recommendation by the CPs remains mostly unutilised.

11. CPs are aware of the potential for diversion of prescribed OST and the risk it poses for others, particularly children and opioid naïve. The measures intended to reduce diversion risk, such as rinsing or looking into the mouth after consumption or a brief conversation to ensure the dose is swallowed, are not regularly observed. SC undertaken in the shop floor is not conducive to perform these interventions without further stigmatising.

12. Withholding a dose from an intoxicated patient can be a critical intervention in preventing overdose. CPs assessment of intoxication in OST patients is subjective depending on experience, knowledge of patient drug-taking behaviours and any training they might have.

13. While CPs can identify the innate overdose danger associated with OST, there are variations in their understanding of risk and their willingness and ability to take remedial actions where concerns exist. The action or inaction of CPs in risk situations can be affected by both clinical and non-clinical factors.

7.2 Recommendations

1. A national framework of addiction care service delivery in community pharmacy primary care is needed to standardise service availability and service standards.

2. Community pharmacy should be part of the OST teams, with closer working between CPs and prescribers. A shared feedback mechanism, beyond the transactional information sharing, should exist between the prescriber and CPs to improve patient care

3. Practice guidance to pharmacists should be clear and specific to deal with the challenges faced by community pharmacists in providing the service (for example identifying intoxication, dose withholding, out-of-hours referrals, dealing with security concerns).

4. Pharmacists providing opioid substitution therapy service should engage in mandatory standardised training, and mechanisms should be in place to monitor their training and competency. An existing mechanism like the ‘Centre for Pharmacy Postgraduate Education CPPE self-declaration of competency’ can be adopted.

5. The non-rigorous approach to patient confidentiality needs to be addressed through a change in the professional practice of CPs individually and collectively. And also, by education and addressing and acknowledging what stigmatised behaviours for both CP and patient are.

6. A patient-centred approach by providing confidential and dignified service, creating conducive environments for patient engagement and monitoring should form the core of OST service.

7. The knowledge and confidence gap in providing OST should be addressed through appropriate coverage of this subject area in the undergraduate course and during the pre-registration training year and standardised training requirements post-registration.

8. OST guidelines should become more inclusive of harnessing CP's strategic position in monitoring and supporting patients to minimise OST-related deaths.

9. SC needs to be undertaken in private space to allow for consumption to be observed in a confidential and non-stigmatising way. This practice will also be conducive to forging a therapeutic relationship between the patient and CP.

10. CPs providing OST services should have training on identifying intoxication and dealing with patients who present intoxicated for their dose.

11. Non-clinical factors like workload, support in delivering the service, security concerns and stigma need to be considered while formulating OST guidance and policy.

7.3 Summary of the thesis

This doctoral research provides an in-depth understanding of community pharmacists' role in preventing opioid-substitution therapy (OST)-related deaths. Different research methods were combined, constituting to the mixed methodology, to explore CPs' OST-related practice. This doctorate's findings constitute original knowledge of the research area, which can help improve the OST service outcomes. The improvements identified in this research can also help design new or improving existing pharmacy services. The findings have been presented at two international conferences and published in peer-reviewed journals (one published, two drafts ready for submission). This thesis has added to the evidence base in improving CPs role in preventing OST-related deaths through its findings.

NHS Community Pharmacy Contractual Framework
Enhanced Service – Supervised Administration (Consumption of Prescribed Medicines)

1. Service description

1.1 This service will require the pharmacist to supervise the consumption of prescribed medicines at the point of dispensing in the pharmacy, ensuring that the dose has been administered to the patient.

1.2 Pharmacies will offer a user-friendly, non-judgmental, client-centred and confidential service.

1.3 The pharmacy will provide support and advice to the patient, including referral to primary care or specialist centres where appropriate.

1.4 Examples of medicines which may have consumption supervised include methadone and other medicines used for the management of opiate dependence, and medicines used for the management of mental health conditions or tuberculosis.

2. Aims and intended service outcomes

2.1 To ensure compliance with the agreed treatment plan by:

- dispensing in specified instalments[1] (doses may be dispensed for the patient to take away to cover days when the pharmacy is closed),
- ensuring each supervised dose is correctly consumed by the patient for whom it was intended.

2.2 To reduce the risk to local communities of:

- over usage or under usage of medicines;
- diversion of prescribed medicines onto the illicit drugs market; and
- accidental exposure to the supervised medicines.

2.3 To provide service users with regular contact with health care professionals and to help them access further advice or assistance. The service user will be referred to specialist treatment centres or other health and social care professionals where appropriate.

3. Service outline

3.1 The part of the pharmacy used for provision of the service provides a sufficient level of privacy and safety and meets other locally agreed criteria.

3.2 The pharmacy will present the medicine to the service user in a suitable receptacle and will provide the service user with water to facilitate administration and/or reduce the risk of doses being held in the mouth.

3.3 Terms of agreement are set up between the prescriber, pharmacist and patient (a three-way agreement) to agree how the service will operate, what constitutes acceptable behaviour by the client, and what action will be taken by the GP and pharmacist if the user does not comply with the agreement. A 'four-way' agreement could also be developed which would include the specialist centre.

3.4 The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service.

3.5 The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols.

3.6 The pharmacy should maintain appropriate records to ensure effective ongoing service delivery and audit.

3.7 Pharmacists will share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements.

[1] In this Service Specification it is assumed that instalment dispensing is provided for by the provisions of the Dispensing or Repeat Dispensing Essential Services. If this is not the case for a particular medicine which may be included in the service, local arrangements will need to be developed.

3.8 The PCO should arrange at least one contractor meeting per year to promote service development and update the knowledge of pharmacy staff.
3.9 The PCO will need to provide a framework for the recording of relevant service information for the purposes of audit and the claiming of payment.
3.10 The PCO will need to provide details of relevant referral points which pharmacy staff can use to signpost service users who require further assistance.
3.11 The PCO should consider obtaining or producing health promotion material relevant to the service users and making this available to pharmacies.

4. Suggested Quality Indicators

4.1 The pharmacy has appropriate PCO provided health promotion material available for the user group and promotes its uptake.
4.2 The pharmacy reviews its standard operating procedures and the referral pathways for the service on an annual basis.
4.3 The pharmacy can demonstrate that pharmacists and staff involved in the provision of the service have undertaken CPD relevant to this service.
4.4 The pharmacy participates in an annual PCO organised audit of service provision.
4.5 The pharmacy co-operates with any locally agreed PCO-led assessment of service user experience.

Background information – *not part of the service specification*

Current guidelines[2] recommend all new treatment of opiate dependence be subject to supervised consumption for the first three months or a period considered appropriate by the prescriber. The rationale for this recommendation is to provide routine and structure for the client, helping to promote a move away from chaotic and risky behaviour.

Supervision of the consumption of medicines used in the treatment of people with mental illness can in a similar way help to reduce chaotic and risky behaviour. Regular contact with the pharmacist and pharmacy staff can help to reduce the social isolation felt by many people with mental illness. Pharmacists and their staff are well placed to spot the deterioration of a person's mental state and alert other members of the health care team to the person's need for further support if appropriate.

Tuberculosis is becoming an increasing problem in many parts of the country, especially among socially disadvantaged groups such as the homeless. The effective treatment of tuberculosis and the prevention of acquired drug resistance relies on full compliance with medication treatment regimens. 'Directly Observed Therapy Schemes' (DOTS) have been used in many countries to improve compliance. A comparison of self treatment versus various forms of DOT has shown that completion of treatment is significantly higher when the treatment is supervised.[3]

An example claim/audit form and 'three-way' agreement form are provided with this service specification which could be adopted locally by PCOs.

Background information for Drug Action Team (DAT) commissioners:
Service Specification Tier (2 or 3), Pharmaceutical Services for Drug Users, National Treatment Agency for Substance Misuse, 2005, www.nta.nhs.uk

[2] 'Drug misuse and dependence: guidelines on clinical management' Department of Health (1999)
[3] Chaulk CP, Kazandjian VA. Directly observed therapy for treatment completion of pulmonary tuberculosis: consensus statement of the Public Health Tuberculosis Guidelines Panel. *JAMA* 1998; 279: 943-948

CPPE training which may support this service:

Opiate treatment: Supporting pharmacists for improved patient care open learning
Public Health – drug users, harm reduction workshop
Mental health workshop series

MODEL TERMS OF AGREEMENT FOR SUPERVISED ADMINISTRATION

I, the client, understand and agree with the following terms of agreement:

- To treat the practice, clinic, pharmacy, its customers and staff with respect.
- To attend the practice, clinic and pharmacy within agreed times and at agreed intervals
- To collect my medicines personally, quietly and promptly at the agreed time
- Not to be a nuisance, abusive or violent to the practice, clinic or pharmacy staff
- That my doctor, pharmacist and drug worker are free to discuss and exchange information on my behaviour, my state of health, attendance and other factors relating to my treatment
- Not to attend the practice, clinic or pharmacy intoxicated with alcohol and/or drugs
- That smoking and consumption of alcohol on these premises is forbidden
- That if I am not in a fit state, the doctor, drug worker or pharmacist has the right to refuse to see me.
- That failure to keep appointments (unless by prior arrangement) may result in the treatment being discontinued
- To take my medication on the pharmacy premises in the agreed manner
- That if I fail to collect a dose on the specified day, I will not be able to collect it on a later day
- To be responsible for my medicine(s) during bank holidays and weekends and to take as prescribed.
- Not to take any drugs other than those prescribed to me and I will provide a urine sample for analysis when requested
- To return to my doctor or clinic for re-assessment if I have not collected my medication from the pharmacy for x(3?) days

As the Pharmacist I agree to:

- Provide a quiet area for supervised administration
- Check the legality of the prescription and correctness of detail
- Register the patient onto the Patient Medication Record (PMR)
- Keep records of attendance
- Arrange and agree a mutually convenient time with the client for administration
- Dispense the medicine in accordance with the prescription and in advance of the agreed time of administration
- Discusses terms of agreement with client
- Liaise with the GP or liaison worker with regard to the treatment
- Refer the client back to the surgery/ clinic if:
    - non-attendance exceeds three days
    - client's behaviour causes problems
    - client's health raises concerns
- Explain that medication will not be dispensed if the client is intoxicated and that missed doses cannot be collected the next day

- Supervise consumption according to local arrangements
- Supply weekend/bank holiday doses for self administration as required
- Complete necessary paperwork
- Ensure that staff and locums are aware of the procedures to allow the service to run smoothly.

As the General Practitioner I agree to:

- Provide a regular prescription for the duration of treatment
- Discuss terms of agreement with client
- Arrange for the prescription to be sent to the nominated pharmacy
- Address the patient's general health needs
- Arrange relevant tests when necessary
- Liaise with the pharmacist and liaison worker regarding the progress of the client
- Re-assess and review at agreed intervals

(Optional) As the Liaison Worker I agree to:

- Ensure that the pathways are set up between the patient's GP and chosen pharmacy
- Complete the initial client assessment
- Complete the relevant paperwork
- Liaise with the GP and pharmacist on the client's behalf
- Discuss terms of agreement with client

	Name	Signature	Contact number	Date
Patient				
GP				
Pharmacist				
Liaison worker				

Surgery/Clinic address:

Pharmacy address:

Copies to: 1. Client 2. Pharmacy 3.GP 4. Liaison worker

THIS INFORMATION IS CONFIDENTIAL TO THE ABOVE PARTIES

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in preventing methadone related deaths (MRDs): an investigation into current UK practice.

Dear fellow pharmacist, 18th January 2013

My name is Ramesh Yadav. I am a community pharmacist and a PhD student at the University of Bath. Currently, I am undertaking the project titled above and would like to invite you to take part in this research.

The current methadone treatment approach, which was introduced from the mid 1990's, has prevented methadone related deaths increasing as prescribing has increased[1]. In brief, guidelines suggest supervising the consumption of methadone, withholding dosing from intoxicated patient's, retitrating patients who have missed several days treatment and ensuring that patients are given overdose prevention advice on completion of detoxification.

Community pharmacists have and do play a key role in delivering this approach successfully. However, we believe practice across the country varies so the aim of this project is to investigate to what extent community pharmacists in England are involved in activities to prevent methadone related deaths? We are also interested in whether more can be done to reduce methadone related deaths?

Your involvement in the research will help us identify best practice and areas of improvement in service provision.

Please take time to have a look at the information sheet included with this letter which explains what the study involves. If you would be willing to take part, please complete and return the reply slip in the freepost envelope provided. Alternatively, you can email the research team on r.yadav@bath.ac.uk

Please feel free to contact myself or Dr Denise Taylor if you have any further queries. This research is being funded by small bursary from the National Pharmacy Association Education Foundation and my PhD studentship comes from the University of Bath.

Yours sincerely,
Ramesh Yadav MRPharms.
PhD student

Research team: Ramesh Yadav r.yadav@bath.ac.uk, Dr Jenny Scott (supervisor), Dr Gordon Taylor (co-supervisor), Dr Denise Taylor (co-supervisor) d.a.taylor@bath.ac.uk.Department of pharmacy and pharmacology, University of Bath, Claverton Down, Bath, UK, BA2 7AY. Telephone (Dr D Taylor) 01225 383677

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in preventing methadone related deaths (MRDs): an investigation into current UK practice.

Participant Information Sheet (version DMDs-IS01)

Please read this information sheet to understand what this research is about and what it involves for you, as a participant. If you are not clear about anything or need further information, please feel free to contact the research team at the address given below.

1. What is the purpose of this study?

This research is aimed at finding out to what extent community pharmacists in England are involved in activities to prevent methadone related deaths. We are also interested in whether more can be done to reduce methadone related deaths.

Introduction of supervised consumption of methadone from community pharmacy in the 1990's has been linked to a reduction in mortality rate among users of methadone. Pharmacists come in contact with service users more frequently than any other health care professional and are in an advantageous position to influence the safety and outcomes of methadone therapy. We believe practice across the country varies and we would like your help in exploring pharmacists' experiences and understanding of dealing with substance misuse services.

2. Why have I been chosen?

You have been chosen from a random list of community pharmacies in your area. Your contact details were obtained from the Primary Care Trust (PCT) list of pharmacies.

3. If I decide to take part, what will it involve?

The researcher will visit you at a mutually convenient time and conduct a one to one interview based around your views and experiences with substance misuse services. This interview will last around 30 minutes, will be audio recorded and will later be transcribed word to word into a paper record. All the recording and transcribing and any subsequent data generation will be anonymised. Any quotations used in publications will be assigned a pseudonym to maintain confidentiality.

4. What if my experience in dealing with substitution therapy is limited?

We would like to hear from you regardless of your experience in dispensing substitution therapy. We want participation of pharmacists with varied experience and expertise with substitution therapy.

5. Is my taking part confidential?

All the information collected is anonymised. Any identifiable data recorded during the interview (for example references to any place, practice or person) will be removed. The data will be stored as per University of Bath data protection policy under the care of Dr Jenny Scott and only the research team will have access to it. All the data will be destroyed 5 years after completion of the project.

6. Has the research received ethical approval?

This research has been reviewed by the Research Ethics Approval Committee for Health (REACH) of the University of Bath.

As all the participants in this study are all healthcare professionals; NHS Research ethics Committee (REC) approval is not required.

7. Who is organising and funding this research?

The research is organised and funded by University of Bath. The student has also received a grant from National Pharmacy Association (NPA) Health Education Foundation towards the cost of the project.

8. What will happen to the result of the study?

This research is being conducted as part of a doctoral degree. A report of this study (interview phase) will be available by May 2013. The information obtained will be analysed to guide the second phase of the research which involves a national survey of community pharmacists regarding opiate substitution therapy. If you want a copy of this report, please let us know. (See option below)

9. What if I change my mind afterwards?

You can withdraw from the research without any explanation prior to data analysis. If you feel uncomfortable at any time during the interview you can ask the researcher to leave without having to give any reason. If you do not wish your data to be included in the study please let us know within one week of taking part in the study. This is because it might not be possible to separate your data once it has been mixed with other data for analysis. Analysis will usually occur the week following the interview.

10. What are the possible benefits of taking part in this research?

Your experience will contribute to identifying the gaps and good practices in the provision of substitution therapy available from community pharmacies.

11. What are the potential risks or disadvantages of taking part in this research?

There is no known risk or disadvantage of taking part in this research. If you feel uncomfortable you can withdraw anytime without any explanation. You can also contact a member of the research team to discuss this further.

12. If I want to take part, what should I do?

If you would like to take part in the research, please complete the reply slip and send it to the research team in the FREEPOST envelope provided. Alternatively, you can email the research team on r.yadav@bath.ac.uk

13. Contacting the research team

Research team: Ramesh Yadav r.yadav@bath.ac.uk, Dr Jenny Scott (supervisor), Dr Gordon Taylor (co-supervisor), Dr Denise Taylor (co-supervisor) d.a.taylor@bath.ac.uk.Department of pharmacy and pharmacology, University of Bath, Claverton Down, Bath, UK, BA2 7AY. Telephone (Dr D Taylor) 01225 383677

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Consent form for interview

Project Title

Community pharmacists' role in preventing Methadone Related Deaths (MRDs): an investigation into current UK practice.

Aim

To investigate community pharmacists' role in preventing Methadone Related Deaths (MRDs) in UK.

1. To what extent do community pharmacists in England contribute towards policy to prevent methadone related deaths?
2. Can community pharmacist in England do more to reduce methadone related deaths?

Declaration *Please tick and*

1. I have read and understand the participant information sheet provided for the project**. (version-DMDs-IS01)**	☐
2. I understand my interview will last about 30mins and will be audio recorded and transcribed into a paper document.	☐
3. I understand my interview data will be anonymous, only the research team will have access to it and will be preserved while the project lasts and 5 years afterwards.	☐
4. I understand the project has been reviewed by the Research Ethics Approval Committee for Health (REACH) of the University of Bath.	☐
5. I have had opportunity to ask questions and have received, where asked, satisfactory answers to my questions.	☐
6. I understand my participation in this research is voluntary and that I can withdraw without giving any reason prior to data analysis.	☐
7. I consent to take part in this research.	☐

Initial

Name of participant: ---------- Signature: ----------

Date: ----------\----------\----------

Researcher/Person receiving consent: ---------- Signature: ----------

Date: ----------\----------\----------

Research team: *Ramesh Yadav r.yadav@bath.ac.uk, Dr Jenny Scott (supervisor), Dr Gordon Taylor (co-supervisor), Dr Denise Taylor (co-supervisor) d.a.taylor@bath.ac.uk.Department of pharmacy and pharmacology, University of Bath, Claverton Down, Bath, UK, BA2 7AY. Telephone (Dr D Taylor) 01225 383677*

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Reply slip for participation in the research

Community pharmacists' role in preventing methadone related deaths (MRDs): an investigation into current UK practice.

Recruitment questions (Please tick or fill as appropriate)
This information will help us recruit a representative sample of community pharmacists. This information will be kept separate from your details provided below.

1. Gender: Female ☐ Male ☐

2. Age: 29 and under ☐ 30-39 ☐ 40-49 ☐ 50-59 ☐ 60 and over ☐

3. How many years have you been practising as a pharmacist? ----------

4. Please name the university you obtained your pharmacy degree from: ---------- ---------- Overseas (Please name the country): ---------- ----------

5. Which best describes your employment status? (tick one or more as appropriate)
   Owner ☐ Pharmacy manager ☐ Locum ☐ Second pharmacist ☐
   Locum ☐ Other ☐ please specify ----------

6. How many patients do you dispense substitution therapy to at the moment?
   5 or less ☐ 6-15 ☐ 16-25 ☐ more than 25 ☐

7. What best describes the location of the pharmacy you mainly work in?
   Urban ☐ Suburban ☐ Rural ☐

I am interested in taking part in the proposed research and I am happy for the research team to contact me to discuss participation further.

Name: ---------- **Signature** ---------- **Date** ---------\----\----------

Phone number: ---------- **Email:**
(If you prefer to be contacted this way):

Pharmacy Address: ----------
-

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Please tick your preferred method of communication.
Phone ☐ Email ☐ Post ☐

If there is any time of the day you do not wish to be telephoned, please state here. ---
----

Please fill in this reply slip and return it in the free pre-paid envelop provided.
Alternatively, you can email your confirmation to r.yadav@bath.ac.uk. **Thank you.**

21/03/13 Interview guide

1. **Can you describe your experience of providing methadone service?**

   Tell me more about your role? What is it like doing this job? (Physically, mentally, emotionally)

2. **What are the first thoughts you get when presented with methadone prescription?**
   Compare with non-methadone prescriptions? Issues? How often? significant?

3. **How would you compare your experience of dealing with methadone patient to that of non-methadone patient?**
   Level of service, engagement with client

4. **How would you identify someone at risk of harm because of methadone treatment?**
   What sort of things can increase risk of harm to patient? How comfortable in doing so? Tell me about things that can shift the balance?

5. **How do you make decision when someone comes intoxicated for their dose?**
   (What affects your decision?)

6. **Can you tell me about the training you have received to provide methadone service? What training should there be?**

7. **What information are you provided when taking new methadone patient?**
   Can you tell me about the communication with other parties involved in the service?

8. **Can you tell me about the local methadone guidance or policy? What is your local policy of missed dose?**

9. **How would you define the responsibility of pharmacist for what happens to the patient as result of methadone treatment?**
   Compare supervised vs non-supervised

10. **How do you see pharmacists fitting in the whole drug treatment service?**

How pharmacists contribute to the service? How important is the role? Why? **What are the limitations in executing the role?**

11. **How do you think pharmacists activity contribute to prevent methadone related deaths/incidents? What more pharmacists can do?**

Well, Amy, first of all thank you very much for taking time to take part in this research. Today, I'll ask you questions about your experience and opinion on methadone service. You might think I am asking some silly questions but that just me trying to get, you know in-depth understanding of the subject so you will have to bear with me on those questions.

That's fine.

Ah, first of all I'll ask you to describe your experience of providing methadone service.

Ah, uff... (Sighs), within my role here we have quite limited a sort of access to methadone usage and methadone patients. We don't have that many on our book and It tends to be just same few that keep rolling round, disappearing off, coming back. Ah, where I did my preregistration training we did a lot more, it was a lot , much greater run, ah, more run down area, ah, a lot poverty a lot of people around who were ah, on the programme and just a completely different sort of environment to be working in really. So we saw a lot more of it there ah, (sighs) my experiences with it, not hugely successful.

Ok, when you say not hugely successful what do you mean?

How many people you've seen actually come off it and stay off it? I think I have seen one and the only way I did was I would immerse with themselves and disappearing out of the country for six months so there is a lot of relapse a lot of abuse of it

Of the system?

Yah, ah.. particularly the non-supervised side of it, so.....

Uhu....ok, when you say abuse of the system in what ways? What do you mean?

Well those they collect, how much of it goes into them and how much of it goes back on to the street? .. I would say probably a lot more of it goes into the street than it actually is used and that has... has been proven in case studies where you see patients switched back onto supervised who refused to drink their dose because they know that quantity would kill them because they haven't been using them they have been selling them instead.

Ok

So, ah...

So, what it is like doing this job then? The actual process of being involved in providing methadone service?

Ah (sighs), its hard work, I mean you got to be able to trust your rapport with, with the clients as we are supposed to call them now. We are not allowed to call them patients,

Oh, Ok

Well that's what I was told anyway (laughs)

I wasn't aware of that anyway

Ah.. I mean yes they, they are clients to the treatment centre in X (PCT) not patients of the treatment centre. Ah, it is an (rephrases sentence) I think it is important to build up a rapport, get them to trust you, I mean these are people who have problems in the past, ah..quite often known shoplifters, so you got to be monitoring them closely without intimidating or making them feel really self-conscious, built up a relationship with them and you can get them to do a lot to help you out as well, and I think that side of it, ah, with pharmacist I have worked in the past when I was stuent, who have got quite good relationship with their clients.. ah..I think if they trust you then.. you always become more of a (pause)...an ally to them than, than their drug workers because they will see their drug workers once a fortnight, once a month ...less than that most of them if they can get away with it, without being put on hold,(slight laugh). If they are supervised, they sees you every day, you are picking upon on things. You can pick up when they are possibly struggling, when they need advice about other things. It's not necessarily just to do with their addiction, their supervised methadone or their or their methadone collection, ah, but they will talk to you about other things.. and that side of it can be very important..for them to feel they have got somebody they can, they can talk to, and who will be able to give them advise if they need to.

(Mobile rings in the back ground, K: I need to get that (in low voice), R: no problem. recording stops briefly (30 seconds or so)

You know, you mentioned that you develop a kind of rapport with the client and that's important, ah, why is that? Why is that important?

I think all..ahh.. (With vigour) it's important with any patient, customer, client, whatever you want to call people who come into the pharmacy. The more you can build a rapport with anybody the more you can benefit them. They will come to you for advice for other things... these people are people who are often, ah..(sighs), well some of them are from neglected background, they haven't got support at home, they don't know where to turn they don't know when they need to turn to people and if can keep them on the straight and narrow rather than deviating back to the illegal substances, by offering them advice , by... sometimes it's as simple as just making that phone call to the treatment centre and getting somebody to call them back because if they can't get hold of their drug worker, they don't know who to speak to and **(exactly)** if you can make just that one phone call, if they can come to you and go, I can't manage

it at the moment, I want, I want to go back onto heroin.. Whatever it is, ah, then.. I think... it's..its quite a step forward to make, to be able to, to people who... have been in situations where they can't trust anybody, you don't know who is giving them what. I mean.. drugs... they will have anything but you don't know what's in them, you don't know what they have been cooked with, for them to have somebody they can trust in, they can turn to and talk to, I think for anybody is importance.

Ok, that's good, also, you know, you said it's important to develop relationship all the clients in the pharmacy or patients as you said, ah... how would you compare the service that methadone clients receive as compared to a non-methadone patient?

I suppose in some ways... they will get a little bit more of your time particularly if they are supervised because you got to..take them to side, you got to make sure, consumed correctly, swallowed not spat straight back out in the bottle which is another know trick that can be used, so you do spent a bit more time with them compared to some other patients but then equally.. people in..patients who comes in asks for your advice or asks for your attention, it's just about the same time with them, it's.. NOT..it's about NOT (emphasis on not) singling them out, not treating them differently, and that something...my experience although its limited, it's important to treat everybody the same and they will respect you for doing so.... So..ah..although they ..uhhh...(sighs) is not something that happens so much here, where I did my pre reg, there was one of the.. former client.. who.. was very self-conscious and didn't want anybody else to realise ..that they were using substitution therapy.. so...its... you need to be spending extra bit of time with them but you need to be making sure that it's not.. obvious to that why you doing it..but.. so you spend time with anybody who asks for it and you know they do get bit more of your time because you got to focus on them when they are in because of shoplifting risks and things like that.. but I would like to think I try and treat.. everybody who comes in..the same.

Ok...ah..What are the first thoughts you get when, when you are presented with methadone prescription or you are asked to deal with a methadone client?

K: If they phone me up, I mean one of my first questions is, is there any history I need to know about? As a small community pharmacy with solely female employees, ninety-five probably percent of the time, ah.. we've obviously got to take our safety into consideration, if they are known to be violent and things, is that somebody we really need to be coming in..I know you can't always say no and you got to consider that but I will always ask about history so I know if there is anything we need to do differently. If they have got sort of history of self harm and abuse and tells you another ways you also need to be aware of that, because you need be letting them know if you are not seeing them for sort of a couple of days and they are turning back up. Is there a reason for that? Is it something that the treatment centre need to be aware of ah.. Ill also ask about whether they are supervised whether they are not? What doses they are on, just to judge, judge what ...what sort of person going to be coming in? Ah..but I

also try to approach it with an open mind, ah...say if the person I know with history that I know it's.. gonna cause trouble for me or or possibly even trouble for some of the clients that we have already got.. because there is friction between.. groups..ah.. And you don't wanna put anybody into danger by having the two, two different sort of group coming in at similar times, **(exactly)** ah, so you do have to consider that but I do try to take it with an open mind as well as, they first come in; open book, look.. you treat me with respect I'll treat you with respect. Couple of ground rules that I ask you to follow, you follow those, we will get on great and if they, they do then that's fine, if they don't then we discuss it over at later date (slight laugh) but... those are the sorts of things I look at when I first get a, a methadone prescription coming into pharmacy.

Ok, ah, ah.. You mentioned about seeking information from the treatment centre, what do you think of the information that is currently being provided?

(silence) quite limited in a lot of cases, ah... I was asked to take on a temporary methadone client from Y region.. ah.. I got very little information really about it. When the client came in to me the, the situation was a lot more intense then I knew about him , possibly would have helped to have more of that information, but then how far do you stray away from patient confidentiality? **(ok)** With, I mean, we are not allowed to feed a lot of information back to the treatment centre. If you got a client who is on the methadone programme and you offer needle exchange and they are repeatedly picking up pack, you are not allowed to feed back to the treatment centre that they are picking up the packs. That is the confidential thing between them and the pharmacy, so likewise, how much are the treatment centre allowed to divulge to you? If it isn't something that's going to..ah..ultimately affect their collection of medication should you be being told that? Should you know this? A court case coming up because of child neglect or if they have children taken off them. Is that the treatment centre's right to tell you or should that be the clients right to choose to tell you that, if they trust you enough to let you know. We, we do, we dealing patient confidentiality with a lot or our clients ah patients on day to day basis so why should it be any different for the methadone patients? I mean you have to know whether they are supervised, not supervised, at risk of ...other substance abuse which we do usually get notified about. I've noticed since moving into the Z.. area that you get a lot less information than A (place) ever provided you with. **(ok)** ah..Whether that because of changes in the system since I've moved or whether that's because..different areas are ...less keen to divulge information or less organised should we say ...which is quite probably the case, talking off the record (laughs), ah, but you do usually get notified if they have other substance abuse so, you know to watch that, if they are known to take a lot in, to take a lot of alcohol, to be watching for sort of intoxication because you don't wanna be providing them with methadone if they are.. very drunk and things like that but, to say, where you put that line of confidentiality.

So what, what sort of information you think would, would enable pharmacist to provide a better service to methadone clients?

.. I think knowing a full sort of medical history can be useful. Where I used to work in A (city), when we used to take on new client, they used to fax a form over to us which would have basically, it would to have name, it would to have address so that we can match it to the script when it came in, date of birth, dose of what they were taking, it would have a list of..ah.. known other problem so whether they were known to have harmers..ah..know to sleep rough regularly, things like that, ah...know tendency for violence, and it also used to list if they were know users of other substances, so whether it would be alcohol, ah,benzodiazipines, things like that. Things like that were useful to know so you, you will know to look out for warning signs because.....we are looking to provide the patients with the safest, safest setup and the safest treatment course ..and as..as we are the ones who see them most often, it is often us who are able to feed that back, ah...think those sort of information are very useful, knowing.. your at risk clients ah, ones who had possible history with others that you may be dealing with so you can keep an eye, not having them, in the shop at the same time to kick off and destroy your shop (laughs) which may happen!

May happen, yes...ah you mentioned intoxication earlier on, how do you make decision about having to dispense to a intoxicated or seemingly intoxicated patient?

Ah.... I mean.....you have to take, each case as an individual, I mean..I've got patients on substitution therapy, who I know are alcoholics, and will come in at 10 o'clock in the morning, stinking of alcohol but they are coherent, they make sense of what they are talking about, they will walk in a straight line, you wouldn't stop serving them, if somebody was so unaware of themself that they didn't know what they were doing..then, you may wanna withhold treatment because ....I've seen some guidance somewhere, I can't remember if it's in CPPE pack on substance abuse, advising on way from sort of issuing medication to patient who are in that stage because it can cause further health problems, sort of acute health problems if they ...take methadone on top of that sort of level of alcohol. So I think I would be looking at signs if they, they weren't able to stand up properly, they weren't able to walk in straight line, whether they were talking properly..ah..I suppose as well... it could be a sign of other health problems...so..again if you are administering a drug to somebody who is in an acute health state you could be provide or causing even further problem, so got to take that into consideration as well.

You mentioned, you know the training bits in there, what sort of training formal or informal you are provided to carry on with this service? Methadone service?

The only..the only training I have really done..ah..other than hands on training under the supervision of my pre-reg tutor was the CPEE pack on substance abuse, I haven't seen anything else , I haven't been asked to do anything else, ah..I'll say, I had good training from my pre-reg because we did deal with a large number of clients in that place but there is very little training really.

Ok. What sort of training should there be then?

uhhhh...that's a hard one, there isn't....I mean because you can't.. training evenings on conditions and things..I mean.. How to supervise somebody, I mean that's.. fairly self-explanatory, do don't need to trained in standing there watching them drink it (makes hand gesture of drinking) them make them to speak afterwards so you make sure that they are not, although they have swallowed or they are supposed to have swallowed..ah...may be ...a training evening once a year or so on the warning signs and the things to look out for overdose, intoxificat...in..in...intoxication, I can't ever say that word sorry...ah...so that you know what you are looking out for few warning signs were not to sort of to be missed and may be advantageous. Ah.. I mean we get, there is an annual training run by A PCT or there has been.....up until now when PCT has existed... on sort of anaphylaxis and how to treat allergy every year, may be something along those lines might be beneficial particularly for newer and inexperienced pharmacists. But then, these sort of training things costs money, have we got the money to spend on it when it could be better spent on.... services that much large population would be using, that's not really my place to ..to call...I'm not, I'm not in charge of the budget(laughs) (both laughs) , and I wouldn't want to be...

aha, ah.... I think we touched this topic slightly in our earlier questions but if can tell me about how you identify someone at risk of harm because of methadone treatment?

Risk of harm because of methadone treatment (thinks). I think you got to be looking at the clients(unclear speech) ....when they come in ah...clients who are showing signs of withdrawal possibly needs referring back because they are not getting adequate treatment and the risk of them using additional substance is going to be high ah…....and as I say, patients they are the patients who are at risk of the patients who would come in appearing unwell for whatever reason, whether it be alcohol related or because of a health sort of condition that may be unaware of , ah, they are going to be at risk of things happening.ahh..they are the ones who we really want to be looking out for. Patients who are known....have known history of depression, self-harm, they are risk of harming themself not necessarily so much from the methadone treatment it's an additional condition additional thing you need to be aware of that less of a, less of a sort of thing because of treatment, it's just a another thing they have to deal with so,..... I think that.

ok

Cause I just...what you looking for (laughs)..

(unclear voice)..Also you mentioned signs of withdrawal and you also mentioned intoxication

huhu

Ah..ah..Do you think we have, we receive enough training to be in a position to make judgement or call the decision at the point at the given time?

Probably not, but then we are asked to deal with a lot of situations that we probably haven't, had sufficient training on. I mean our first aid training, I don't know, had was for a day. I mean we can be presented with all sorts of things in pharmacy that we are asked to deal with. Ah..But ya we probably aren't...we don't get enough coverage on things like that ah.....I would be very wary if sort of trying to withhold treatment. It would be a decision I wouldn't make lightly, ah, because as much as anything else you have got somebody who is after their methadone and you are trying to withhold it they can kick off if they are already in a fragile state you don't know what's gonna happen next so it, it isn't something that I would want to have to deal with but should the need arise I hope I have the confidence in myself to be able to deal with it. Fortunately so far the need hasn't ever risen.

Ok, Amy can you tell me something about missed dose policy in your area?

..Again, I think that varies quite significantly from areas to areas within X (PCT) and also from pharmacy to pharmacy within, within X (PCT). I know .....where I was, we used to report every missed dose via fax to A treatment centre so that it went on to their records. When I started here I asked one of the key workers if they wanted me to do that for their patients, and they were like oh, oh I hadn't thought of that, oh, I suppose we should be doing that. So the, the input from different areas and the different key worker is different. I tend to report missed doses, ah... that I don't necessarily get warned about. Have couple of clients who work full time and they may not be able to get to the pharmacy within working hours but they will warn me if that so it's not an unknown, it's not an worry, it's not a concern to anybody because they are clearly well, they are clearly ah..in ..they are able to communicate with people so suppose we treat them with less concern because as much as anything as reporting a missed dose is, is for the client safety. When it gets to three days it's got to be reported because if they start back up on a dose that's too high for them its gonna cause problem, if they are repeatedly missing a set day every week then that need to be logged and noted ah..because may be something is happening on that day that needs investigating.ah.....missed doses of somebody which is an at risk patient who may be at risk of self-harm, why they not turned up? Do we need to get somebody out to see them? Do we need to report it to the police? the treatment centre know them much more than we do so if we are giving them that information then then we can pass that on ...ah...so I do try and report all missed doses. I do it by fax (unclear speech) it's that because across across other pharmacies across Z and I know, when I started Z treatment centre weren't particularly aware of that being used as a procedure so.....possibly not (slight laugh).

Ok, ah, again coming back to this question we might have discussed this in slight bit but, you know when you are presented with methadone prescription as a

pharmacist when you are processing it what are the main concerns or the things you look for?

I'm checking, checking the legality of it. obviously it's the controlled drug, ah , I will be checking the patient against it, so I would, if it's the patient I don't know I'll always be asking for them, if it's the first time they are coming to be bringing identification of some sort with them ah.. and I always ask whenever their key workers phone up if it's somebody you haven't met before I'll be asking for identification. Obviously if it's somebody who is returning to the pharmacy and I know them then that's that's less the case because I know who they are, I've met them before, I can identify them myself, ah if it's a locum day I would be advising that they say coming in the next day they need to be bringing identification because the locum may not know them. Ah, I'll be checking what the dose is ah this will be based on what I'm told by the treatment centre ah key worker when they phone us up. So, if they ah on a titrating dose I'll be checking the titrating dose makes sense, I'll be checking what day the prescription was supposed to start so if they have missed a day or two, because if they have missed a day or two I need to be checking that they are still safe to star on it, because if it's a two day titration then , step up in the next two days then I need to be ah, informing them that they missed their first titrating dose. Us, us or have you, which has happened ah and they have to start again with a new script ah, sort be checking for the safety of it as well.

Having said all these things how do you see pharmacist fitting in the whole drug treatment service?

I think we have huge role to play. We are the ones they see most often. We don't see, when they first start and supervised they don't see the key worker every day, they don't see any other health care professional every day, it's only the pharmacist they sees that often and for us to be able to (unclear speech) built up the relationship then we have, we have that knowledge about that person, ah, we have got huge role to play. We can be reporting about if we have got concerns about them, with the missed doses, ah...it..they will talk to us, we are not ...the one who holds the big iron bar that or hold them and or have them over that if you don't do this we won't help you. We provide the medication that makes them feel better, they will open to us, they will see us as provider to them ah, people who will help them and possibly guide them if they need it so, it's a huge role that we can (rephrases) we have the option of providing and I know not all pharmacist will but I've seen a lot more success with the ones who will get involved than someone who won't.

That's interesting

I mean where I used to work, we did, I said we had one success story, but he used to come and he used to asking a lot questions obviously he used be getting involved with it. He used to come in and talk to us, I want to drop down every 15 days, are these going to work, I have one here who is.....a few days into stopping now, but beforehand

she was coming in she was asking me what her options were? They, they had mentioned it to her in clinic and nobody had explained her details. Could I help her, could I give her more information on these things so that she can make the informed choice so for them to have the feeling they can come in and talk to you about that rather than you wanting them out in 30 seconds flat, which I have seen some pharmacist do, it's as open doors and it does allow then to have the ability to get them out of the treatment and hopefully, finger crossed, get couple of success stories.

Good, and what do you think are the limitations in, in what pharmacists can input in the service?

I mean, obviously our hands are tight to a degree with the confidentiality areas, ah.....so patient who are abusing the system and things like that we are not allowed to to necessarily let, let the treatment centre know about that. I mean we are allowed to notify on missed doses and things like that but we are not allowed to let them know if we know they are using, on the side and the things like that, thats .. not, we are not allowed to do, so that's limitation. ah... and the degree of flexibility we have I men we know we can contact key workers to get things altered, get things amended if we need to....and...I...I necessarily would not want the responsibility of writing prescriptions and things but ...if they are coming to you for help and advice and things we need to be able to do things to put those steps in place and it isn't always possible to do so. if you are trying to get hold of people you need to speak to, stuff like that..

You mentioned flexibility; can you explain it bit further? What sort of flexibility?

.....(long pause, sighs), you got me there. ah.....talking about the flexibility to, to change things, I mean....as I say we we, I don't want too much flexibility for our role but ....if... if a patient , I don't know, we are supposed to... issue...a....ah.. I suppose, I don't know, I suppose flexibility isn't truly right term to use. ah..... I suppose I was more talking about the sort of the ability to get steps in place, we can't , we can't often do that because we are tide by who can and can't speak to when we can and can't speak to them so.. that isn't always an option that possibly we want to. I think flexibility; I am using the wrong term now. My apologies for that.

No that perfectly fine, I mean whatever you think of it is, is important, isnt it? Well, Amy that's pretty much what I wanted to ask on the topic unless there is something else that you think is important and I haven't asked and you would like to tell me about that.

I don't think so ...I think we have covered most of it.

Well thank you Amy, thank you once again, ok, I understand it's your lunch hour, but thank you for that.

You are welcome, no problem. (Laughs)

REACH Feedback

REPLYREPLY ALLFORWARD
Mark as unread

James Friedlander-Boss <J.D.Friedlander-Boss@bath.ac.uk>

Thu 13/12/2012 13:08
To:
Ramesh Yadav;

Flag for follow up. Start by 07 March 2018. Due by 07 March 2018.

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Dear Ramesh,

Full title of study: Community pharmacists' role in preventing drug related deaths (DRDs): an investigation into current UK practice.

REACH reference number: EP 12/13 18

The Research Ethics Approval Committee for Health (REACH) reviewed the above application at its meeting held on 12th December 2012.

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion of the above research on the basis described in the application form and supporting documentation.
Please inform REACH about any substantial amendments made to the study if they have ethical implications.

Kind Regards

James Friedlander-Boss

Department Co-ordinator

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in providing opioid substitution therapy (OST) service: an observation of the UK practice.

Date: 13th Feb 2017

Dear fellow pharmacist,

I hope this letter finds you in good health. My name is Ramesh Yadav. I am a community pharmacist and a PhD student at the University of Bath. Currently, I am undertaking the project titled above and would like to invite you to take part in this research.

This is an observation study, a follow on research from my previous study which you kindly participated in the past. The results from the previous study have shown differences in approach in which OST service is provided from community pharmacies. We would like to observe the provision of OST service in community pharmacy to support the findings from the previous study.

I have included some Participant Information Sheet (PIS) with this letter, which explains what this study involves for you. As the observation will also include other members of staff present or involved in providing OST service, I would greatly appreciate if you could distribute the PIS among the pharmacy staffs. Please feel free to make copies of the PIS or contact me if you require further copies.

Your involvement in the research will help us identify best practice and areas of improvement in the provision of OST services in community pharmacy.

If you would be willing to take part, please return the reply slip in the pre-paid envelop provided. Alternatively, you can email the research team on r.yadav@bath.ac.uk

Please feel free to contact myself or any member of the research team if you have any further queries. My PhD studentship comes from the University of Bath and I have also received grants from Pharmacy Research UK and The Harold and Marjorie Moss Charitable Trust.

Yours sincerely,
Ramesh Yadav MRPharmS.
PhD student

Research team: Ramesh Yadav r.yadav@bath.ac.uk, Dr Jenny Scott (supervisor) j.a.scott@bath.ac.uk Dr Gordon Taylor (co-supervisor), Dr Denise Taylor (co-

supervisor) d.a.taylor@bath.ac.uk Department of pharmacy and pharmacology, University of Bath, Claverton Down, Bath, UK, BA2 7AY. Telephone (Dr Scott) 01225385775

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Participant Information Sheet (v2, 22/07/2014)

Community pharmacists' role in providing opioid substitution therapy (OST) service: an observation of the UK practice.

Please read this information sheet carefully as this explains what this research is about and what it, as a participant, will involve for you. If you are not clear of anything or need further information, please feel free to contact the research team at the address given below.

What is the purpose of this study?

This research is being carried out as part of PhD study at the University of Bath. This is an observation study and will focus on observing how OST service is provided in the community pharmacy. A previous study has shown differences in approach in which OST service is provided from community pharmacies, this study is to support the findings from the previous study.

Why have I been chosen?

The contact detail of your pharmacy was obtained from the local NHS authority. You have been chosen following your/your pharmacist's participation in an earlier stage of this doctorate research.

If I decide to take part, what will it involve?

The researcher will visit your pharmacy on an agreed day/s and will spend some time observing how the service is provided, how medicines are organised and dispensed and the documentation carried out. The time spent will depend on your convenience and the volume of substance misuse services your pharmacy provides. We expect the observation to last for up to four hours. The researcher may ask you a few questions at the end to better understand your role and the reasoning behind your actions. The researcher will make anonymous hand written notes of what he observes. You and other member of staff willing to participate in this study will be asked to provide a written consent before the observation can take place. Every effort will be made not to interfere with the normal running of the pharmacy.

Is my taking part confidential?

All the data collected by the researcher will be anonymous. The researcher will not access or collect any confidential data. The observation data will be stored as per University of Bath data protection policy and only the research team will have access to it. All the data will be destroyed 5 years after completion of the PhD.

Has the research received ethical approval?

This research has been reviewed by the Research Ethics Approval Committee for Health (REACH) of the University of Bath and the NHS Research Ethics Committee, South West - Central Bristol.

Who is organising and funding this research?

The research is organised and funded by University of Bath. The student has also received a grant from Pharmacy Research UK and The Harold and Marjorie Moss Charitable Trust.

What will happen to the result of the study?

This research is being conducted as part of PhD study. The information obtained will be analysed to guide the next phase of the research which involves a national survey of community pharmacist regarding opiate substitution therapy. Results of this study may well be written up for publication or presented at conferences and seminars. If you are interested in the results of the study, please contact the lead researcher.

What if I change my mind afterwards?

You can withdraw from the research without any explanation prior to data analysis. If you feel uncomfortable at any time during the observation you can withdraw from the observation without having to give any reason. However, it might not be possible to separate your data once it has been mixed with other data for analysis, this will usually be a week after the observation.

What are the possible benefits of taking part in this research?

Your experience will be counted in identifying the gaps and good practices in the provision of substitution therapy from community pharmacies.

What are the potential risks or disadvantages of taking part in this research?

There is no risk or disadvantage of taking part in this research.

Action in the event of a matter of concern

As a matter of professional obligation, if we see serious malpractice that raises concerns, we may have to act on this. In the first instance our concerns will be discussed with you. Only if we consider that you or others remain at significant risk of harm will we pursue disclosure of our concerns to the relevant authorities e.g. GPhC.

If I want to take part, what should I do?

If you would like to take part in the research, please complete the reply slip and send it to the research team in the FREEPOST envelope provided. Alternatively, you can express your interest by emailing the research team on r.yadav@bath.ac.uk

Appendix 11: Participant information leaflet (observation)
Participant Information Sheet version 2, 22/07/2014

Research team: Ramesh Yadav r.yadav@bath.ac.uk, Dr Jenny Scott (supervisor) j.a.scott@bath.ac.uk Dr Gordon Taylor (co-supervisor), Dr Denise Taylor (co-supervisor) d.a.taylor@bath.ac.uk Department of pharmacy and pharmacology, University of Bath, Claverton Down, Bath, UK, BA2 7AY. Telephone (Dr Scott) 01225385775

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in providing opioid substitution therapy (OST) service: an observation of the UK practice.

Recruitment questions (Please tick or fill as appropriate)
This information will help us recruit a representative sample of community pharmacists. This information will be kept separate from your details provided below.

1. Gender: Female ☐ Male ☐
2. Age: 29 and under ☐ 30-39 ☐ 40-49 ☐ 50-59 ☐ 60 and over ☐
3. How many years have you been practising as a pharmacist? ----------
4. Please name the university you obtained your pharmacy degree from: ---------- ---------- Overseas (Please name the country): ---------- ----------
5. Which best describes your employment status? (tick one or more as appropriate)
   Owner ☐ Pharmacy manager ☐ Locum ☐ Second pharmacist ☐
   Locum ☐ Other ☐ please specify ----------
6. How many patients do you dispense substitution therapy to at the moment?
   5 or less ☐ 6-15 ☐ 16-25 ☐ more than 25 ☐
7. What best describes the location of the pharmacy you mainly work in?
   Urban ☐ Suburban ☐ Rural ☐

I am interested in taking part in the proposed research and I am happy for the research team to contact me to discuss participation further.

Name: ---------- **Signature**---------- **Date** ---------\---------\----------

Phone number: ---------- **Email:**
(If you prefer to be contacted this way):

Pharmacy Address: ----------
-

--

Please tick your preferred method of communication.
Phone ☐ Email ☐ Post ☐

If there is any time of the day you do not wish to be telephoned, please state here. ---

---

Please fill in this reply slip and return it in the free pre-paid envelop provided.
Alternatively, you can email your confirmation to r.yadav@bath.ac.uk. **Thank you.**

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Consent form for observation study

Project Title

Community pharmacists' role in providing opioid substitution therapy (OST) service: an observation of the UK practice.

Aim

1. To study the professional practice & clinical decision-making of community pharmacists when dispensing opioid substitution therapy.
2. To observe the professional communication and interactions with patients receiving prescriptions.

Declaration *Please tick and Initial*

1. I have read and understand the participant information sheet provided for this study. (version 2, dated 22/07/2014)	☐
2. I understand the observation data will be anonymous, only the research team will have access to it and will be preserved while the project lasts and for 5 years afterwards.	☐
3. I understand that relevant sections of my data collected during the study may be looked at by individuals from University of Bath, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records	☐
4. I have had opportunity to ask questions and have received, where asked, satisfactory answers to my questions.	☐
5. I understand that my participation in this research is voluntary and that I can withdraw without giving any reason prior to data analysis.	☐
6. I agree to take part in this research.	☐

Name of participant: ---------- Signature: ----------

Date: ------\------\----------

Person taking consent: ---------- Signature: ----------

Date: ------\------\----------

Appendix 13: Consent form (observation) Consent form for observation study
version 2, 22/07/2014

Research team: Ramesh Yadav r.yadav@bath.ac.uk, Dr Jenny Scott (supervisor) j.a.scott@bath.ac.uk Dr Gordon Taylor (co-supervisor), Dr Denise Taylor (co-supervisor) d.a.taylor@bath.ac.uk Department of pharmacy and pharmacology, University of Bath, Claverton Down, Bath, UK, BA2 7AY. Telephone (Dr Scott) 01225385775

The Name of the Pharmacy

A researcher from University of Bath is currently present in the pharmacy to study how community pharmacies operate. No confidential information relating to any patient or customer will be collected.

Please ask to speak to the pharmacist if you would like any further information.

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Department of pharmacy and pharmacology
University of Bath
Claverton Down
Bath, BA2 7AY
r.yadav@bath.ac.uk

Appendix 15: Data measurement tool (observation)

Data measurement tool Version 2, 22/02/2017

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in providing opioid substitution therapy (OST) service: an observation of the UK practice.

Qualitative Observation Data Measurement Tool

Site number: **Date:** **Day:** **Time:**

Pharmacy Setting (complete once per location)

General description: (Layout, staffs present, leaflets)

Provisions for OST service: (Communication and record keeping, any special arrangements)

Researcher's reflection:

Appendix 15: Data measurement tool (observation)

Data measurement tool Version 2, 22/02/2017

Site number: **Observation number:** **Date:** **Day:**

Time:

Presenting customer – pharmacy interaction

General characteristic of patients, reaction of pharmacy staff (any differences):
Pharmacists role: (any change in activity, nature of interaction)
Dispensing/clinical checking: (missed doses, change in dose, on-hold scripts)
Prescription Handing out: (supervision, intoxication, counselling, confidentiality)
Other observations /researcher's reflection:

Appendix 16: Anonymised observation data (sample)

Data measurement tool Version 2, 22/02/2017

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in providing opioid substitution therapy (OST) service: an observation of the UK practice.

Qualitative Observation Data Measurement Tool

Site number: 6 **Date: 01-03-2017** **Day: Wed** **Time:- 9.15**

Pharmacy Setting (complete once per location)

General description: (Layout, staffs present, leaflets)
It is an independent pharmacy, city location, a little walk (10mins) from main city centre. The inside of the pharmacy is very traditional looking. The dispensary is located in the back and is not visible from the shop. The counter and the shop areas are not visible from the dispensary either. The consultation room is located behind the counter.
A A4 size poster 'preventing overdose campaign-briefing for pharmacies' is displayed in the dispensary. Pharmacist reports it was from some tie back (years). No other leaflets available for OST.
Pharmacy is busy with stream of customers walking in and out. Pharmacist is on his own till 9.15, a counter assistant (female) and a dispenser (female) arrived at this point.

Provisions for OST service: (Communication and record keeping, any special arrangements)
Pharmacist reports that he prepares the OST prescriptions as and when the patients come for it. This is because sometimes they miss dose and it means a lot of undoing everything.
While on site, the pharmacist receives a phone call from the treatment centre chasing a prescription that has gone missing. The pharmacist notifies the treatment centre that the patient does not attend this pharmacy anymore; not for the last 6 months.

Researcher's reflection:
All OST patients were greeted by the pharmacy staff in the same way. The patient-pharmacy/pharmacist interaction has been no different to those of non-OST patient.

While there were good examples of supervised consumption, i.e use of consultation room, water after consumption the supervision of buprenorphine consumption lasted not more than a minute. In one case of buprenorphine consumption, the pharmacist kept eye on the patient after he has left the pharmacy. The pharmacist kept watching him as he crossed the road and walked along away from the pharmacy. When the pharmacist asked about this said because he has been a bit concerned about this patient. He did not look alright. He has noticed over last few weeks the patient has not been his usual self. He has also been notified by the treatment centre that this patient is at risk and thus to be more watchful.

Reported by Pharmacist:

Appendix 16: Anonymised observation data (sample)

Data measurement tool Version 2, 22/02/2017

Pharmacist reports some patients coming for their dose having had alcohol but no necessarily intoxicated to withhold dose. The general guidance from treatment centre is to withhold dose if they are drunk. In one case the participant dispensed to patient who might have had alcohol when she came for her dose. She slurs because of stroke thus it was difficult to say. Two hours later he had phone call from treatment centre complaining of dispensing to intoxicated patient, as the patient had presented at the treatment centre intoxicated, smashed her face. Pharmacist reported that while it is generally alright contacting the treatment centre (by phone); it can be difficult if he is expecting a call back from them.

Appendix 16: Anonymised observation data (sample)

Data measurement tool Version 2, 22/02/2017

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in providing opioid substitution therapy (OST) service: an observation of the UK practice.

Qualitative Observation Data Measurement Tool

Site number: 6 Observation number: 1 Date: 1-3-17 Day: wed
Time:

Presenting customer – pharmacy interaction

General characteristic of patients, reaction of pharmacy staff (any differences):
Middle aged customer walks in and waits to be served. The counter staff greets him and says hello. The patient then takes seat. Counter staff notifies pharmacist in the dispensary of the waiting patient.
Pharmacists role: (any change in activity, nature of interaction)
Pharmacist is checking prescription for a patient already present in the pharmacy. He completes the task and hands out the script. Pharmacist reached for the blue script he has prepared for the patient. Comes out, says hello and addresses the patient by his first name. He invites the patient into the consultation room.
Dispensing/clinical checking: (missed doses, change in dose, on-hold scripts)
Prescription Handing out: (supervision, intoxication, counselling, confidentiality)
Supervised consumption carried out in the consultation room. Could hear (not clear) patient and pharmacist having a friendly chat. They say good bye to each other as they come out of the consultation room.
Other observations /researcher's reflection: Pharmacist reported the patient to be on supervised buprenorphine. Also reported the patient going on the smoking cessation clinic. Patient has tried to change (his lifestyle?) since a drug raid in the city. The patient's partner is serving 2 years in jail for drug related crime.

Appendix 16: Anonymised observation data (sample)

Data measurement tool Version 2, 22/02/2017

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in providing opioid substitution therapy (OST) service: an observation of the UK practice.

Qualitative Observation Data Measurement Tool

Site number: 6 Observation number: 2 Date: 1/3/17 Day: Wed Time: 12.00

Presenting customer – pharmacy interaction

General characteristic of patients, reaction of pharmacy staff (any differences):
Middle aged man walks in the pharmacy. Counter staff is busy serving other customers. He walks in towards the dispensary (on the side of the shop counter) and says hello to the pharmacist, to notify of his presence (shop floor cannot be seen from the dispensary). He then takes seat in the waiting area.
Pharmacists role: (any change in activity, nature of interaction)
Pharmacist responds by saying hello to the patient without actually looking at the patient as he is checking prescription facing the other way. Once finished checking the prescription, pharmacist gets a blue script out, and dispenses by himself. Takes the buprenorphine tablets in his hand and asks the patient to come in to the consultation room.
Dispensing/clinical checking: (missed doses, change in dose, on-hold scripts)
Prescription Handing out: (supervision, intoxication, counselling, confidentiality)
Supervised consumption of buprenorphine tablets occurs in the consultation room, visible from the dispensary as the doors are open. It, however, cannot be seen from the shop floor. The supervision lasted less than a minute and no drinking water was offered. Pharmacist did not ask to check/ see if the tablet was all dissolved.
Patient walked out of the pharmacy. Pharmacist followed the patient to the shop floor as the patient walked out and kept looking at the patient after he was outside the pharmacy.
Other observations /researcher's reflection: The supervision of the consumption of buprenorphine tablet was to brief and that there was good chance that the tablet had not completely dissolved.

Appendix 16: Anonymised observation data (sample)

Data measurement tool Version 2, 22/02/2017

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in providing opioid substitution therapy (OST) service: an observation of the UK practice.

Qualitative Observation Data Measurement Tool

Site number: 6 **Observation number: 3** **Date: 1-3-17** **Day: wed**
Time:

Presenting customer – pharmacy interaction

General characteristic of patients, reaction of pharmacy staff (any differences):
Middle aged man with walking stick. As there is no staff at the counter he walks in towards the dispensary and says hello to inform of his presence. He then takes seat in the waiting area.
Pharmacists role: (any change in activity, nature of interaction)
Pharmacist prepare his prescription (green form non-OST), comes out and hands it to the patient sat on the chair. Pharmacists asks the patient to wait for the other prescription.
Dispensing/clinical checking: (missed doses, change in dose, on-hold scripts)
Pharmacist dispenses a blue prescription; labels and dispenses methadone by himself. Supervised dose is dispensed in a disposable glass and the take away dose in a plastic bottle.
Prescription Handing out: (supervision, intoxication, counselling, confidentiality)
Pharmacist invites patient to come into the consultation room. The dispensary side door is left open thus the activity in the consultation room is visible from the dispensary. The patient and the pharmacist talks about the non-OST prescription (omeprazole) while in the consultation room. Patient consumes the dose and also drinks from water from the tap in the consultation room.
Other observations /researcher's reflection: The use of disposable cup for dispensing supervised methadone dose was not observed in any other sites.

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in providing opioid substitution therapy (OST) service: an observation of the UK practice.

Qualitative Observation Data Measurement Tool

Site number: 6 Observation number: 4 Date: 1-3-17 Day: wed Time:

Presenting customer – pharmacy interaction

General characteristic of patients, reaction of pharmacy staff (any differences):
Young man, about 25 years, walks in to the pharmacy. There is already another patient waiting for the OST (observation no 3). Counter staff greets this new patient. Patient gives his name and says he has come for 'daily pick up'. Counter assistant notifies pharmacist of the new patient.
Pharmacists role: (any change in activity, nature of interaction)
Pharmacist carries on with the previous OST patient. On this occasion the dispenser dispenses the OST prescription (diazepam).
Dispensing/clinical checking: (missed doses, change in dose, on-hold scripts)
Pharmacist by now have finished with the previous patient, he checks the prescription and bags it.
Prescription Handing out: (supervision, intoxication, counselling, confidentiality)
Pharmacist comes out in the shop and hands out the prescription to the patient.
Other observations /researcher's reflection: The interaction between the pharmacist and the patient on this instance was much brief and limited as compared to the previous 3 supervised consumption.

NHS
Health Research Authority
NRES Committee South West - Central Bristol
Whitefriars
Level 3, Block B
Lewin's Mead
Bristol BS1 2NT
Email: nrescommittee.southwest-bristol@nhs.net

Telephone: 0117 342 1335
Fax:0117 342 0445

07 August 2014

Mr Ramesh Yadav
Community Pharmacist/ PhD Student
University of Bath
Department of Pharmacy and Pharmacology
University of Bath
Bath BA2 7AY

Dear Mr Yadav

Study title:	**Community pharmacists' role in preventing opiate substitution therapy (OST) deaths: an investigation into current UK practice**
REC reference:	**14/SW/0140**
IRAS project ID:	**140414**

Thank you for your letter of 29 July 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Alternate Vice Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Naazneen Nathoo, nrescommittee.southwest-bristol@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Additional conditions specified by the REC:

1) In the Participant Information Sheet (V2, 22/7/2014)
   - Under What is the purpose of this study?, please insert "the" between the words "how" and "OST"
   - Under "Why have I been chosen?", the first sentence should be corrected to: "The contact details of your pharmacy were obtained……"
   - Under "If I decide to take part, what will it involve?", please change "anonymous" to "anonymised"; "member" to "members" and delete "a" after "provide"

2) In the Invitation Letter (V2 22/7/2014)
   - In the third paragraph, the word "sheet" should be corrected to "sheets"; please insert "the" between the words "providing" and "OST"; "staffs" should be "staff"

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper		11 March 2014
IRAS Checklist XML [Checklist_30072014]		30 July 2014
Letter from sponsor	Letter from University of Bath	
Letters of invitation to participant	2	22 July 2014
Other [Letter from funder (PRUK)]		13 November 2013
Other [Summary CV for supervisor Gordon Taylor]		11 March 2014
Other [Pharmacy poster]	2	22 July 2014
Other [Data Measurement Tool]	1	29 July 2014
Other [Summary CV for supervisor for Denise Taylor]		11 March 2014
Other [Participant reply slip]	2	22 July 2014
Other [Summary CV for Jennifer Scott]		
Other [Letter from City Road & Hampstead REC]		14 April 2014

Participant consent form	2	22 July 2014
Participant information sheet (PIS)	2	22 July 2014
REC Application Form	3.5	28 March 2014
Research protocol or project proposal	2	22 July 2014
Response to Request for Further Information [letter]		29 July 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

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

User Feedback

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

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/SW/0140	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Mr Trevor Beswick
Alternate Vice Chair

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Professor Jane Millar,*

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in preventing opioid substitution therapy-related deaths: a quantitative survey of UK practice.

2nd January 2019

Dear fellow pharmacist,

My name is Ramesh Yadav. I am a community pharmacist and a PhD student at the University of Bath. Currently, I am undertaking the project titled above and would like to invite you to take part in this research.

Please take time to have a look at the information sheet included with this letter which explains the purpose of this study and what it involves for you as a participant. I hope this research is of your interest and you would be willing to help us by participating in this research. However, if you do not wish to be contacted for the survey please return the reply slip attached below in the FREEPOST envelope provided and we will remove you from our contact list.

Please feel free to contact myself or my supervisor if you have any further queries. My PhD studentship comes from the University of Bath and is supported by a research fellowship from Pharmacy Research UK.

Yours sincerely,
Ramesh Yadav MRPharmS.

Research team: Ramesh Yadav r.yadav@bath.ac.uk, Dr Jenny Scott (supervisor) j.a.scott@bath.ac.uk. Department of pharmacy and pharmacology, University of Bath, Claverton Down, Bath, UK, BA2 7AY. Phone No 01225 385775

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Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in preventing opioid substitution therapy-related deaths: a quantitative survey of UK practice.

Non-participation reply slip.

If you do not want to take part in this research then please cut this section along the dotted line above and return it in the FREEPOST envelope provided within seven days.
You do not have to provide your pharmacy details in this reply slip. The unique ID code in the footnote will help us identify your pharmacy. We will remove your pharmacy from our list of potential participants.

Thank you for your time.

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Participant Information Sheet (v02, 28/08/18)

Community pharmacists' role in preventing opioid substitution therapy-related deaths: a quantitative survey of UK practice.

Please read this information sheet carefully as this explains what this research is about and what it, as a participant, will involve for you. If you are not clear of anything or need further information, please feel free to contact the research team at the address given below.

What is the purpose of this study?

This study is being conducted as part of my doctoral thesis and is a follow-on research from my previous works on this topic. The results from the previous studies have shown differences in approach in which opioid substitution therapy (OST) services are provided from community pharmacies in different areas. This study aims to take a snapshot of the current UK practice of community pharmacists providing OST services. This doctoral research is aimed at finding out to what extent community pharmacists are involved in activities to prevent OST-related deaths? We are also interested in whether more can be done to reduce OST-related deaths.

Why have I been chosen?

Your pharmacy has been selected from a randomised list of community pharmacies registered with General Pharmaceutical Council (GPhC). Your contact detail was obtained from the GPhC and/or NHS choices website.

What will this research involve for me?

The research team will contact you by phone in the near future to administer the survey. We expect the survey to last 13-15 minutes. The survey will be in the format of yes-no and multiple-choice questions based around your practice, understanding and opinion on opioid substitution therapy. If we happen to call you at an inconvenient time please let us know and we will callback at a time that suits you. Alternatively, you could also complete the survey online please let us know and we will provide you with the online link to the survey.

Is my taking part confidential?

All the data collected by the researcher will be anonymous. The researcher will not ask for any personal or confidential data. The survey data will be stored as per University of Bath data protection policy and only the research team will have access to it. All the data will be destroyed 10 years after completion of the project.

Has the research received ethical approval?

This research has been reviewed by the Research Ethics Approval Committee for Health (REACH) of the University of Bath.
As all the participants in this study are all healthcare professionals; NHS Research ethics Committee (REC) approval is not required.

Who is organising and funding this research?

The research is organised and funded by University of Bath. The student has also received a research fellowship from Pharmacy Research UK.

What will happen to the result of the study?

This research is being conducted as part of PhD study. Results of this study may well be written up for publication or presented at conferences and seminars. We also intend to publish an executive summary of our findings to inform pharmacists, policy makers and other stakeholders. If you are interested in the results of the study, please contact the lead researcher.

What if I change my mind afterwards?

You can withdraw from the research without any explanation prior to data analysis. If you feel uncomfortable at any time during the survey you can ask the researcher to stop the survey without having to give any reason. However, it might not be possible to separate your data once it has been mixed with other data for analysis, this will usually be a week after the survey.

What are the possible benefits of taking part in this research?

Your experience will be counted in identifying the gaps and good practices in the provision of substitution therapy from community pharmacies. It will help inform the policy makers and commissioners of the challenges faced by pharmacists providing the service.

What are the potential risks or disadvantages of taking part in this research?

There is no risk or disadvantage of taking part in this research.

If I do not want to take part, what should I do?

If you would not like to be contacted by the research team, please complete the reply slip, attached to the accompanying letter and send it to the research team in the FREEPOST envelope provided. Alternatively, you could also inform of your choice when we contact you by telephone.

Contacting the research team

Ramesh Yadav (lead researcher, PhD student) r.yadav@bath.ac.uk, Dr Jenny Scott (supervisor) j.a.scott@bath.ac.uk, Department of pharmacy and pharmacology, University of Bath, Claverton Down, Bath, UK, BA2 7AY. Phone No 01225 385775

Department of Pharmacy & Pharmacology | UNIVERSITY OF BATH

Community pharmacists' role in preventing opioid substitution therapy-related deaths: a survey of UK practice.

Participant consent

The participant was provided an explanation of this research in writing or orally and was given opportunity to ask any questions they might have. The participant has provided oral consent to participate in this study.

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Name of the person obtaining the consent Date

Demographic questions

Now the first few are demographic questions are related to you and your pharmacy.

1	Which OST related services do you offer?	a. Dispensing blue (FP10MDA) prescriptions b. Supervised consumption c. Needle exchange service d. Take home naloxone service e. Other (state)……
2	How long have you been working as a pharmacist?	a. In years…….
3	How would you describe your employment status? (tick one or more as appropriate)	a. Owner b. Pharmacy manager c. Locum d. Second pharmacist e. Relief f. Other (specify)……..
4	What type of pharmacy do you work in?	a. Independent (1 store) b. Small multiple (2-4 store) c. Medium sized (5-25 store) d. Large Multiple (over 25 stores
5	What best describes the location of the pharmacy you mainly work in?	a. Urban b. Suburban c. Rural
6	Where do you usually supervise the consumption of OST?	a. Shop floor/counter b. Consultation room c. Screened area d. Other (specify)……..
7	Approximately how many patients do you dispense substitution therapy to?	a. (Number)……
8	Can you please confirm your gender?	a. Male b. Female c. Prefer not to say d. Other…….
9	Can you please confirm your age range?	a. 29yrs and under b. 30-39yrs c. 40-49yrs

		d. 50-59yrs e. 60yrs and over

Next we have got some yes/no questions. I will read out some statements and if you could reply in yes or no as we go along. So the first statement is

1	I have received formal training to provide OST services in pharmacy?	Yes	No
2	I have been asked to provide evidence of further training on OST by the local commissioner or my employer?	Yes	No
3	I have completed CPD related to OST in the last 12 months.	Yes	No
4	I use clinical guidance **or other source of information** on OST to inform my practice.	Yes	No
5	I find clinical guidance **or other source of information** on OST to be helpful in my practice.	Yes	No
6	Can you name the clinical guidance or the source of information you use to inform practice on OST? a. Drug misuse and dependence (orange guide) DH b. NICE c. SLA (service level agreement) d. BNF e. RPS f. Others ……		
7	I suspect certain patients use drugs while receiving OST.	Yes	No
8	I have on occasions dispensed a dose to a patient who appears intoxicated.	Yes	No

Now for the next set of questions/ statements you have the answer choice of always, sometimes or never.

		Always	Sometimes	Never
1	I counsel OST patients about overdose risks. **(If the answer is Never go to Q4)**			
2	I counsel the patient about overdose risks when they first start on OST.			
3	I counsel patients about overdose risk when there is a change in dose or circumstances that I am aware of.			
4	I check OST prescriptions to make sure they meet the legal requirements for controlled drugs.			
5	I check OST prescriptions for clinical appropriateness of the medicine being prescribed.			
6	I consult the prescriber if 3 or more consecutive days of a prescription have been missed.			
7	I check with patients to ensure they have access to naloxone to treat opioid overdose.			
8	I withhold the dose if I suspect the patient to be intoxicated.			
9	I report to the prescriber when I suspect patients are using drugs while on OST.			
10	I provide feedback to the prescriber on the treatment progress of the patient.			

Next, I will read out some statements. Please tell me where you would place your response on the scale of agree, strongly agree, disagree, strongly disagree or neutral

(Please ensure participant understands the scale)

		Agree	Strongly Agree	Disagree	Strongly Disagree	Neutral
1	I believe that opioid substitution therapy is an important service provided by community pharmacists for patients.					
2	I believe that input from community pharmacists helps to prevent opioid overdose in patients receiving opioid substitution therapy.					
3	I believe pharmacists are integrated into the primary care/ community provision of OST services.					

	About OST services	**Agree**	**Strongly Agree**	**Disagree**	**Strongly Disagree**	**Neutral**
4	I am aware of how the community/ primary care drug treatment service operates in my area.					
5	When needed, I can get professional advice and support to provide OST services.					
6	If needed, I can get advice and support during out of hours. **(If the answer is negative go to Q8)**					
7	Can you tell where do you get such support/advice from? ……					
8	When needed, I can contact the prescriber of OST promptly?					
9	I feel that my feedback on patients is valued by the prescriber of OST.					
10	I feel that my feedback affects the future treatment plan of OST patients.					
11	I speak to the patient when I suspect them using drugs while on OST.					
12	Reporting suspected drug use to the prescriber breaches patient confidentiality.					

	Knowledge and confidence	**Agree**	**Strongly Agree**	**Disagree**	**Strongly Disagree e**	**Neutral**
13	I feel confident about my ability to provide OST services.					
14	I feel confident to challenge a prescriber when I have concern about their OST prescribing.					

15	I feel I can identify patients who are at risk of harm from OST.					
16	I can identify OST patients who present intoxicated.					
17	The actions I take when I have concerns about OST patients can be affected by my workload.					
18	My decision to dispense to an intoxicated patient can be affected by the behaviour of the patient.					

	Patient monitoring	**Agree**	**Strongly Agree**	**Disagree**	**Strongly Disagree**	**Neutral**
19	Pharmacist are the best placed health professionals to monitor patients receiving OST.					
20	I am aware of my patients who divert their OST medication.					
21	My interaction with OST patients **does not** give opportunity for meaningful input.					
22	I feel that my interaction with OST patient is different to those with non-OST patients.					

	Dispensing	**Agree**	**Strongly Agree**	**Disagree**	**Strongly Disagree**	**Neutral**
23	Dispensing an OST prescription is different from dispensing other controlled drug prescriptions.					
24	I feel more anxious dispensing OST prescriptions compared to other controlled drug prescription.					
25	I ensure the privacy of the patient receiving OST is protected.					

Thank you very much for your time today, your participation in this research is greatly appreciated. If you have any questions about this research please contact the research team at r.yadav@bath.ac.uk or j.a.scott@bath.ac.uk

Community pharmacists' role in preventing opioid substitution therapy-related deaths: a quantitative survey of UK practice.

Verbal script for telephone survey

Hi, my name is [ ] and I am a PhD student at University of Bath, Department of Pharmacy and Pharmacology. Could I please speak to the pharmacist? *(If not already speaking to the pharmacist)*. I am conducting a research on 'community pharmacists' role in preventing opioid substitution therapy-related deaths'. Is it a good time to speak or would you like me to ring back later? *Make note of time and date, if appropriate.*

We sent you some information about this research in the post, have you had chance to read through the information?

If the answer is YES

Do you agree to participate in this survey? Do you have any question?

YES: Document the consent below and continue with the survey.

NO: Thank the participant for their time.

If the answer is NO;

Establish if the participant would prefer a callback at a more convenient time. Make a note of time and date, if appropriate. Establish if the participant would like the information sent over again or they or would be happy to hear the summary of the information sheet. If so, ready out the summary of the information sheet.

'I am conducting this as part of my PhD studies. This research is organised and funded by University of Bath and is supported by a research fellowship from Pharmacy research UK. This research has been reviewed by the Research Ethics Approval Committee for Health (REACH) of the University.

Your pharmacy has been selected from a randomised list of community pharmacies registered with General Pharmaceutical Council (GPhC). Your contact detail was obtained from the GPhC. Any information you provide will be anonymous. While the results of this research will be published in scientific journals and presented in conferences, you or your pharmacy will not be identified in any publications.

This survey will last about 13-15 minutes and is in the format of yes-no and multiple-choice questions based around your practice, understanding and opinion on opioid substitution therapy.

Your participation in this research is voluntary and you can ask to stop the survey anytime without giving any reason.'

Do you agree to participate in this survey? Do you have any question?

YES: Document the consent on the survey form and continue with the survey.

NO: Thank the participant for their time.

From: Health Ethics <health-ethics@bath.ac.uk>
Sent: 09 October 2018 16:22
To: Ramesh Yadav <R.Yadav@bath.ac.uk>
Cc: Jenny Scott <J.A.Scott@bath.ac.uk>
Subject: EP 17/18 220

Dear Ramesh
Full title of study: **Community pharmacists' role in preventing opioid substitution therapy-related deaths: a quantitative survey of UK practice**
REACH reference number: EP 17/18 220

On behalf of the Committee, I am pleased to confirm that the Committee would be happy to provide a favourable ethical opinion of the above research on the basis described in the application form and supporting documentation.

If you intend to display recruitment posters/materials, please ensure you obtain the appropriate permission to do so from those who manage the location(s) you choose.

Please inform REACH about any substantial amendments made to the study if they have ethical implications.

Please make sure you quote your unique REACH code, EP 17/18 220, in any future correspondence.

Kind regards

Rebecca

UNIVERSITY OF BATH

Rebecca Wise, DC (Research Ethics)
PREC
wiki: https://wiki.bath.ac.uk/display/PEC/Psychology+Research+Ethics+Committee+Home
SSREC
wiki: https://wiki.bath.ac.uk/display/SSREC/Social+Science+Research+Ethics+Committee+%28SSREC%29+Home
REACH
wiki: https://wiki.bath.ac.uk/display/DfHealthREACH/Research+Ethics+Approval+Committee+for+Health+%28REACH%29+Home
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Tel: 01225 386141
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Ramesh Yadav
Dept of Pharmacy & Pharmacology

27 February 2014

Dear Ramesh,

Community pharmacists' role in preventing OST related deaths: an investigation into current UK practice

I am pleased to confirm that the University is prepared to act as sponsor under the Department of Health's Research Governance for Health and Social Care (2005) subject to the following:

1. The University requires you, as Chief Investigator, to conduct the study in compliance with the requirements of the Framework so it is able to meet its obligations as sponsor.
2. University professional indemnity and insurance will apply to the study as appropriate, within the UK.
3. As the Chief Investigator for the study, the University requires you to comply with the University policy on research data and all systems of good practice.
4. Substantial amendments and reports should be submitted to the undersigned.

Yours sincerely

[redacted]

Professor Jane Millar
Pro-Vice-Chancellor

National Pharmacy Association

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Tel 01727 832151
Fax 01727 840858
email npa@npa.co.uk

Mr Ramesh Yadav
[redacted]

14th June 2012

Dear Ramesh

I know that Janet Misson has already contacted you informally but I am now delighted, on behalf of the Trustees, to write and confirm that a 2012 Health Education Foundation Bursary has been awarded to you to undertake the first phase of the following research project.

> "Community pharmacists' role in preventing drug misuse deaths (DMDs): an investigation into current UK practice."

The Trustees believe this is an area of relevance and were supportive of the Phase 1 costs of the project. They felt that Phase 2 requires more development and reduced reliance on postal methodology with increased use of on-line technology such as Survey Monkey. I accordingly have pleasure in enclosing a cheque made payable to you for £3,000.

Please accept my apologies that this confirmation has taken rather longer than I would have wished but we received a considerable number of applications and it has taken some time to carefully consider all the research study proposals placed before us. The Foundation has been able to award three bursaries this year, and I am delighted that yours is one of them

We anticipate publicising the awarding of our 2012 bursary recipients and seek your consent to this. We are equally anxious at the completion of your work, to be able to disseminate the outcome, and the preparation of a report and a public presentation at an event are a condition of the grant.

With kind regards
Yours sincerely

[redacted]

DR IAN CUBBI
Chairman
NPA Health Education Foundation

THE HAROLD AND MARJORIE MOSS CHARITABLE TRUST

(Reg Charity No. 1022715)

KSR/19986
June 2013

Dear Mr Ramesh Yadav

PhD Research Award – 2013/14

On behalf of the Trustees of the above, I am very pleased to confirm that your application for a PhD research award in respect of your degree course at Bath University has been successful.

On the basis of the information you have supplied, the Trustees have agreed to award you the sum of £5000 and this is payable in three equal instalments at the end of September 2013, end of December 2013 and end of March 2014 **once you provide confirmation of your enrolment.**

This award is made for one academic year only. You are free to reapply for an award for 2014/15, provided you submit an update on your research, including an outline of proposed costs for the remainder of your study.

To assist in the payment of your award direct to you by instalments, could you please confirm details of your personal bank/building society current account as follows:

- Name and address of your bank/building society.
- Account name and account number.
- Bank/building society sort code number.

Finally, could you please acknowledge your acceptance of the conditions of this award by signing a copy of this letter and return to me at the address shown below or by email to thurstonj@shipleys.com and wallacem@shipleys.com.

Yours sincerely

[redacted]

K S Roberts
(for and on behalf of the Trustees)

[redacted]

I acknowledge the terms and conditions of the award ..... 17-06-2013 ..... Date

10 Orange Street, Haymarket, London WC2H 7DQ
Tel: 020 7312 0000 Fax No. 020 7312 0022

Pharmacy Research UK

TERMS AND CONDITIONS

PHARMACY RESEARCH UK – PRACTICE RESEARCH AWARDS

1. The Awards must be used solely for the purposes set out in the application, approved by the Trustees and described in the letter of award.

2. The Award holder(s) will be responsible for the conduct of the work and for adhering to the terms and conditions of the Award.

3. The host organisation must ensure that all necessary ethical committee approvals and requirements of regulatory authorities are in place before the work begins and are maintained for the duration of the Award. The Award holder(s) must ensure that all facilities, agreements about access and collaborations necessary for the work are obtained before the work commences and can be ensured throughout the grant period. The Award holder(s) must be aware of the requirements in the NHS Research Governance framework (which can be found at http://www.dh.gov.uk/assetRoot/04/12/24/27/04122427.pdf) and as part of project approval and supervision, the host institution should agree to accept responsibility for ensuring the requirements laid out in the research governance framework are met.

4. Any financial support for the project obtained from other sources must be made known to the Charity as soon as possible. The Charity reserves the right to withdraw/modify its funding if it perceives dual funding.

5. The Charity should be informed immediately if the Award holder(s) is unable to take up the Award or unable to continue with the Award (e.g. due to illness or other circumstances). Decisions about the transfer of the award will rest with the Charity.

6. Award holders are encouraged to publish results of their research in peer reviewed academic journals and conference abstracts and to send three copies of such publications to the Charity. The Charity's support for the project should be acknowledged in any publication (written or electronic), poster or presentation and, where possible, in any newspaper article or radio or television programme about it.

7. If Award holders or their employers wish to issue press statements that mention the Charity, the Charity should be given an opportunity to comment on the draft. The text should acknowledge that the work has been funded by the Charity, but that the views expressed are those of the Award holder and not those of the Charity.

8. Where a project involves collection of original data the Award holder should ensure that the data are held appropriately in accordance with the Data Protection Act (1998) and should be available for verification if required by the Charity.

9. (1) Work produced by the Award holder may be subject to or give rise to intellectual property rights (including copyright, design rights, rights in data, patents, know-how, trade secrets, confidential information and any other intellectual property rights, whether or not registered or applied for).

   (2) The Award holder shall ensure that no work (including any associated intellectual property rights) produced by the Award holder which has commercial value and which the Charity has wholly or partly funded is:

   a) Disclosed, published or made publicly available; or

Pharmacy Research UK

b) Sold or transferred or
c) Licensed or otherwise exploited

Without gaining express prior written consent from the Charity for the particular action in question.

(3) A work shall be deemed to have been funded by the Charity if it is based on or incorporates research or other work conducted while Award funding was provided, even if the work is completed after Award funding has ended.

(4) As a condition of granting consent under subclause (2), the Charity may require a written agreement to be entered into and/or payments to be made to the Charity (sharing revenue derived from the work or otherwise) in each case on terms reasonably acceptable to the Charity.

(5) The Award holder shall provide the Charity on request with reasonable access to information, records or personnel which has any bearing on the commercial exploitation of a work.

(6) In the absence of an agreement under subclause (4) above, the Award holder shall pay the Charity half of all the gross consideration (whether in cash or otherwise) received from any commercial exploitation of any work that the Charity has wholly or partially, funded without any deduction of any costs, taxes or other sums.

(7) The award holder shall ensure performance of its own obligations hereunder and shall be liable for any acts or omissions which put in breach of these terms. No party shall enter into any obligations with any third party which are incompatible with these terms and conditions.

10. Award holders are to keep the Charity informed of progress of the project and particularly of changes (to personnel or circumstances) that may affect the outcome of the work, or important findings.

11. The Charity reserves the right to terminate an award if the Award holder(s) funded by the grant is in breach of any of the conditions of award or becomes unfit or unable to pursue the work funded by the Award.

12. A final report of a publishable standard, accompanied by a financial statement relating actual expenditure to the original budget, should be submitted within three months of the termination date of the award. The final report is the property of the Charity and may be published. Failure to submit a final report as outlined above may result in the Charity withholding final payment, or a request for financial reimbursement.

If the research project requires more than 12 months for completion, an interim report must be submitted one year after receipt of the Award, detailing work done to date and estimated finish date. An interim financial report must also be included.

DETAILS OF LEVERHULME PHARMACY RESEARCH FELLOWSHIP

Award Holder Details

Project Title: **Community pharmacists' role in preventing drug related deaths (DRDs): an investigation into current UK practice**

Pharmacy Research UK

Name: Ramesh Yadav

Address: 1 [redacted]

Tel: [redacted]

Email: r.yadav@bath.ac.uk

Supervision

Supervisor Name/s: Denise Ann Taylor

Address: Room 5W 3.27
Department of Pharmacy and Pharmacology
University of Bath
Claverton Down
BATH
BA2 7AY

Supervisor's Signature:..... [redacted] .....

Date: 13th November 2013

Method of Payment:

Payment Schedule – 90% of the award will be paid upfront to the university with 10% held back until the final report has been received by Pharmacy Research UK.

Total Awarded: £18,000

Please send invoices to:

16200 90%
1800 10%

Duncan Walsh
Research Administrator
Pharmacy Research UK
Royal Pharmaceutical Society
1 Lambeth High Street
London SE1 7JN

13120211

Pharmacy Research UK

Award holder's declaration:

I agree to the above terms and conditions and shall comply with the obligations identified in these

Signature: [redacted]

Date: 13-11-2013

Name (Block Capitals): RAMESH YADAV

Please send reports to:

Charlotte Coates
Research Manager
Pharmacy Research UK
Royal Pharmaceutical Society
1 Lambeth High Street
London SE1 7JN
Tel: 020 7572 2466
Fax: 020 7572 2506