Title Page

‘My Healthcare Journey Through Pregnancy and Substance Use'.

An Investigation of the Lived Experience of the Healthcare Journeys of Women with Opioid Use Disorder who Become Pregnant.

Author: Susan Elkington

Doctoral portfolio submitted in fulfilment of the requirements for the

Professional Doctorate in Counselling Psychology (DPsych)

City, University of London

Department of Psychology

School of Health and Psychological Sciences

September 2024

Signed Declaration

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

Table of Contents

I List of Contents, Tables, Figures and Abbreviations

List of Tables

List of Figures

List of Abbreviations and Glossary

All Sections (Add Section B)

AFS	Alcohol Foetal Syndrome
CCO	Child Care Orders
CNS	Central Nervous System
CPTSD	Complex Post Traumatic Symptom Disorder
CP	Counselling Psychology
DoH	Department of Health
DRD	Drug Related Drugs
EACG	Expert Advisory and Co-production Group
GT	Grounded Theory
HRA	Health Research Authority
HCRW	Health & Care Research Wales
IPA	Interpretative Phenomenological Analysis
MBU	Mother and Baby Units
MDT	Mixed Disciplinary Team
NAS	Neonatal Abstinence Syndrome
NET	Narrative Exposure Therapy
NHS	National Health Service
NHS SMS	National Health Service Substance Misuse Services
NICE	National Institute for Health and Care Excellence
NOWS	Neonatal Opioid Withdrawal Symptom
ONS	Office of National Statistics
OST	Opioid Substitution Therapy
OUD	Opioid Use Disorder
PHE	Public Health England
PTSD	Post Traumatic Stress Disorder
RTA	Reflexive Thematic Analysis
SAMHSA	Substance Abuse and Mental Health Services Administration
SUD	Substance Use Disorder
TA	Thematic Analysis

Glossary (DrugWise, 2024; NICE Clinical Knowledge Summary, 2024)

Buprenorphine	Buprenorphine is an opioid-receptor partial agonist (it has opioid agonist and antagonist properties). Used as medication in the treatment of opioid use disorder
Buvidal	Buvidal is a weekly or monthly injection of buprenorphine, used for treating opioid dependence
Methadone	Long-acting synthetic opioid used for pain management and treatment of opioid use disorder.
Naloxone	Naloxone is a synthetic opioid antagonist and medication used to reverse the effects of opioid overdose; it has a short duration of action; repeated doses or infusion may be necessary to reverse effects of opioids with longer duration of action.
Opioids	An opioid is either a natural derivative of opium or a synthetic/semi-synthetic substance that acts on opioid receptors in the brain.
Oxycodone	Oxycodone is an opioid based analgesic (painkiller).
Nitazenes	These are strong synthetic opioids which have no current medical use. Nitazenes can be injected, inhaled, smoked, or swallowed as tablets.
Subutex	Medication containing buprenorphine is used as a medication in the treatment of opioid use disorder.
Tramadol	Tramadol is an opioid based analgesic; they work by mimicking the effects of the body's natural painkillers – endorphins – namely by blocking the pain signals sent from the nerves to the brain.

II. Acknowledgements

I would like to start by thanking the women who participated in this research and who shared their unique life stories, feelings and experiences with me. The interviews caused me to stop and reflect on what it takes to share such personal parts of oneself with a researcher, equipped with consent forms and a recording device. Several of the women sent me messages afterwards to thank me for listening to their story, and to say what it felt like to describe their experiences. I would like to find out how they are getting along. I would like to continue talking with them and I check myself at times. I feel as if I know them well, having listened to and studied every word, months after the interview. The relationship feels bigger than the duration of the interview. I would like the women to know how important their contribution is, and I hope I have done justice to their lived experience and journeys. I would also like to thank and pay tribute to Jan, on whom my client study is based. Thank you for the trust you put in me for sharing your life story, your openness and for your courage in talking about so many difficult episodes in your life.

Our qualitative work only exists because of a willingness of others to talk, to relate and to share something. I hope that this research will improve how women who have become dependent on substances, especially those with Opioid Use Disorder (OUD) who become mothers are cared for within the NHS, within social care and our legal system, and by society at large.

Thank you to my field NHS supervisors, Dr O'Ryan and Dr Dent for their unwavering support, as I trod my path through NHS Ethics to the field work of recruitment and data collection. They may never know how much I valued their practical and solution focused advice which allowed me to implement the research. Thank you to Dr Sharad for his time on many clarifications on the pharmacology of medication used to treat substance misuse. Thank you to the many Keyworkers and staff of the NHS Substance Misuse Services who referred many women and who made me feel welcome at the many weekly team meetings. Thank you to all those who work in substance misuse services where your daily work counts to so many but may be seen by so few.

Thank you to my swimming friends, Kate and Denise, for listening and being supportive on our many walks to the ponds, to Alison and Durell, to my sisters for encouragement, and to Lydia for the wonderful dinners where I could leave it all behind.

And my heartfelt thanks to Professor Carla Willig for her unwavering support and advice. Her choice of words to encourage me through challenging moments was always perfect.

III. Declaration of Power

I grant powers of discretion to the University Librarian to allow this Doctoral thesis to be copied in whole or in part without further reference to me. This permission covers only single copies made for study purposes, subject to normal conditions of acknowledgement.

IV. Preface to the Portfolio

The portfolio represents a window onto a journey of personal and professional learning during my Counselling Psychology Doctorate. My starting point as a Trainee Counselling Psychologist was tentative, almost resistant. I am interested in biology and the physiology of how distress is manifested, and I have tended to focus my learning on clinical presentations of serious mental health conditions such as Bipolar Disorder, Psychosis and Dementia. I found myself somewhat lost in the early part of the academic teaching of the Counselling Psychology Doctorate. The focus on reflexivity, the intersubjective space between client and therapist, and the use of self were new concepts for me. I took time to understand their important role in therapeutic practice. My interest in the medical model of mental health was assailed by Rogerian theories and practices which were relatively new to me (Rogers, 1961).

Where were the aetiologies, epidemiology and current research on defined and diagnosed clinical presentations? As my understanding of the discipline of Counselling Psychology has developed, I realise how important the Rogerian principles are to the work we do as Counselling Psychologists, how we are guiding and supporting the client to take tiny steps in self-actualisation and to become confident in becoming an expert in themselves. These small and sometimes imperceptible changes are important across many presentations.

In my NHS placements, I was drawn to work in specialised NHS mental health services using diagnostic measures and models, where presentations are defined in the DSM V(2013) or ICD 11 (WHO, 2022). In my clinical practice on placement, I started to understand the importance of the therapeutic alliance, the client's personal meaning making, sense of self and congruence. I learnt that these were important in the therapeutic work across the placements and diagnostic categories, and that this holistic approach is at the heart of Counselling Psychology. A key part of my development as a Counselling Psychologist in my doctoral training, has involved re-examining my beliefs in a medical model of mental health. I have learnt to approach therapeutic work, with a balance of understanding between a clinical model of mental health presentations with the rich principles of Counselling Psychology, and a respect for *'the personal, subjective experience of the client'* (Bury & Strauss, 2006, p.113).

Lane and Corrie (2006) argue that we have the opportunity to re-examine our relationship with science as Counselling Psychologists. I have spent time examining my ontological approach and position as a Counselling Psychologist. I have positioned myself as critical realist in my research, and in this portfolio of work. I stress that I also have a deep appreciation and interest in social constructionism and its benefits for examining language and beliefs, and many different stakeholder's perspectives. This portfolio represents for me a personal journey in widening my 'appreciation of different scientific stories' , and not 'becoming overly enmeshed in our own ideas about what science is or should be. Our personal definition of science is simply one story about how we can better understand the world' (Lane & Corrie, 2006, p.76). As a Counselling Psychologist working within NHS healthcare settings, operational guidelines and procedures, it is the client's perspective and meaning making which I have learnt to focus on, not the diagnosis. I appreciate the importance of the many dimensions of a client's experience of distress and factors which have contributed towards their sense of self, including biological, developmental and psychological factors. As a critical realist, I have learnt to pay attention to the subjective experience narrated by my clients, as they interact with structures and processes within the healthcare system and society, some of which are invisible. This is based on the philosophical work Bhaskar (1975). The portfolio focuses solely on women and their experiences of a world which is substantively made up of structures against which they construct their realities. These might be constructed into different layers of reality, including physical, biological and social which might be seen or not observed by the women, but which real effects on them. Critical realism allows space for the complexity of the real world faced by the women presented in my portfolio, as well as the meaning making of the extensive socially constructed and inter-relational processes they have experienced, which contribute to their sense of self.

The Sections of the Portfolio

The portfolio is based on research with women with Opioid Use Disorder and therapeutic work with a woman diagnosed with Complex Post Traumatic Stress Disorder (CPTSD). The women are aged between 26 years old to 56 years old and were all registered within specialised services within an NHS Mental Health Trust. This portfolio comprises three sections. Section A comprises the Doctoral Thesis, section B the Combined Case Study and Process Report and section C, a publishable paper based on the Thesis research. A brief outline of each of these is set out to enable the reader to situate the key themes I have sought to demonstrate in the portfolio. All participants and clients have been de-identified, and names are pseudonyms.

Section A is an original piece of qualitative research investigating the lived experience of the health care journeys of women with Opioid Use Disorder (OUD) who become pregnant, and journey into motherhood. My interest in this topic stemmed from clinical work during my first-year placement as a Trainee Counselling Psychologist in an NHS Substance Misuse Service. My second client in this placement was a young woman aged thirty-three who was eight months pregnant. She had used illicit heroin since the age of 26 and was diagnosed with OUD. OUD is a clinical diagnosis given to individuals who have become dependent on opioids, illicit or prescribed (APA, 2013). Dependence is associated with physical and psychological symptoms and opioid tolerance which requires increased quantities to attain the desired effect, and a range of difficult withdrawal symptoms if the opioids are withdrawn or reduced (APA, 2013; Dydyk et al., 2024). Our weekly therapy sessions lasted for six months, and much of our work focussed on her experience of the complex interactions with NHS departments, social services and the family court system. I was deeply interested in her experience and her struggle to maintain abstinence from illicit heroin amidst the unfolding pressures of interactions with many NHS teams around her. I started to look at UK and US qualitative research which described and reported women with OUD feeling judged within healthcare settings. My Doctoral research is very much an extension of my work with this client, driven by two primary motivations. Firstly, a desire to know more about the experiences of women navigating NHS healthcare systems as they seek to manage both pregnancy and motherhood, and their own opioid dependency. Secondly, I wanted to see whether findings drawn from the lived experience could contribute to the care of women with OUD. The thesis research is set within an NHS setting, with the participants recruited from NHS Substance Misuse Services in north London.

Section B is a case study and process report based on therapeutic work with a 56-year- old black British woman called Jan, diagnosed with Complex Post Traumatic Stress Disorder (CPTSD) in a specialized CPTSD Pathway in a Mental Health Trust. (She is not part of the research in Section A). I worked with her using Narrative Exposure Therapy (NET) (Schauer et al., 2011) over twenty sessions, over seven months, with each session lasting 90 minutes. I was particularly interested in Jan's presentation of CPSTD, and her lived experience as a victim of coercive control. Coercive and controlling behaviour was defined in UK criminal law in 2015 (Stark, 2016) and evidence suggests that PTSD/CPTSD is associated with mid-life women subject to intimate partner violence (IPV) of which coercive control is a particularly insidious form of abuse, resulting in the erosion in belief systems of self-determination (Carthy et al., 2023; Lohmann et al., 2024). I was extremely grateful for the therapeutic time I had with Jan, in that it allowed us to work carefully through many

traumatic episodes in her life. This not only allowed the NET processes to occur but provided us time to understand how the coercive control had developed over time. It also gave us time for Jan to let go of the guilt and shame she felt about putting her son and herself in a dangerous situation. It was a powerful and moving moment when we read Jan's narration from the start to the end. It made me realise how narrating and reliving the lived experience is a powerful tool. It validated my newfound understanding of how rich and varied each person's experience was, and the power of narrative therapies.

Section C is a publishable article aimed Qualitative Health Research (QHR), SAGE, and is based on the research with women with OUD in Section A. I was keen to set the research within an NHS setting for the purposes of design and aims. I am hoping the clinical findings make a contribution to outcomes for women with OUD. I also hope the article reaches the Counselling Psychology (CP) profession and encourages more of us to participate in substance misuse work where I believe CP has an important role to play.

The lived experience and use of narrative are play important parts of sections A & B. This was a key development for me over my previous focus and interest in quantitative methodologies. My epistemological approach in the portfolio is phenomenological and is informed by Heidegger's hermeneutics (1962) and theory of meaning making which seeks to uncover hidden meanings in experience and the possibility that it is not feasible to bracket the role of the researcher on the meanings brought forth by the participant (Zaborowski, 2011). I was delighted in the rich and varied experience of the women, and I have aimed to represent patterns in the data as well as differences.

During my Doctoral training, I have discovered the power of narrative in therapy and in research. I also have a better understanding of the contribution Counselling Psychology can make in NHS mental health services, alongside other disciplines such as Psychiatry and Clinical Psychology. In UK, the discipline of Counselling Psychology has been accepted since 2004 (Bury & Strauss, 2006). I felt curiously surprised at the reflexivity and openness of colleagues within Clinical Psychology and Psychiatry to discuss presentations, using a holistic approach. I have often wondered whether this stems from the influence of Counselling Psychology. The highly experienced Clinical Psychology lead of one of my placements said that she had never been trained or received any guidance in reflexive practice, though it had now become an integral part of her own practice and indeed of our team's time together and was highly valued by us. My sense is that the Counselling Psychologists are trained to work using a diagnostic framework, a comprehensive exploration of the client's family history and presenting problem, yet capable of retaining the

richness of the clients lived experience and meaning making, including working integratively, supporting the client's context, needs and aims.

Concluding Comments

My aim here was to introduce the sections of the portfolio and to provide insight for the reader of my own personal journey of learning and development, within the portfolio. I was drawn to placements in specialised services in NHS Mental Health Trusts. In these settings, I moved from following a more medical and diagnostic model of distress and to one in which I recognised the individual's experience and meaning making, as being more important than the diagnosis of CPTSD or OUD. I also recognise that my clients would not have reached the mixed discipline teams of psychologists without a clinical diagnosis and referral to a specialist pathway. As a Counselling Psychologist, within NHS Mental Health Trusts, we are capable of integrating and using tools of diagnostic assessment and evidence-based practice effectively. The research with women with OUD was a long and hard project. It allowed my understanding of the importance of the lived experience to grow, and I believe the findings of the research of women with OUD can be generalised more widely. My learning as a Counselling Psychologist practitioner continues.

References to the Preface

American Psychiatric Association. (2013). *Diagnostic and Statistical Manual of Mental Disorders* 5th ed.). Arlington, VA: American Psychiatric Publishing.

Bury, D., & Strauss, S. M. (2006). The scientist-practitioner in a counselling psychology setting. *The modern scientist-practitioner: A guide to practice in psychology*, 112-126.

Dydyk, A. M., Jain, N. K., & Gupta, M. (2024). Opioid Use Disorder. *In StatPearls*. StatPearls Publishing.

Carthy, N., Best, D., Heckels, V., Weber, L., & Eberhardt, J. (2023). Complex posttraumatic stress disorder symptoms among midlife to older female survivors of intimate partner violence. *Psychological Trauma: Theory, Research, Practice, and Policy, 15*(2), 331–339. https://doi.org/10.1037/tra0001238

Heidegger, M (1962) *Being and Time*. Translated by John Macquarrie and Edward Robinson. Norwich: SCM Press.

Lane, D. A., & Corrie, S. (2006). *The modern scientist-practitioner : A guide to practice in psychology*. Taylor & Francis Group.

Lohmann, S., Cowlishaw, S., Ney, L., O'Donnell, M., & Felmingham, K. (2024). The trauma and mental health impacts of coercive control: A systematic review and meta-analysis. *Trauma, Violence, & Abuse*, 25(1), 630-647.

Rogers, C.R. (1961*). On becoming a person*. Houghton Mifflin

Schauer, M., Neuner, F., & Elbert, T. (2011). *Narrative exposure therapy: A short-term treatment for traumatic stress disorders* (2nd rev. and expanded ed.). Hogrefe Publishing

Stark, E. (2016). From domestic violence to coercive control in the United Kingdom. Domestic Violence Report, 21(2), 23-26.

World Health Organization. (2022). ICD-11: International classification of diseases (11th revision). https://icd.who.int/

Zaborowski, H. (2011). Heidegger's hermeneutics: Towards a new practice of understanding. In Interpreting Heidegger: Critical Essays (pp. 15–41). Cambridge University Press. https://doi.org/10.1017/CBO9780511974465.003

V. SECTION A: DOCTORAL THESIS: Research Abstract. 'My Healthcare Journey Through Pregnancy and Substance Use'': An Investigation of the Lived Experience of the Healthcare Journeys of Women with Opioid Use Disorder who Become Pregnant.

Research Abstract

Objectives. This qualitative study investigates the lived experience of women who have used illicit opioids such as heroin who become pregnant, and their complex journey of peri-natal and post-natal healthcare. The study seeks to identify findings from the women's lived experiences and to inform current practice, interventions and services aimed at supporting women with opioid use disorder (OUD) who become pregnant.

Design. The study is a qualitative cross-sectional design based on interviews with a single cohort of five women, aged between eighteen and forty-five who were registered in the NHS and had been diagnosed with opioid use disorder (OUD). The cross-sectional design allows the lived experience to be investigated at different stages of a perinatal to post-natal healthcare journey, into motherhood. Parental custody was not required to participate.

Methods. The study received NHS Ethics approval in April 2023. The women were recruited from NHS Substance Misuse Services. Each participant was interviewed once and was between twenty-four weeks pregnant and eight years post birth. The participants were engaged in opioid substitute therapy (OST), at the time of the interview, or had recently ceased OST. Semi-structured interviews were conducted with five women and were transcribed verbatim by the author. Data were analysed using Reflexive Thematic Analysis (RTA).

Results. The findings include four themes: ***The Promise of Motherhood*** illustrates the surprise and joy on discovering pregnancy and engagement/re-engagement with substance misuse services. ***Managing Mother, Me as Risk*** describes the difficulties the women experience with multi-agency health care in processes which are not fully understood and are anxiety provoking. ***What Helps*** portrays actions which the women felt were supportive and helpful. ***The Development of Self*** conveys changes in psychological processes indicating that the women's reflexivity and insight develops over time, and that their recovery is non-linear.

Conclusions. The findings suggest that pregnancy and the promise of motherhood represent a pathway of potential change and recovery for the women, yet the women's feelings of stigma and experiences of being objectified as a risk in multi-agency health care serve to undermine the women's nascent recovery and sense of self. Clinical implications include repositioning and adaptations in multi-agency health care, providing the women with more information about multi-agency healthcare, a greater role for NHS Substance Misuse Services to which the women display

high levels of attachment, improved availability of therapeutic support at key phases, stigma training incorporating motivational interviewing and the use of mid-wives trained in substance misuse.

1 CHAPTER 1 Introduction

This qualitative research focusses on a group of women who are amongst the most marginalised people in UK today. The study seeks to investigate how women aged 18+ years old who have used illicit opioids such as heroin and who become pregnant, experience their healthcare journeys from pregnancy to the post birth years. The participants in this study have used illicit opioids, such as heroin, rather than prescribed opioid medication e.g. tramadol, or codeine. The reasons for focusing on women who have used illicit opioids, rather than medication containing opioids obtained under prescription will be set out. The women in this study are registered in NHS Substance Misuse Services (SMS) and have been diagnosed with Opioid Use Disorder (OUD), a diagnostic term used to describe a chronic condition in which individuals using opioids become dependent (APA, 2013). OUD is defined as being a physiological and psychological dependence associated with opioid tolerance requiring increasing quantities to attain the desired effect. Dependence results in a range of difficult symptoms including withdrawal symptoms if the opioids are withdrawn or reduced (APA, 2013; Dydyk et al., 2024). Many of the women registered in NHS Substance Misuse Services are of childbearing age, become pregnant, or are mothers who have given birth to children. The women diagnosed with OUD navigate unique journeys of complex NHS multi-agency healthcare treatment through pregnancy, birth and the post-natal stages. They also face immense personal challenges of managing pregnancy, motherhood, childcare proceedings and their own opioid dependency (Whittaker et al., 2020; Thomson et al., 2021).

Women who use class A drugs such as heroin run the risk of being considered to have deviated from societal norms (Terplan et al., 2015), and many have difficult histories of mental, physical illness, physical violence and sexual abuse (Gilchrist et al., 2019; Hammond & Chisolm, 2022). They may be considered to have broken UK law where heroin is categorized as a Class A drug under the UK Misuse of Drugs Act (1971). The women run the risk of legal proceedings, which may be initiated during pregnancy, resulting in uncertainty, fear and variable outcomes, with many losing parental responsibility of children to foster, or kinship arrangements, or potentially no custody or legal right to parent their children at all (Hunt, 2020).

The experience of stigma and the fear of legal action can make it difficult to reach drug using populations in research, making it complex to understand whether well intentioned healthcare guidelines are working. In a healthcare setting, stigma is a social process where an adverse social judgement of rejection, blame or devaluation, based on a health problem is

anticipated or experienced (Scambler, 2009). In this study, the participants are women who are registered NHS service users who are participating in a healthcare process which seeks to care for both the mother and child. Yet, the combination of pregnancy and OUD make the experience of pregnancy and the promise of motherhood extremely challenging to manage or attain for the women. Societal norms place substance use as a deviance and motherhood as an ideal, and the women face the challenge of managing both.

The Department of Health (DoH, 2017) and the National Institute for Clinical Excellence (NICE, 2010) provide clinical guidelines for the treatment of pregnant mothers diagnosed with OUD. This includes the assessment and treatment of the opioid disorder, initiation of opioid substitution therapy (OST), specialised maternity care, the monitoring for neonatal abstinence syndrome (NAS), as well as psychosocial and onward social support. The disciplines of psychiatry, pharmacology, substance abuse, midwifery, obstetrics & gynaecology contribute to the guidelines defining these journeys resulting in a model of multi-agency clinical treatment for pregnant women with an OUD (Thomson et al., 2021).

The present study uses a qualitative approach to investigate the women's lived experience and aims to improve health care approaches for women with OUD who become pregnant, or who are mothers. Reflexive Thematic Analysis (RTA) (Braun & Clarke, 2022) and an inductively orientated approach has been used to produce experiential analysis and patterns in data collected from a socially marginalised population of women (N=5), recruited within the NHS. It seeks to inform current practice, interventions and services which are designed to support women with OUD and the wider community of women with substance use disorders. It also seeks to contribute towards the UK's developing field of research amongst women with substance misuse disorders (SUD).

1.1 Substance Use in the UK

It is helpful to place this study of women with OUD in the wider context of substance use in the UK and the EU. In the UK, substance using individuals can self-refer to NHS Substance Misuse Services for treatment which includes testing, monitoring, and medication to support withdrawal and abstinence, as well as psychosocial support which may include group therapy, key working and individual therapy. The UK Government (2020) reports that there were 270,705 adults in contact with drug and alcohol services between April 2019 and March 2020, and that adults with opiate problems form the largest substance group, at 52% of those registered in NHS Substance Misuse Services. The second largest substance group is alcohol at 28%. Within the EU, cannabis is reported as the most widely consumed substance, with 22 million EU adults reporting use in 2021,

whilst 1 million Europeans are estimated to have used heroin or another illicit opioid (EMCDDA, 2022). The UK has the highest rate of opioid use amongst countries within the EU.

A significant issue with illicit opioids, is that it is associated with 74 % of fatal overdoses reported in the European Union and the UK. The 2022 trend in England and Wales for drug related deaths (DRD) attributable to any drug use is increasing overall year on year, though the underlying data indicates that the mortality rate for women is increasing, and decreasing for men (ONS, 2022). In Scotland, the percentage increase in the number of DRDs was greater for women (169%) than for men (60%) between 2012-2016 (Scottish Gov., 2018). The general trend overall indicates that even though substance use disorders are more prevalent in men, this difference is narrowing over time. In 2021, the UK Government published a 10-year strategy, 'From Harm to Hope', with multiple aims, including tackling the drug supply chain and providing more places for rehabilitation. It cites opiate and crack use as the biggest section of the illegal drugs market, with an estimated value of £5.2 billion a year and estimates that those using opiates and crack are likely responsible for around half of all theft, burglary, and robbery. No reference for this is given. The report later refers to trauma (physical, sexual or psychological) and mental ill-health as driving and accompanying much addiction, and that addiction should be recognised as a chronic health condition like diabetes (UK Government, 2021). The problem is distributed across the UK, with a concentration in the northern counties.

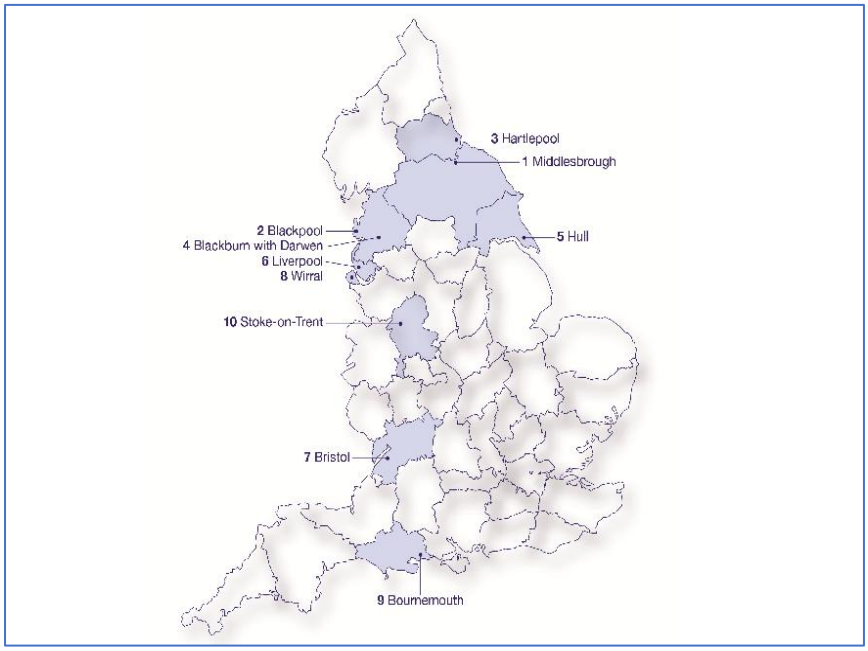


Figure 1: Opiate And Crack Use UK Map

1. Middlesbrough 25.51
2. Blackpool 23.45
3. Hartlepool 20.63
4. Blackburn/Darwen 18.84
5. Hull 18.15
6. Liverpool 17.06
7. Bristol 15.66
8. Wirral 15.63
9. Bournemouth 15.05
10. Stoke-on-Trent 14.67

(ranked by local authority per 1,000 population; Source: UK Government, 2021

1.2 Women and OUD

This study focuses intentionally on women who have used illicit heroin, rather than on other substances widely used in the UK such as cocaine, ketamine, benzodiazepines. Women using illicit heroin are under researched in the UK and represent an important research field. Women are relative newcomers to substance use research and the development of treatment models and women using substances continues to be under reported (Meyer et al., 2019). In the US, the National Institute on Drug Abuse (NIDA) started reporting gender in 1995, with prior research focussed on men or animals and recommends a move including more women in research (NIDA, 2024). The UN reports that one in three people with a substance use disorder (SUD) is female, yet only one in five of people in treatment is a woman (UN, 2015). The roles of sex (hormones, anatomy, physiology, genetics) and gender (identity, social normal, relations, power) are understood to play very different roles on how substance use evolves, the social context and the impact on the life trajectory (NIDA, 2024). The term telescoping is often used to describe the more severe impacts of substance use on women. Biological factors include how women metabolise substances due to larger deposits of fat than men, the hormonal cycle, pregnancy and menopause (Peters et al., 2019). Women who use illicit opioids are understood to start using heroin at a younger age than men, be influenced by opioid using partners, advance more rapidly to dependency, experience more cravings and suffer more medical, psychiatric and adverse consequences than men (Back et al., 2011; Brady & Lydiard, 2021). Issues of intimate partner violence (IPV), past and present histories of trauma, including sexual abuse, other aggravating health conditions and complex social needs are associated with more than 50% of women diagnosed with OUD (Moran-Santa & Brady, 2015).

In the UK, data indicates that 4.2% of opiate users presenting to substance abuse clinics are pregnant, and 58% of females receiving substance abuse treatment are parents or lived with children (Public Health England, [PHE] 2019). A study of four thousand electronic patient records in the addiction services of South London and Maudsley (SLaM), an NHS Foundation Trust indicates 39.6% of service users were mothers. Opioid and/or crack cocaine use was associated with younger mothers, housing problems and experiences of trauma and domestic violence victimization (Canfield et al., 2021). The clinical and healthcare guidelines (DoH, 2017; NICE, 2010) which describe a model of multi-agency clinical treatment were not developed with contributions from women themselves. It is not understood if this model of care is working or indeed, how the proposed healthcare journey is experienced by the women themselves. The present study

therefore seeks to contribute to the care of an under researched and marginalised group of women using NHS services,

1.3 Context and Definitions

The research question uses several key terms, and the following brief descriptions aim to clarify the parameters of the research question.

1.3.1 'My Healthcare Journey through Pregnancy and Substance Use'.

This title is a short form, user friendly, title of the study and was used on externally facing materials e.g. the Research Poster (Appendix A).

1.3.2 Lived Experience

Investigating lived experience is common in phenomenological qualitative research and is understood as a representation of human experience, perception of knowledge and meaning making, which in turn are shaped by ethnicity, class and the Social Graaaces (Burnham, 2018). Social Graaaces is a concept and anacronym conceived by Burnham (2018) to capture the essence and aspects of our identity which influence interactions and perceptions of another person. Whilst it is mainly used in the client-therapist relationship to encourage reflection on our own biases and perceptions, it is useful in the context of the lived experience. Lived experience is used here to describe not simply the experiencing of parts of the care received e.g. opioid substitution therapy, but the potential meanings assigned to the experience by the women, in context, and retrospectively. Lived experience provides a contrast to the dominant approaches which inform the NICE healthcare guidelines, and which are grounded in the natural sciences, distinct from human sciences. My use here of the lived experience relies on the philosophy of Dilthey (2018) who made a clear distinction between human meaningful action and the scientific approach. It requires the researcher to bring perception, understanding and insight to the relationship between the individual and their world, and seeks to be descriptive rather than explanatory.

1.3.3 OUD: Opiates, Opioids and Heroin

Opioid Use Disorder can be understood in the context of opiates and opioids. The human brain has opioid receptors, and opioids reduce the perception of pain and reaction to it and usually leads to states of euphoria, and sleep (Lorman, 2015). Dependence on opioids disrupts normal neurochemistry in the brain, and dependence can develop over a relatively short period of regular use e.g. 2-10 days (NICE, 2022). Opiates are naturally occurring in the poppy plant, *Papaver somniferum* and a principal ingredient of thebaine, opium, codeine, and morphine. Opioids is a broader, more modern term which includes naturally occurring (i.e. opiates), semi-synthetic, and synthetic opioids. The latter are made in laboratories independent of the poppy plant e.g. Fentanyl

whereas semi-synthetics are produced by slight alterations in the opiate drug e.g. heroin, Oxycodone (Lorman,2015). New synthetic opioids (NSOs) include copies of Fentanyl, which is a very powerful pain killer and Nitazene, which currently has no medical use and is 50-100 times stronger than morphine. Current investigations indicate that they are being found in other illicit drugs e.g. heroin and cocaine as adulterants. The rise in the UK is attributed to the decrease in heroin production in Afghanistan. Naloxone is a medicine widely used in NHS Substance Misuse Services, with training, to reverse the effects of an overdose caused by opioids e.g. heroin, methadone, morphine, codeine or buprenorphine. Opiates slow down and stop breathing, which is life threatening, and Naloxone blocks this effect, thereby reversing the breathing difficulties (Drugwise, 2024; Advisory Council on the Misuse of Drugs, 2024).

OUD as a diagnosis may also be given to individuals whose dependency stems from prescribed opioids. The increase in opioid prescribing by the NHS is an important research topic (Alenezi et al., 2021). but not the focus here. I have deliberately focussed my study on women whose opioid use relates to illicit opioids such as heroin, rather than women who have become dependent on prescription opioids e.g. Tramadol, or Oxycodone, prescribed from a GP or healthcare provider, though both may be diagnosed with OUD. Both deserve a research focus, though the populations of women dependent on prescription opioids versus the population of women dependent on illicit opioids are different and the populations risk lacking homogeneity. My research focus on women using illicit heroin is due to this group of women being under-researched and the fact they present differently to women dependent on prescription drugs.

I have deliberately incorporated the term ‘OUD’ in my research title as this is the term used in practice in the NHS in clinical settings, though it is also referred to as Opioid Dependence by NICE. OUD is not a term likely used by my participants. The diagnostic term contrasts with the term ‘lived experience’, with OUD originating in natural sciences and lived experience in the philosophy of human sciences. A diagnosis of OUD may be given in the NHS to an individual following an assessment by an Addiction Psychiatrist, a medical examination, use history, personal history and current presentation.

The street price of heroin in the UK is estimated to be £30-40 per half a gram and is widely available in the UK (Appendix B). Heroin is usually a soluble white powder which is diluted in water, injected, smoked or occasionally inhaled. The effects are rapid, usually between 5-15 minutes depending on the method and the extent to which it has been cut with other products e.g. starch, sugar, talcum powder. The adulterants themselves can be extremely harmful (Lorman, 2015).

1.3.4 The Healthcare Journey

The prescribed guidelines for the treatment of pregnant mothers with OUD is complex and the following provides detail on some of the core elements of the healthcare offered, though is not definitive. The healthcare journey also includes consideration of the mother-infant dyad and outcomes, as experienced by the mother. The basic elements include the assessment and treatment of the addiction disorder, initiation of opioid substitution therapy (OST), specialised maternity care, the monitoring for neonatal abstinence syndrome (NAS), as well as psychosocial and onward social support (DoE, 2017; NICE, 2010, 2022). It also includes the automatic notification of childcare services, which is usually the local authority. It may also include, but not always the offer of Tier 4 services post birth which are residential stays for the purposes of rehabilitation. There are variations in services across the UK as well as the use of Child Protection Orders.

1.3.5 Opioid Substitution Therapy

Opioid Substitution Therapy (OST) has been used to treat OUD since the 1970s and is typically a synthetic long-acting opioid e.g. methadone, buprenorphine, Subutex which aims to support opioid detoxification (NICE, 2017; Boardman et al., 2022) . The replacement opioids help stabilise brain neurotransmitters by binding onto the same opioid receptors as illicit heroin, without producing the same euphoric effects. The treatment dose is titrated, prescribed, and helps reduce the risk of overdose by allowing individuals to focus on recovery, and abstain from the supply of street drugs. Women with OUD who become pregnant, who are not already on methadone, will be prescribed OST which is associated with reduced risk of miscarriage and reduced use of illicit opioids. Opioids cross the placenta wall, and the use of OST is associated with better outcomes for infants (Thomson et al., 2021). Women prescribed OST are required to collect prescriptions two to three times a week and be subject to testing for illicit opioids throughout their pregnancy. Women in the care of NHS Substance Misuse Services may undergo detoxification of OST in the later stages of pregnancy, under management, or may continue to receive OST for many years post birth.

1.3.6 Neonatal Abstinence Syndrome (NAS)

Neonatal abstinence syndrome (NAS) is a term which was initially used in 1974 to describe a cluster of symptoms of withdrawal following prenatal exposure to methadone or heroin. The term is more broadly used to describe any sign of withdrawal observed in a newborn after prolonged prenatal exposure to any substances, including caffeine or medication as well as heroin. The term Neonatal Opioid Withdrawal Symptom (NOWS) is considered a more accurate description of the

withdrawal syndrome relating to opioid exposure (Boardman et al., 2022). I am using NAS here, as this is the term which is used in guidelines (NICE, 2017;2022).

1.3.7 Care Orders and Family Courts

NHS Substance Misuse Services are not routinely carrying out pregnancy tests, and women registered in services will often report possible suspected pregnancy to their key worker. This triggers a process between different agencies. A woman registered in an NHS clinic with OUD who becomes pregnant causes the automatic notification of social services (i.e. the local authority) who are deemed responsible for child protection policy at a local level under UK law (Children Act, 1989). A social worker will be assigned to an unborn child, infant or child deemed at risk and the local authority will undertake a series of assessments to assess the needs of the infant or child. Child Care Orders (CCO) grant parental responsibility to the local authority allowing them to collect a child and place them in alternative care for the duration of the care order, which may last until the child's 18th birthday, or a court lifts the order (Thoburn, 2023). Family Courts whose hearings are held in private determine the path of care for a child. They may place a child with other members of the family, a children's home, a foster carer or for adoption, under an Adoption Order which ends the legal relationship with the child's birth family and gives parental responsibility to its adopters.

1.3.8 Tier 4 Services

Some women may be offered Tier 4 services after birth. Services for substance use disorders are organised in tiers, and a Tier 4 service is an in-patient setting which aims to achieve detoxification, stabilisation and assessment in medically managed and/or monitored facility and residential rehabilitation centres (UK, Government, 2006). These are typically run by their sector and private organisations. Services are approved usually by the relevant NHS Trust and funding is sought from the local authority.

1.3.9 Mother and Baby Units (MBU)

Mother and Baby Units (MBU) are specialist in-patient units designed for women and their babies where the mothers need specialist care for their mental health, post birth. There are an estimated 17 units in the UK., though there is also recent evidence to suggest that this number is decreasing. MBUs are recommended by NICE for women pre and up to 12 months post birth (NICE, cg192, 2014)

1.3.10 Summary

Women with OUD undertake a healthcare journey which is delivered by many different agencies and specialist teams. Figure 1 aims to capture the intense complexity of the women's journey and

elements of healthcare which women with OUD may experience, within a short period of time. Interactions with healthcare workers and clinicians are likely to be influenced by societal and personal views on motherhood and substance using women. Each woman will make sense and derive meaning from these interactions, according to her own personal history.

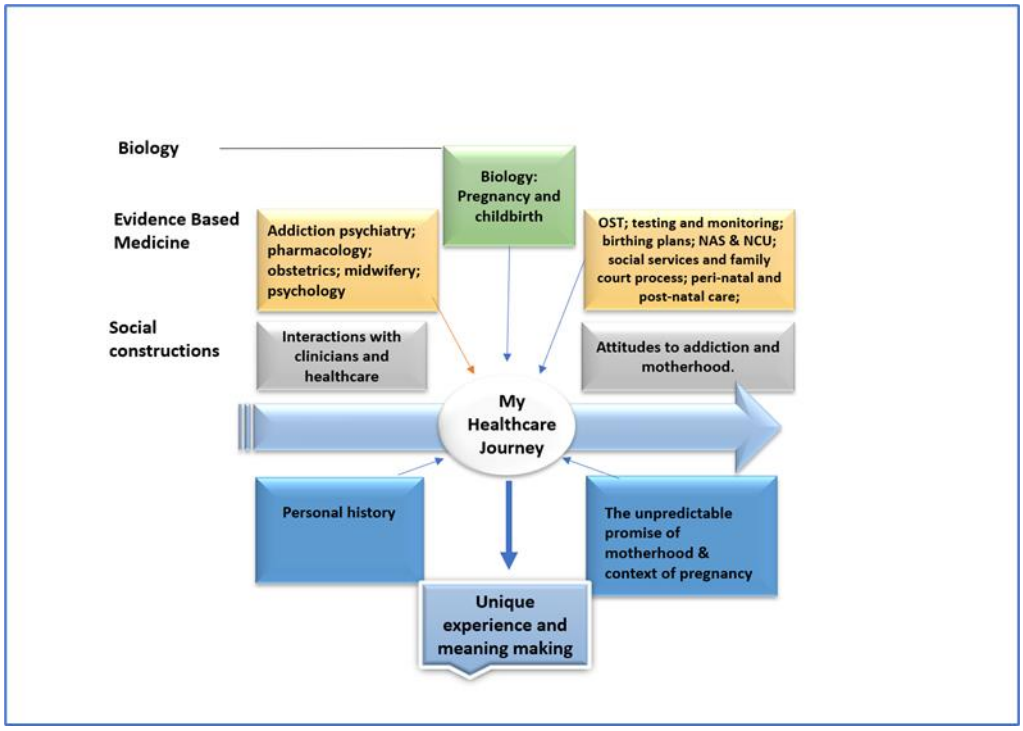


Figure 2: ***The Healthcare Journey.*** *Illustration to show the healthcare journey and complex interaction with services.*

1.4 Background to the Research

. My year 1 placement as a Counselling Psychologist Trainee was in an NHS substance misuse clinic in north London and my case load included clients with opioid (e.g. illicit heroin) and non-opioid (e.g. crack, cannabis, ketamine) dependencies. I enjoyed the work, though found it challenging. I felt very green, yet highly involved and included in the clinic's work. I experienced significant growth in learning and personal development, and I extended the placement in the same clinic to my second year.

This research grew from my interest and concern in the experiences described by women diagnosed with opioid use disorder (OUD) during psychological therapy sessions over the course of 2021-2022. In December 2021, I started work with my second client, a female aged 33 years old, who was 8 months pregnant. We started weekly therapy sessions during the final month of her pregnancy, until seven months post birth. During this time, she described distressful experiences in which she described being made to feel different to other women on the labour ward and in the neo-natal care unit (NCU), in the following weeks post birth. Much of our work was taken up talking about these incidents, her experiences and distress at feeling judged. I was motivated to

understand her experience and I started to investigate the literature and put forward the topic of research of women with OUD to City University in March 2022.

1.5 My Positionality as Researcher

Positionality is important as it describes the researcher in relation to the participants and the topic (Shaw et al., 2020). Agar (1996) describes positionality as how the researcher sees oneself, either a neutral investigator or something else. I did not feel an entirely neutral investigator. My motivation to research the lived experience of women with OUD came from clinical work, and from listening to difficult childhoods and the beginnings of heroin use. As a researcher, I struggled at times not to revert to my earlier role as therapist. I was deeply moved by the interviews at times, and felt I wanted to step out of my researcher role, to offer therapy, support and at least to offer hope. My understanding of the importance of boundaries developed through the research process, and I recognise equally how important they are to think about. I feel deeply compassionate for the women in my study, all of whom started using heroin as teenagers. I reflected on the power imbalance between myself, and my participants and I tried never to lose sight of the implications of this for a vulnerable and under researched population, with whom I share very little in terms of lived experience, education, economics and privilege. I thought about the implications of my dual role as researcher and clinician, and the importance of keeping boundaries between these two roles. I was curious about whether there is always a power imbalance between researcher and participants. I thought about our differences and what contributed towards this power imbalance between my participants and myself. I am white, middle class, educated at University, with a left of centre political position, and I am economically independent. I pursued a career in business for 30 years, prior to training as a Counselling Psychologist. I chose not have children or to get married, both of which were agentic choices. I am in good health and fit. I sense that I have been judged negatively for not having pursued societal norms, yet I have had little contact or experience with the social context and environment of the population of women at the heart of my research. I am not a member of this group, and I am an outsider researcher, though I have felt highly motivated to investigate the experiences of the women and this has always spurred me on through difficult moments.

Undertaking research with women with OUD is challenging. This group is considered to be vulnerable and high risk, by NHS Ethics Committees. I have tried to illustrate how I have managed some of these challenges and mitigated some of the risk in the section on ethical considerations, reflexivity and the risk management the study has required.

2 CHAPTER 2 Literature Review

2.1 Literature Search Strategy

The literature search was conducted at two points during the research, in March and April 2022, and in June 2024. Important research was published in 2023 and 2024 and added to the findings. The search was conducted using the following data bases selected: CINAHL, Medline, PsycINFO via EBSCOhost and Embase, Medline via Ovid Online. Searches were also carried out on PROSPERO, Cochrane Library, and Google Scholar. Individual searches were undertaken in specialised journals covering substance abuse, gynaecology and obstetrics, and UK addiction websites and The Substance Abuse and Mental Health Services Administration (SAMHSA). Key search terms included variations relating to pregnancy, stages of pregnancy, expectant mother, opioid use disorder, opioid substitution therapy (OST), or methadone maintenance treatment (MMT). Date limits were set as 2017-2024, English language and peer reviewed. Attention was paid to current variations in terms e.g., NAS which may include pre-term neonates, and Neonatal Opioid Withdrawal Syndrome (NOWS) reserved for opioid exposure, or OST and alternatives e.g., opioid maintenance treatment (OMT).

The searches yielded a dominance of US-led research on maternal prescription opioid use disorder and the opioid epidemic which is less severe in Europe (Humphreys et al., 2022). The research field is notable for the quantity of pharmacological research e.g. on outcomes of methadone versus buprenorphine and neurological studies on neonatal abstinence syndrome (NAS). The focus of the search was for qualitative research and the following represents a synthesis of qualitative research in the US, Canada and the UK. Care was taken to identify US studies focussing on participants who had used illicit opioids in order to focus on the phenomenon of interest, rather than prescription opioids. Abstracts were scanned and files exported to Mendeley to create a dedicated library for analysis.

2.2 Key Findings: US and Canada

2.2.1 Stigma, Guilt, Being a Bad Mother

Stigma is a recurrent theme in the lived experience of mothers with SUD, with recent studies providing evidence of its persistent presence. Stigma theory posits that stigma is a process which is context specific, and which disempowers those with characteristics not acceptable by society and can be particularly pervasive in healthcare settings (Link & Phelan, 2006; Stangl et al., 2019). Research using Thematic Analysis (TA) on data from two 2-hour focus groups conducted in Washington State in 2019 with mothers (N=24), divided in three groups, 88% of whom were heroin users and who had given birth in the previous two years highlighted a main theme of disrespectful

care (Kim et al., 2022). Fear of accessing services, inconsistencies in care received, and limited health and social services were identified as lead themes. Participants felt judged, dehumanised and treated differently once the nurses became aware of their drug use. Fear from the impending threat of the involvement of child protection services was widely felt by the participations as well as frustration with high daily variability in scores for neonatal abstinence syndrome (NAS) which participants experienced as a persistent pending threat of separation. The study cites the use of snowball recruitment which is not uncommon in hard-to-reach populations (Sadler et al., 2010). Snowball recruitment is defined as a self-directed, chain-referral, recruiting mechanism used to reach the hard-to-reach target group in a more pragmatic and culturally competent way (Wasserman et al., 2005). In the Kim et al., study (2022), the funding by a state health authority and a useful summary of clinical implications and experiences suggests it is a balanced paper with participant participation in the development of questions and themes.

Proulx & Fantasia (2021) used Transcendental Phenomenology to analyse interviews with mothers (N=10) in a substance abuse clinic tailored to postpartum women with OUD, with the approach allowing for deep analysis of meaning. Stigma from health care providers was the main theme identified, as well as the fear of being reported to child services and loss of custody. Children were identified as the primary motivation for staying in treatment. The feeling of stigma and being treated differently was felt in interactions with clinical staff, pharmacists and future employers and many felt accused of deliberate harm to their child. The transition to motherhood and having children was identified by nine mothers as motivation to stay in treatment, with several recounting considerable efforts to regain custody of their children.

Discursive analysis was used to investigate how the language of the participants (healthcare workers) persisted and functioned as the norm of a professional group working with women with OUD (Nicols et al., 2021). Data from direct interviews, focus groups, workshops and committee meetings amongst maternity nursing and social workers collated over seven years (November 2011 - October 2018). The inclusion of this study here is deliberate. It provides valuable insight and context to the experience of stigma. The results provide a startling summary of prejudice and stigma embedded in language in interactions with mothers, including disapproval of the use of methadone and appropriation of the role of carer in the place of a failing mother. The use of discursive analysis with healthcare staff is valuable, though the research is a sub-analysis of data from a broader Grounded Theory project, and the design is not clear.

2.2.2 Lack of Agency, Choice and Fear of Losing a Child

Papers investigating specific aspects of experience in the perinatal and postpartum periods identified important themes on engagement in recovery post birth. Research by Schiff et al., (2022) investigated factors influencing mothers' (N=26) engagement in opioid substitution therapy (OST) medication who were, on average, 10 months post-delivery. The approach uses semi-structured interviews based on models of health behaviour research, and Grounded Theory, with questions updated as interviews progressed to allow for development of theory. Four themes are identified, including the lack of agency and autonomy surrounding medication, hesitation to use medication and methadone clinics being unresponsive to their needs as women and mothers. The lack of agency was associated with feeling forced to take medication, prior to the establishment of a trusting relationship, and feeling caught in a double bind of being punished for engaging with treatment which clinical advice mandated, or risk losing their child. Participants highlighted the challenges of juggling multiple different venues and timetables to manage their own medication, nurse their babies or take them into methadone environments. The research provides useful insight into mothers' engagement and experience of opioid treatment combined with a role as parent.

A meta-analysis of twenty-three qualitative studies from 2000-2018 (Renbarger et al., 2020) investigates how women with an SUD experience health care encounters in pre and post birth. The results provide a taxonomy of adverse and positive interactions with health care providers. Statements (N=446) were extracted and grouped into topics (N=18), with the frequency effect size range of .09 to .53. Over half of the reports (53%) experienced their treatment as poor due to behaviours or comments, and half (50%) experienced a feeling of being judged. A smaller number of extracts indicated that at least some of the participants had positive relationships with their providers (41%) and received good medical care (39%). Positive encounters notably included those where the substance abuse was treated and supported, and mothers felt they could be open about use, relapses and where recovery could be incorporated into their overall care. The design and method of the analysis appears thorough. Three main clinical findings indicate that women experience their treatment as disparaging and judgemental, and that education is needed amongst clinical community to reflect on biases and to improve understanding of the challenges faced by women with SUD.

2.2.3 Relapse and Recovery in the Post-Partum Period

Previous qualitative research has identified the post-partum period as a catalyst for mothers to engage in recovery, personal growth and assume a new identity as caregiver (Hiersteiner, 2004). The period is also volatile and associated with the strengthening of the parent-

child attachment, as well as the risk of relapse (Rankin et al., 2023), and there are also views that attention on the mother may decrease at this stage to focus on the baby (Martin & Parlier-Ahmad, 2021). Mixed methods research which included semi-structured interviews with women (N=8), aged 28.6 years old (M), recruited from a specialist perinatal addiction clinic 2-6 months post birth yield a theme of transformation in the post-partum period (Shadowen et al., 2022). All participants had been engaged in taking medication for OUD during pregnancy and were in recovery. Recovery was experienced as a new relationship with oneself of self-love, forgiveness and acceptance and a desire to curate mindfully a new social network, to engage in activities to promote mental and physical health and to develop resilience to past trauma. The sample is small, and the data analysis method used was informational redundancy (Lincoln & Guba, 1985). Informational redundancy means data saturation where enough data has been collected to understand the topic and further information would yield repetitive or redundant information. There is real value in understanding from the women's point of view what a model of recovery feels like. Transformational development as a mother and woman in recovery emerges as a key concept in a number of studies where women identify with their ability to meet the challenges of childbirth, and parenting to regain a sense of self and self-care. The relationship with the women's environment is transformed, though the process of recovery may be non-linear and dynamic (Goodman et al., 2020; Peacock et al., 2021). Rankin et al., (2023) interviewed forty-two women post birth, and used inductive content analysis to investigate patterns of recurring or outstanding responses grouped into emerging themes based on content frequency, based on frequency, specificity, and emotion. Seven themes related to the mothers urge to use substances in the post birth period and served to inform the risk of relapse. The findings were mapped to the women's post birth urges to use, or not use substances, with the aim of gaining clarity over factors which contributed to risk of relapse factors or abstinence. For example, not having birthing support or poor post birth bonding, and difficulty with breast feeding was associated with greater urges and relapses. The risk of relapse in the years after birth is estimated to be higher than the year before birth (Schiff et al., 2018). The focus of Rankin et al.,'s (2023) research is important in understanding the factors which influence how recovery can be supported, and relapse avoided in the post birth year.

The results of research by Skogseth et al., (2024) identified themes of self-efficacy, having access to resources and a treatment structure as being important factors in women's success at reaching and maintaining recovery. This was based on interviews with twenty women with OUD, and recovered from OUD, and twenty-two professionals working with SUD. Thematic Analysis was used as the analytical approach. The researchers conclude that interventions which enhance

women's social support, their material and educational resources, and treatment protocol may be effective in supporting women in recovery. The importance of this area of research is that it provides a focus gaining insight into what helps the women in recovery.

2.2.4 Substance Use and Intimate Partner Violence (IPV).

An important field of research focusses on the associations between OUD, IPV and pregnancy. IPV is associated with an increased risk of substance use and predicts poorer treatment outcomes (Ogden et al., 2022) and substance use itself is understood to manage abuse-related trauma (Philipps et al., 2020). The term 'substance use coercion' has been developed to represent a range of violent, intimidatory and controlling behaviours which form coercive tactics towards partners' use of substances, as part of a wider pattern of control and abuse (Warshaw & Tinnon, 2018). The pattern of control includes an abusive partners' efforts to intentionally undermine their partner's abstinence, sobriety or interfere with their treatment or medication, or recovery. Morrison et al., (2023) investigated the barriers that impact women with co-occurring OUD and IPV through interviews with forty-nine professionals from a range of services including substance misuse services, criminal justice or perinatal services caring for women with OUD and IPV. Using a two-coder iterative approach for analysis, themes relating to the different ways in which barriers impeded women with OUD and IPV to access help were illustrated. For example, having a substance use issue impacted the women's ability to leave an abusive partner. For pregnant women or those with young children, participants described feeling reluctant to break up the family, in spite of the abusive relationship, or they felt dependent on the financial support. For women with OUD, pregnant or with young children, faced great hardship in being able to leave an abusive relationship, with a lack of access to housing or support network.

2.2.5 Birth and NeoNatal Abstinence Syndrome (NAS): Pain and Anxiety

A number of studies focus specifically on the experience of women with OUD of birth and Neonatal Abstinence Syndrome. Neonatal abstinence syndrome (NAS) is a term used in the NHS and widely to describe a cluster of symptoms of withdrawal observed in a newborn after prolonged prenatal exposure to any substances, including, caffein, medication as well as heroin.

O'Rourke-Suchoff et al., (2020) identified a key theme emerging from the experience of labour and pain management which women felt was poorly understood and managed by standard obstetric teams. A key experience voiced by mothers in the following days post birth is the anxiety and uncertainty in the post- partum period whilst waiting for a diagnosis and preparing to care for a baby with potential Neonatal Abstinence Syndrome (NAS). New-borns exposed to opioids are at risk of withdrawal, damage to the cardiac, central nervous system (CNS), respiratory and digestive

tract following delivery, and are subject to a range of tests and routine scoring using the 10-item Finnegan Neonatal Abstinence Scoring System (sFNAS) (Finnegan et al., 1975). NAS is difficult to predict and diagnose. It may be detectable in babies exposed to heroin within 24 hours of birth, or 2-3 days later with an opioid such as methadone or buprenorphine (Thomson et al., 2021).

2.3 Key Findings: UK

There is less qualitative research in the UK than in the US from the same period 2017-2024. In order to make up for the lack of qualitative literature in the UK, I have sought to provide context for the lived experience of women with OUD in the UK by reviewing and including here research from a wider perspective to include a recent systematic review of current clinical practice, as well as qualitative studies with professionals and women with OUD

2.3.1 Current UK Practice

A significant UK research project, the Stepping Stones Study (Radcliffe et al., 2024) recently published the first of its reports. The multi-site study led by Dr Polly Radcliffe of King's College, London and Professor Helen Cheyne of the University of Stirling, with researchers at the University of Stirling and Homerton University Hospital Foundation Trust reviewed UK's clinical guidelines and undertook a longitudinal qualitative study to investigate how health and social care NHS providers and UK services meet the needs of women who use drugs, and the needs of their babies. Its first report, a UK wide scoping review has recently been published (Gilmour et al., 2024). The study identified 968 clinical guidelines published between 2000-2022 and in use in NHS Trusts across the UK, relating to different aspects of the care of women who use substances and become pregnant. The paper extracts 111 guidelines from the 968, and reports on the range of recommendations for women who use substances, including illicit, and prescribed opioids and benzodiazepines. The complex array of recommendations and practice mainly recommended an integrated model of care, multi-agency care and information sharing. The review also identified significant gaps in UK's current guidelines. The gaps related especially to the provision of care for women whose babies are taken away, a lack of patient or public involvement in the creation of guidelines, and in some cases, a lack of evidence underpinning the guidelines. Inconsistencies on testing protocols during pregnancy and the observations of newborns for NAS were identified. Some of the more recent documents included references to trauma-informed care approaches to mothers, but not all. The study includes a longitudinal qualitative study which is yet to report. Stepping Stones is a significant step forward in focussing on women with OUD and other substances, highlighting that approaches across UK vary widely, and that some may lack an evidence base.

2.3.2 Professional Views: Strengths and Weaknesses of Clinical Care

Another recently published qualitative study with thirteen practitioners delivering antenatal care for women in Scotland using opioids (Hughes et al., 2024) explored the experiences of professionals who work with women during pregnancy. The study highlights some interesting results, notably a strength of the current approach being the assignment of a single midwife throughout care, and post birth which promoted trust and reduced non-disclosure. Examples of specialized care which supported a wide set of needs of the mother are given, with mid-wives conducting home visits to better understand the home environment and seeking out women e.g. at their OST dispensing pharmacies if they are non-responsive. Challenges included the poor engagement of some women, and the lack of tailored psychosocial support especially for trauma.

2.3.3 Neonatal Abstinence Syndrome (NAS)

As in the US, there is also qualitative research in the UK about NAS. Chandler et al., (2020) investigated the experience of parents (N=16) preparing to care for a baby with NAS. Mothers were given the opportunity to include partners and were interviewed 1-6 months post birth. Participants aged between 23-47 years old were recruited from two adjacent areas in Scotland, urban and semi-rural, and reported current use of opioids, methadone, or polydrug use. The interviews were analysed using inductive coding and the findings include themes of inconsistency and a lack of clarity in the diagnosis of NAS, and how the score charts are used, as well as feelings of anxiety. NAS is assessed using the Finnegan Neonatal Abstinence Scoring System. Newborns are typically assessed every 3-4 hours. The score sheet includes a list of symptoms which are scored based on the severity and frequency of each symptom (Finnegan et al., 1975). Feelings of powerlessness and exclusion from the care of new born babies were expressed. Differences in experiences emerged between parents in the two study areas. In one are some parents were encouraged to use the scoring system, and in the semi-rural area, managed by standard maternity services, parents were not aware that their baby was being scored, or had to ask about their baby's score. Parents were extremely sensitive to the scoring of NAS, especially where symptoms were logged, due to fears of losing custody and being judged as unsuitable. Parents also experienced wide variations in scoring from different clinical staff adding to anxiety and uncertainties. This study by Chandler et al., (2020) illustrates how anxiety-provoking the diagnosis of NAS can be. The authors propose that NAS is a variable clinical diagnosis and the process of anticipating, identifying and responding to NAS are marked by significant levels of uncertainty among parents and health and social care practitioners. They propose that NAS is a controversial diagnostic label and socially constructed, and that it would be more constructive to have NAS framed as a social diagnosis which recognises the inequalities and hardship faced by many parents.

Chandler et al., (2020) draw on the term, social diagnosis developed by Mol (2002) who proposed that social factors such as the environment and resources which contribute to diagnoses should be examined and addressed.

2.3.4 Gender: Recovery Capital, Identity and Agency

There has been an increased focus in the UK on treatment and recovery (UK Gov, 2021), yet factors which influence and support recovery in both women and men are understood to be different and emerging as an important topic. An understanding of how gender impacts women with OUD who become pregnant is relevant to their lived experience. During active addiction women report more experiences of violence and greater mental health distress and lower levels of well-being, whereas, in recovery, the evidence indicates that women fare better than males who use drugs (Andersson et al., 2021). In earlier qualitative research investigating recovery with forty current or former heroin users, (21 men, 19 women), Neale et al., (2014), point to differences in recovery as a result of gender and emphasise that multi-dimensional factors influence outcomes. Neale et al., (2014) propose that the participants experience can be better understood in the context of factors of race, class, immigration status and education, and Crenshaw's theory of intersectionality (1991). The research team propose that the complex interplay of gender and social disadvantage is key to understanding processes of recovery, rather than gender alone.

Understanding how access to resources determines recovery outcomes for women with OUD, feels important, especially in an environment where councils struggle to deliver social housing. Patton (2024) investigates pathways to housing stability amongst women in substance use disorder recovery in the UK, including women with OUD. Patton underlines the importance of recovery capital, especially for women with children who use drugs. Access to housing is defined as a social process for women in recovery providing them with a means to escape from negative social relationships, environments or abusive partners. The participants included fifteen men and fifteen women (N=30) in recovery. Twelve of the fifteen women used heroin and eleven of were mothers. The findings from Thematic Analysis indicate that housing insecurity, instability, and frequent transitions are common experiences for the women. Notably, escaping negative relationships with male partners emerged as a primary cause of homelessness among these women. Patton identifies eight themes which relate to transitional points in which negative social capital is replaced with positive social capital. Positive social capital includes becoming pregnant, leaving an abusive partner and becoming an active mother. These support the development of self-esteem, confidence and a sense of a new identity. Only one male participant described parenting factors as a motivator in recovery and no male cited being a victim of domestic violence.

Patton (2024) makes a cogent case, that solving insecure housing itself does not itself deliver recovery. Rather, he proposes that housing transitions are essentially a social process for women in recovery which can support and enhance women's emerging confidence and identities as mothers.

2.4 Strengths And Weaknesses Of Literature Review For The Current Study

The literature review illustrated some strengths and weaknesses which are relevant for the current study. The literature was reviewed from the period 2017-2024 and undertaken twice, in April 2023 and in June 2024. This time period was selected in view of the lack of literature in UK in the earlier decade. The literature review during the selected period showed two key factors, relevant to the UK and the current study. Firstly, there is a marked difference in the quantity of qualitative research produced in the UK on women with OUD versus the US. It is not that research was not being produced with this population of women in UK, it is just that there are very few studies, and there has been a geographical focus on Scotland. The literature review was carried out twice. New studies in UK were identified in the second review (June 2024) suggesting that there is greater attention on women who use substances, and indeed women with OUD who become mothers. This suggests that interest in substance use research which focusses on gender, and the unique experiences of women who use illicit heroin has increased. This suggests that the current study is timely and well placed to make contributions towards a developing research field which is recognised as a legitimate topic of research in UK.

A strength of the review was the deliberate focus on qualitative approaches. This illustrated useful information about the similarities and differences in the themes identified in the UK and US qualitative literature. The difficult experience of having NAS assessed post birth is expressed by women is consistent in US and UK qualitative research. This suggests that the diagnostic category of NAS, and its prevalent use as a measurement tool post birth in western approaches to women with OUD, is extremely difficult for women in the post birth period (Chandler, 2020; Kim et al., 2022;O'Rourke-Suchoff et al., 2020). Experiences of stigma, the presence of fear and lack of agency are reported in the healthcare systems in both sets of research (Kim et al., 2022; Neale et al., 2020; Proulx & Fantasia, 2021) as well as the role of IPV in the histories of women (Shadowen et al., 2022; Goodman et al., 2020). Researchers in the UK have notably investigated the relationship between substance abuse and IPV (Gilchrist et al., 2021). There is common ground in the theme of pregnancy and mother hood as a catalyst for recovery (Patton, 2023; Peacock, 2021; Shadowen et al., 2022). The Gilmour et al., (2024) paper suggests that clinical guidelines have had little input from service users. This suggests that we may not fully understand the lived experiences of women with OUD who become mothers. Differences and similarities provided useful context and

validation for findings in the current study. The review suggests that there is value in using qualitative methods to investigate the experiences of women with OUD including pregnancy, motherhood, IPV and social capital.

A key factor in reviewing the UK and US literature in tandem is that there is noticeably more substance use research being produced in the US, with references to national bodies such as the National institute of Drug Abuse (NIDA) and Substance Abuse and Mental Health Service Administration (SAMHSA) cited as funders. In the UK, funding for research follows a different route, and is likely to have to compete with non-substance use research topics. Additionally, there are structural differences in the health care systems in the UK and the US, with the US system organised through private healthcare insurance, with some public services, whereas the UK has a nationwide, free at the point of access, national healthcare system, with community-based services. The review suggests that funded research in the UK comes from bodies such as the National Institute for Healthcare Research (NIHR) or the Economic and Social Research Council (ESRC). The difference in funding suggests that UK substance use research is less driven by a central policy or strategy organisations since these bodies meet a wide range of research needs and objectives.

A weakness in the literature review is that it did not seek to summarise the considerable pharmacological literature relating to the use of opioids and development of opioid substitutes which appeared beyond the scope of the present study, and the lived experience, though this plays an important role in outcomes for the mother and child.

In summary, the literature review illustrated that qualitative methods provide important insights into the treatment of women with OUD , and the methodical approach in the current study has scope to make a useful contribution to a developing research field in the UK.

3 CHAPTER 3 Counselling Psychology

3.1 Why Counselling Psychology?

Counselling Psychology (CP) has the potential to contribute to the theory and model of care for women with OUD. The current approach is dominated by diagnostic, bio-medical approaches and complex legal frameworks in which women's rights to motherhood are assessed and frequently terminated. CP's holistic approach uses theory to interpret and reflect responsibly the women's' experiences of being within a healthcare system on which they depend, yet which they may also fear. There are four theoretical models which inform CP and have guided this research.

Firstly, CP seeks to understand how substance use may be a coping mechanism for distress and a reaction to pain, fear and trauma, and can be considered within the Power Threat Meaning Framework (PTMF) (Johnstone et al., 2018). This framework allows potential consideration of the women's lived experience as reactions to 'the negative operation of power' (Cromby, 2022; p.52), yet also considers other levels of interpretation, including the biological impact of opioids and pregnancy. Secondly, CP recognises how a diagnosis itself e.g. OUD has the power to enact stigma in healthcare settings where the use of a diagnostic and defined term itself contributes to stigma, shame, deviance and blame (Scambler, 2009). Thirdly, CP uses principles of Crenshaw's (1991) intersectionality theory to help understand the circumstances and context in which women have started to use heroin. CP considers holistically how the women's lives have been shaped by issues of gender, class, and race. Their interactions in a healthcare setting are compounded by multiple forms of discrimination and societal attitudes towards motherhood, and substance-using women. CP considers how the complex interplay of social disadvantage applies to the women's lived experience in a healthcare system which may sustain and contribute to their feelings of inequality and of powerlessness. Lastly, CP has the potential to consider the experience of the participants within treatment models for trauma-informed care where associations with child sexual abuse, intimate partner violence (IPV) and OUD are high (Staudt, 2018). The theoretical approaches outlined here, PTMF, stigma in healthcare settings, intersectionality and trauma are closely linked and help point to the complexity in the experience of women with OUD.

I am not seeking to deny notions of personal responsibility, or the risks of opioid use to the women and child, but rather to consider alternative theoretical approaches to the study in order to find new insights from the women's lived experience.

3.2 Reflexivity

The research reflects my own development as a Counselling Psychologist Trainee in my first placement within an NHS Substance Misuse Service in 2021. In the therapeutic work with my second client of a new case load, I can recall moving from a position of not fully understanding my client, to an uncomfortable awareness of how much more I was starting to hear. My client was a woman with a diagnosis of OUD who had just given birth, and she recounted weekly episodes of distress of being looked down on, and of being treated differently to other mothers in the Neonatal Care Unit (NCU) in her local NHS Trust hospital. I started to examine the topic more fully, turning it into a fully-fledged research project with NHS approval.

This sense of being judged by others was a key phenomenon of the women's experience. It caused me to reflect on how I felt about illicit heroin use, and my own feelings and the potential

bias towards substance use by my participants. I have always felt high levels of compassion for the substance using community, especially illicit opioid dependency in young women. I felt I approached the research with a non-judgemental stance towards my participants. I wondered how my feelings might evolve, as they described becoming pregnant and mothers. My compassion remained, as I heard their stories of early introduction to heroin and their onward struggles to adhere to methadone, or to abstain entirely. I felt my non-judgemental stance remained, throughout the women's accounts of pregnancy, and motherhood. I felt concern for their difficult trajectories in the post birth period and their experiences of feeling judged during pregnancy in the healthcare system. I reflected on the possibility that healthcare workers do not feel impartial on this topic. I continued to feel empathy for the women, through all stages of their journey. This stance was tinged by curiosity, by one participant who actively chose to continue using heroin at the weekends, with her own mother caring for the children. I wondered whether she had the right to choose and manage her heroin use in the way she did, and whether she would be open to alternative choices. My empathetic feelings about the women's heroin use followed the trajectory of the women's pregnancy and journeys into motherhood , but fundamentally did not waver from being non-judgemental throughout.

The use of reflexive practice in qualitative research can increase the transparency of the research process and help the reader evaluate the research. I recognise my potential role as contributing to meaning making in this research. I am indeed part of my research, and that reflexivity is key to monitoring how this contribution is made (Frost, 2016). I have deliberately added some personal reflexive notes throughout the thesis to share some inner thoughts and feelings at different stages of the research process.

4 CHAPTER 4 Rationale for the Study's Methodological Approach

4.1 Rationale and Aims

Addiction research is a broad field and seeks to investigate a range of topics including epidemiology, factors influencing recovery, treatment outcomes as well as the biological mechanisms of drugs. Much addiction research is quantitative, yet the role of qualitative research in addiction is being recognised for the contribution it can make to the field (Miller et al., 2010). Qualitative methods can help us understand how substance and behavioural addictions develop from the individual's perspective. They can provide rich information about how healthcare is being experienced and understood by those it is intended for, and help contribute to revisions in guidelines, or training for those implementing it (Simpson & Bluthenthal, 2021).

Both literature searches revealed a paucity of qualitative studies in the UK which investigate the lived experience of pregnant women with OUD, as they navigate through the complex interplay of multi-agency healthcare in pregnancy, labour and post-partum. The present study aims to address this gap by investigating the personal journeys of these women as they learn to manage their OUD, and the early years of motherhood.

The study aims to inform current practice, interventions and services aimed at supporting women with OUD who become pregnant and has three aims summarised in Table 1.

Table 1: ***Research Aims***

1	To gain an understanding of how women with OUD who become pregnant experience and understand the complex journey of peri-natal and post-natal healthcare.
2	To contribute towards clinicians' understanding of factors which impair, or which promote better outcomes for mother and infant (e.g., adherence to opioid substitution therapy (OST); engagement in psychosocial support and recovery from substance use).
3	To inform current practice, interventions and services aimed at supporting young adult female population with OUD

4.2 Contribution to Knowledge

CP has a number of strengths in its approach in investigating complex phenomenon, its practice of adopting solid procedural and methodological approaches, and its ability to produce results which may improve healthcare approaches for these women. CP can undertake both quantitative and qualitative research. Willig (2019a) underlines that qualitative research is not seeking causal relationships or hypothesis testing but is focussed on accessing meaning making which can generate new approaches to therapy, treatment models and the development of theory.

In this study, I am seeking to investigate the lived experience of a marginalised group of women in a healthcare setting with a model of care for pregnancy and OUD. The findings are grounded in data and organised coherently, with transparent procedures and researcher reflexivity. I hope that that the current study will contribute towards a better understanding, within NHS settings, of what promotes better outcomes for mother and infant.

5 CHAPTER 5 Methodological Overview

5.1 The Development of the Research Paradigm

Guba and Lincoln (1994) emphasise the importance of the researcher being clear about the paradigm which informs and guides the research approach. I have sought to ground this study in relevant theory and develop a research paradigm which supports the research question. Qualitative research paradigms comprise positions on ontology and epistemology which are 'logically intertwined' and consistent with each other (Malterud, 2016 p.122). Madill & Gough, (2008) propose that the 'paradigmatic frameworks help confer order on the complex array of research methodologies… in psychology and the social sciences' (p. 262).

The research paradigm developed for the study firstly aims to provide a methodology appropriate for the research question and aims. The lived experience of the healthcare journey of women with OUD who become pregnant and have children is complex and evolving. The lived experience is unique to each woman and is influenced by personal histories. The study seeks to investigate and understand the participant's psychological processes that occur and accompany a series of events and interactions in a concentrated time period. I am interested in the meaning making of the women as they interact with people, processes and structures in the NHS. Their experiences are influenced by trajectories which may be both biological e.g. pregnancy, and structured e.g. family court processes, and by constructions of a public health and social care system, implemented by healthcare professionals working in particular contexts. The healthcare professionals themselves have their own unique belief systems, within varied frameworks of pharmacological and clinical disciplines (Figure 2, p.30). The objective is to produce data, which, following a methodical process and paradigmatic framework, provides a better understanding of how the treatment model for the population of women managing opioid dependency, pregnancy and the promise of motherhood is experienced within NHS and Social Care settings.

This chapter sets out my position on ontology and epistemology and seeks to clarify why these decisions were taken. The framework is also informed by ethics and social responsibility which Walsh et al., (2014) position as the two philosophical branches underpinning Psychology. Willig (2019b) distinguishes qualitative research from other forms of knowledge production e.g. journalism and recognises its commitment 'to using a systematic series of steps to arrive at its conclusions…to provide an understanding of people's experiences and the meanings that they give to their experiences'. (p 4)

5.1.1 Ontology: Critical Realism

Ontology is the study of existence and the nature of the world, poses questions about what exists and what is real, and how things basically are (Malterud, 2016; Walsh et al., 2014). Philosophical theories of reality are understood to exist on a continuum ranging from positivism to realism to relativism. Positivism assumes that there is an objective reality which exists and can be measured objectively, whereas relativism asserts that the nature of existence is dependent on individual contexts and is contingent on the context in which it is observed (Walsh et al., 2014). My research area is characterised by topics which could be examined using different ontological positions. The study of biological processes such as pregnancy, biomedicine and pharmacology might be underpinned by scientific theory, positivist and process ontology (Malterud, 2016). The study of alcoholism or addiction might be investigated using a relativistic approach to understand how these behaviours are regarded in society, rather than trying to prove whether they exist, or whether they can be considered as a moral failing or an illness (Sullivan & Forrester, 2019; Burr, 2015).

Critical realism lies along the continuum between positivism and relativism and challenges assumptions of positivism and relativism by seeking to understand and distinguish between what is real and what is observable through interpretation and experience (Bhaskar, 1975; Bhaskar & Hartwig, 2010). It acknowledges the possibility of social structures which depend on the action of individuals to exist and proposes that there are layers of realities, separate from human thought, with transitive dimensions which may evolve in relation to it, and which may not all be observable (Roberts, 2014). Critical realism is widely used in healthcare research for its overt recognition of complex healthcare models, health inequalities and interventions and what is working in specific contexts (Scambler & Scambler, 2015; Williams et al., 2017).

In the present study, critical realism allows for the subjective experience of the biological condition of pregnancy, or the neurochemical processes involved in the use of opioids to be accepted as real, as well as feelings and meaning making of these states to be investigated. Critical realism allows space for the complexity of the real world faced by the women to be considered and investigated, as well as their meaning making of the extensive socially constructed and inter-relational processes encountered during the healthcare journey. (e.g. healthcare guidelines, attitudes towards motherhood and addiction).

5.1.2 Epistemology: Phenomenology

The second feature of the research paradigm concerns epistemology, the branch of philosophy which poses questions about the nature of knowledge, the methods for generating it, as well as the limits of our knowledge (Walsh et al., 2014). The methodological approach adopted

for the research is firstly informed by the phenomenological philosophy of Edmund Husserl who developed the theory that the world is experienced by the individual through consciousness, making it unique and subjective (Cudjoe, 2023). Secondly, my methodological approach is informed by Heidegger's hermeneutics which seeks to uncover hidden meanings in experience, and which represent an extension of Husserl's position on experience and consciousness. Heidegger's theory of meaning making through experiencing includes the possibility that it is not feasible to bracket the role and influence of the researcher on the meanings brought forth by the participant (Zaborowski, 2011). This research seeks to investigate the lived experience and meaning making of women through a complex journey and adopts a hermeneutic phenomenological approach. The findings and insights produced by the research are based on the feelings, thoughts and experiences of the participants and can be described as "phenomenological knowledge" which is rich, varied and textured (Willig, 2013, p.16). My epistemological approach assumes that there will be variation in the experience of the participants but that each experience is valid in contributing to knowledge. My approach will allow me to draw conclusions about some of the social and psychological processes associated with their healthcare journeys.

5.1.3 Qualitative Method: Reflexive Thematic Analysis (RTA)

The third feature of the research paradigm is the choice of Reflexive Thematic Analysis (Braun & Clarke, 2022). In order to clarify reasons for locating my approach as a researcher and selecting RTA, it is helpful to consider briefly the diversity, tension and variations and attributes associated with RTA as a qualitative method, and its origins within Thematic Analysis (TA). The main school of TA was developed by Boyatzis (1998) and utilised a coding reliability approach which could be used by multiple researchers to identify themes at a surface level or latent level. This approach was underpinned by a positivist position which suggested that reality was reflected in the data and was waiting to be identified. The relevance here is the considerable evolution of Braun and Clarke's RTA from the TA method developed by Boyatzis.

Terry et al., (2017) summarise two broad categorisations of TA as having an experiential or critical orientation. In the first approach, the focus is on what the participant feels and thinks, and their language is seen as reflecting this. In the second critical approach, patterns in language are investigated, with language understood as creating meaning. The processes for investigating data across these orientations also vary. In the experiential approach, the subjectivity of the researcher is integral to the coding and theme development process which is flexible and iterative. The researcher is continually immersing herself in the data, moving from surface and semantic levels of meaning to deeper latent levels (Braun & Clarke, 2022). This is in marked contrast to the critical

orientation in which theory may initially inform the coding process and a codebook or code framework with clear labels and code definitions which more than one researcher may identify in the data is used. This approach assumes that the codes and themes exist within the data. The code book acts as a measurement tool to follow, and the possibility of reliable and good coding between researchers on the same data can be demonstrated (Yardley, 2008). Braun and Clarke (2006; 2013; 2019) have significantly clarified and refined the TA method in which the researcher is intrinsically embedded in the data as Reflexive TA and this approach stands distinct from the codebook approach.

A further key attribute of TA is its theoretical independence. It is not a methodology with a defined ontological and epistemological approach and in this way, is different to Interpretative Phenomenological Analysis (IPA) and Grounded Theory (GT) (Willig et al., 2017; Braun & Clarke, 2021). TA not only allows the researcher flexibility and theoretical independence to think about theories of reality and knowledge production but requires the researcher to clarify and state these.

5.1.4 Reasons for Selecting RTA

There were five main reasons which led me to select RTA to complete my design paradigm. Firstly, I felt strongly about seeking to answer the research aims and giving results back to the NHS and felt that RTA would allow me to focus on data which helped me answer the research question, and in a way that would be useful to healthcare workers working with women with OUD. Themes, patterns and differences in the data felt a useful way of understanding how outcomes for this group of women might be supported or improved. It would also allow me to analyse and present the experiences of the women. Secondly, having undertaken two years of clinical work in north London NHS substance misuse services, I was interested and motivated to use myself as a creative resource within the analysis process, and to engage with what my interviewees said in a thoughtful and reflexive way. Reflexivity is practised by all qualitative researchers and in different ways (Finlay & Gough, 2003). I understand RTA as a qualitative method which has embraced reflexivity fully and has sought to embed it functionally and responsibly throughout the research process. Thirdly, I was keen to position the research in an ontological frame of critical realism. RTA and its inherent theoretical flexibility allowed me to do this. The fourth reason related to language. I was aware that this group of women have complex personal histories yet are marked by difference in their personal stories, ethnicities and use of the English language. I wanted to be able to engage flexibly with their narratives and language as a reflection of their experience, rather than to consider the language as constructing their realities. Finally, I set out to take an inductive approach, but I also wanted the analysis process to be informed by other theories e.g. stigma theory (Scambler, 2009;

Stangl et al., 2019) if I felt this assisted an interpretation of the women's experiences and to help me answer the research question. A framework of analysis in which my main approach was inductive but also consider any deductive meanings felt useful (Braun & Clarke, 2022).

5.1.5 **The** Research Paradigm Summary

The initial literature review undertaken in March 2022, illustrated to me that my research topic area, the healthcare model of women with OUD is dominated by key disciplines e.g. pharmacology, addiction psychiatry and obstetrics. These are disciplines typically positioned in a positivist, and realist framework of research, from which healthcare models are developed and which inform formal guidelines. These, when implemented, form a real-world context in which the women experience their individual healthcare journeys. The setting of my research is clinical, and I have felt motivated to clarify my methodological approach, in order to be able to introduce it, to explain it and to distinguish it from a positivist position, since 2022. It has also felt important, in view of the future task of presenting research findings within the NHS.

I also recognise Malterud's (2016) point that qualitative research findings come from different interpretative positions and that it is important to clarify and state these clearly. In order to consider the coherence of my research paradigm, and to position myself within the complexities of different philosophical underpinnings of ontologies and epistemologies, I have summarised (see Table 2) the key attributes of my research paradigm that I felt were especially useful to my approach. The paradigm allowed me to retain the flexibility to produce and explore patterns in the data, as well as single examples, both of which might be useful in a clinical healthcare setting, and which helped answer research questions.

Table 2: ***Summary of Research Paradigm***

Research Questions	1. To gain an understanding of how women with OUD who become pregnant experience and understand the complex journey of peri-natal and post-natal healthcare. 2. To contribute towards clinicians' understanding of factors which impair, or which promote better outcomes for mother and infant (e.g., adherence to opioid substitution therapy (OST). 3. To inform current practice, interventions and services aimed at supporting young adult female population with OUD.
Ontology: Critical Realism	• Lies at a mid-point between positivism and relativism. • Acknowledges the possibility of social structures (e.g. healthcare models) and layers of realities experienced by the women which may not all be observable. • Critical realism is a recognised research approach within healthcare research, and complex healthcare models (Koopmans et al., 2022; Sturgiss et al., 2020) • Recognises the biological condition of pregnancy as well as the neurochemical processes involved in the use of opioids as real, material processes as well as the feelings and meaning making associated with these states as real, embodied experiences. • Supports the investigation of the extensive socially constructed and inter-relational processes encountered during the healthcare journey. (e.g. healthcare guidelines, attitudes towards motherhood and addiction).
Epistemology: Hermeneutic Phenomenology	• Recognises that the knowledge produced is based on experience which may be rich and varied but that each experience is valid • Recognises and places value on the women's lived experience, which is unique and subjective. • Recognises an approach to knowledge generation which includes the possibility of identifying social and psychological processes associated with the healthcare journey.
Qualitative Method: Reflexive Thematic Analysis	• Motivation to use myself as a creative resource within the analysis process. • Theoretical flexibility allowed me to develop a paradigm with preferred and relevant ontology. • Participant heterogeneity required flexible approach to use of language, narratives and data. • Possibility to develop both inductive and deductive analysis and interpretation.

5.2 Choice of Qualitative Methods

5.2.1 Critical Comparison of Other Methodologies

The literature review demonstrated a paucity of qualitative research with this population of women. There are however some useful approaches which I considered with interest whilst investigating the topic and earlier in the development process. I considered qualitative methods which could be scaled to my study – specifically Grounded Theory (GT) (Glaser & Strauss, 1967, 2017), Interpretative Phenomenological Analysis (IPA)(Smith et al., 1996) and Discourse Analysis (DA) (Wetherell et al., 2001).

5.2.1.1 Grounded Theory

The qualitative method, Grounded Theory seeks to develop and identify theories which are grounded in the data and context in which the data is produced; it has developed considerably since its original conception by Glaser and Strauss (1967), but it is associated with an approach that 'the data speaks for itself' (Willig, 2013, p.78). This aligns GT more closely to positivist epistemologies and Willig (2013)points to its potential limitation as a methodology as it lacks the

place for reflexivity and the acknowledgement of the role of the researcher. Madill et al., (2000; p 4) refers to GT as a form ` soft positivism' which positions the research as a process of discovering pre-existing phenomena and the relationships between them. Charmaz (2000; 2003) developed a GT approach positioned within a constructivist framework which gives greater space for the researcher's interpretation and reflexivity, and which acknowledges that meaning is contextual, and that the emergent theory is shaped by the researcher.

I did not select any of the GT approaches as a method for theoretical and methodological reasons. I wanted flexibility to position the study ontologically where I felt it naturally sat. I also sought to give space to the lived experience of the women in context. I had worked in this area for two years as a Trainee and wanted to be involved in the interpretation of the data and to have the time and space to engage reflexively throughout the data collection and analysis process.

5.2.1.2 Interpretative Phenomenological Analysis

Interpretative Phenomenological Analysis (IPA) is a phenomenological method which seeks to explore the experience of the participant, and which also recognises the subjective role of the researcher in exploring the participant's world (Smith, 1996; 2017). Analysis is undertaken in stages, which, whilst not prescriptive, follow the identification and clustering of themes which result in summary of master themes based on interpretation and the experience of the participants.

I considered IPA fairly carefully in view of how it approaches the detailed analysis of the experience of participants and the reflexive and interpretative position of the researcher. I also recognised that it remains an important qualitative research method within clinical and healthcare settings (Smith, 2011; Larkin & Thompson, 2011). I considered additionally that aspects of the methods e.g. data collection via interviews and small participant number were relevant to my study as a method.

I had reasons for not adopting IPA. An initial concern was due to IPA's relationship to language. English would not be the first language for some of my participants, even if it was sufficient to participate in the study. For others, the use of English might vary. Therefore, the communication of the lived experience might be hemmed in by language and I needed to be able to work with the diversity of my participants and analyse transcripts where the use of the English language may vary. IPA emphasises the idiographic, i.e. the experience of the individual, whereas I wanted to have the flexibility to produce and explore patterns in the data, as well as single examples. I wanted to look for insights which might be useful in a clinical healthcare setting, and

which helped answer research questions. I was concerned that IPA may limit the scope of analysis, rather than open it.

5.2.1.3 Discourse Analysis

Discourse Analysis (DA) is a theoretical and analytical approach which focusses on language as an object of study and the role of language in how it constructs our social reality (Potter & Wetherell, 1987). There are different approaches to DA which may address different research questions though they have important features in common, notably the focus on the use of language and what social function is being gained or accomplished through the use of language (Wetherell, 2001; Wiggins, 2017).

I find DA particularly compelling and have read with great interest some of the hybrid approaches incorporating Thematic Analysis and DA which Braun and Clark refer to as 'critical thematic analysis' (Braun and Clarke, 2022; Terry & Braun, 2013) . The use of language by my participants was important, especially in relation to words like 'clean', or language which related to help seeking behaviour, or the sense of being judged. Within the RTA method, I had the flexibility to engage analytically with the use of language to examine what it might mean for the participant in context. My reason for not adopting a DA approach in full was partly in relation to the theoretical positions I had in locating my research within a critical realist approach, which was contrary to theories of language and social construction underlying DA. I also felt that a DA approach would be more appropriate in the same setting, with a wider set of data e.g. clinical notes, clinical and case discussion minutes, and applied to a different research question.

5.2.1.4 Team Based Approaches

A number of approaches related to large scale qualitative studies, with analysis carried out by more than one team member. For example, Neale et al., (2021) interviewed forty women with OUD in the south of England to explore contraceptive choice and power, specifically to understand behaviours that affect the implementation of new contraception practices They used Theoretical Domains Framework (Cane et al.,2012) and the COM-B system (Michie et al.,2011) both of which methods support the development of new interventions. In the US, Schiff et al., (2022) used constant comparative methods to explore the experiences and perceptions as a mother with OUD of twenty-six women with OUD, on average 10 months post birth. The team analysed transcripts, and a codebook was developed by the research team, with a resultant kappa coefficient of 0.88. My qualitative method clearly had to support the resources I had – including my own time and being a sole researcher with recruitment settings distributed across two Trusts.

5.3 Research Ethics, NHS and Sponsor (City University) Approvals

5.3.1 Introduction to the Study's Ethics

There is physiological and ethical complexity in recruiting pregnant women and vulnerable women with OUD, navigating pregnancy, substance use, significant life change, as well the rights of an unborn child. It was necessary to take into consideration key ethical and regulatory factors, and to recognise the unequal and dependent relationship the women have with the NHS and social services (Oates et al., 2021).

5.3.1.1 The Rights of The Child

A major consideration was the rights to anonymity in perpetuity, of the unborn foetus, the future child, and any existing children. All processes of recruitment, data collection and management concerned not only the mother but the child too. There were practical implications to this, in the early stages of recruitment where emails were being exchanged with clinical staff.

5.3.1.2 Anonymity, Confidentiality, Safety and Risk Management

The safety of the foetus, and the psychological and physical wellbeing of the woman pre and post birth were also paramount. Steps were taken to embed risk management into the study design and to ensure the women understood the meaning of consent, their right to say no to participation as well as their right to withdraw, and to confidentiality for themselves and children. The steps taken to operationalise this are set out in detail under the headings Recruitment, Participants Wellbeing, Safeguarding and Risk Management and Data Management. I also was careful to adhere to codes of practice from the BPS (BPS 2018) and HCPC (2016) and undertook NHS training in research.

5.3.1.3 Ethical Issues Inherent in My Role as Researcher.

I recognised that I would be seen as part of a healthcare setting and power structure, on which the women were dependent. I reflected carefully on the ethical complexity of my study. In spite of my belief that this population of women have a right to participate in research, I questioned myself as to why I wanted to give them a voice and to what end. I recognised that I had to embed procedures in the recruitment and interview process which made it clear what my role was and was not. I also had to make it clear that I was a Trainee, and that it was not a therapy session, and it would not change outcomes for them personally e.g. that it would not change the course of any child protection order or housing issue they were experiencing.

5.3.1.4 Privilege, Difference and Representation

There are ethical issues in all research, and these run throughout the process from the initial 'why', though multiple stages of the research, to the results (Brinkman & Kvale, 2017). There are, in particular, ethical issues where there is an imbalance of power between the researcher and

participant. Wilkinson & Kitzinger (1996) pose the question in the context of feminist psychology and ask if and how we should represent others from groups to which we do not belong. I am white, middle class, educated, economically independent. I have taken a series of steps to organise my research on a population of women who are impacted by the intersections of gender, economic status, substance misuse, ethnicity and idealised models of motherhood. I am an outsider, and do not belong to this group. The ethical responsibility of how I manage the research process, especially the recruitment and interview process was significant. How I represented the women's experience needed to be undertaken with diligence, fairness and responsibility.

Ethics: Reflexive notes

I realised after my first two interviews how live ethical issues are in the interview process. The emotional content of the interviews was high in the first two interviews, with one participant describing it as important to get stuff off her chest (anger, a sense of injustice, and being hurt) and another, seeing, as if for the first time, the long, difficult yet positive journey she had been on. I found myself feeling very moved hearing these first two women's experiences. After two years of clinical work, I felt somewhat unprepared. I had an urge to reach out to the women in the following days of the interviews to provide encouragement and took time to notice and process transference and countertransference . I think I understood the importance of the researcher's ethical responsibility in making clear and repeated statements about the boundaries of the research and that ethics is an active process throughout the interview and all interactions with the participant. I understood more clearly that the boundaries applied to me, in how I responded. I approached the third interview with stronger boundaries in place and felt possibly less emotionally involved as the interviews progressed.

5.4 Introduction to the Study's Approvals Procedure

The study design included the setting of NHS Substance Misuse Services, and this required approvals from the HRA, an NHS Ethics Committee, the individual NHS Trusts and the Research and Development Agency operating on behalf of the Trusts, Noclor (www.noclor.nhs.uk).

Figure 3: ***Sequence of Research Approvals***

5.4.1 NHS Ethical Review

The Committee selected for review by me was the Greater Manchester West REC and I attended an online Committee meeting on February 3rd, 2023, following online submission. I made an approach to this Committee in view of them having a speciality in qualitative research projects. The Ethics Review Committee was chaired by a Research Midwife and questions ranged from the content of the proposed interview topic guide to my own personal safety and the potential posed threat from an interview participant. An initial response requesting further information was received on February 14th, 2023. A series of queries were answered by me in the following weeks, including but not limited to the provision of insurance for high-risk participants (i.e. pregnant women), and the management of risk.

5.4.1.1 Integrated Research Application System (IRAS) Online Submission

All research caried out in the NHS is submitted via an online portal, the Integrated Research Application System (IRAS) and is reviewed by the HRA and an NHS Ethics Committee, selected by the researcher. The online submission was approved by City and submitted on December 22nd, 2022. The submission included a research protocol (see Appendix C) and a set of study documents.

5.4.1.2 Approval NHS Ethics and HRA

Approval was received from the Committee and the HRA on April 27th, 2023 (Appendix D). The Ethics Committee requested that the role of Chief Investigator be assigned to my academic Supervisor, Professor Carla Willig. This request was discussed with the Course Director of Research, City University and Professor Carla Willig. It was agreed that in view of the Ethics Committee request, that these roles would be assigned, with the research being carried out by myself acting as Principal Investigator (Appendix E).

5.4.1.3 NHS Trust Approvals

The research was conducted in two adjoining north London NHS Trusts, NHS Camden and Islington (C&I) Foundation Trust and NHS Mental Health Trust, Barnet, Enfield and Haringey (BEH). The Clinical Directors of the two participating Trusts, Dr Shamir Patel, the Clinical Director of NHS Mental Health Trust (BEH) and Dr Liz McGrath, Clinical Director, Islington Borough Services gave their approval on June 14th, 2023. The final approval was issued by Noclor on behalf of both Trusts on June 27th, 2023 (Appendix F). Noclor signed and issued Organisational Information Documents (OID) on behalf the two Trusts and City (Appendix G).

5.4.1.4 City Approval, Sponsor and Insurance

City University acted as sponsor of the research and provided insurance (see Appendix H). A key requirement from the NHS Ethics Committee was confirmation that there were no applicable exclusions that would affect the insurance cover available for study participants (i.e. women ≥24 weeks pregnant, with a diagnosis of OUD). The query was confirmed by City Insurance. (see Appendix I).

5.5 Study Design

The study design was a qualitative cross-sectional based on interviews with a single cohort of twelve women, aged 18+ who have been diagnosed with opioid use disorder (OUD) and were registered within NHS Substance Misuse Services. Each participant was interviewed once and was between 24 weeks pregnant and eight years post birth and was taking opioid substitution therapy (OST) or had completed the course during pregnancy. The cross-sectional design allowed the lived experience to be investigated at different stages of a perinatal to post-natal healthcare journey.

Early in the design phase, I made an adaptation in view of a challenge I anticipated. My initial interest was in a longitudinal design in which I would interview women more than once, to collect data at different stages on the healthcare journey. I recognised that women with OUD may be averse to increasing interactions in clinical settings and may not maintain commitments to participate in research. A longitudinal study in which a small sample was interviewed twice at different points to explore themes of change felt complex to achieve. Therefore, procedures were kept to a minimum. This meant that data was gathered at a single interview, and the invitation to keep a diary for the following 3 weeks was deliberately designed to be non-onerous and short.

5.5.1 Setting

The research was conducted in the substance misuse services (SMS) in two adjoining north London NHS Trusts, NHS Camden and Islington (C&I) Foundation Trust and NHS Mental Health Trust, Barnet, Enfield and Haringey (BEH). These two Trusts cover five boroughs and a population of 1.6 million. The Trusts formed a partnership in July 2022, the North Central London Integrated Care System (NCL ICS) to bring together local health and care organisations to work in joined-up ways to improve health outcomes for residents and tackle inequalities that currently exist.

5.5.1.1 NHS Substance Misuse Clinics

Each of the two participating Trusts operates several substance misuse services which are community-based clinics employing a specialist team of substance misuse practitioners, addiction psychiatrists, doctors, nurses, social workers, psychologists and pharmacists, as well as complementary therapists, volunteers and peer mentors. Clinics may also be operated with a third sector not-for profit (NFP) e.g. Humankind who provides some of the operational non-medical staff such as Keyworkers and Recovery Practitioners.

5.5.1.2 'Scripting Services

The prescription of medication is a key part of the recovery process, and the clinics are known as 'scripting' services, which means the Psychiatrists and Doctors working with the clinics prescribe medications, in particular opioid replacement therapy, (ORT) in the form of prescriptions. Prescriptions follow defined and strict criteria and procedures (NICE) and are collected by the client on a routine basis and dispensed via a network of approved chemists.

5.5.1.3 Key-working

Key-working is fundamental to recovery and each client registered is assigned a Keyworker (KW) who maintains routine contact with the client and represents their progress at the weekly Multi-Disciplinary Team (MDT) meetings, as well as interfacing with other agencies, e.g. GPs, social care, housing, the police, safe houses. Clients are also tested on a weekly basis by the Keyworkers to monitor for the presence of illicit drugs as well the ORT.

5.5.2 Participant Inclusion criteria

The study design was cross sectional and aimed to recruit women at different stages across the span between >24 weeks pregnant and eight years post birth. These inclusion criteria (Table 3) vary from the original inclusion criteria submitted to the NHS Ethics Committee. The summary below include minor amendments which served to increase the recruitment potential from the bank of women with OUD registered in NHS Substances Misuse Services. The key amendments aimed to increase the maximum age of the child from 24 months to 36 months, to 96 months (eight years old). All amendments were submitted to the HRA and approved on the basis that they were considered minor. These amendments are summarised (Appendix R). The main impetus behind amending the inclusion criteria was the recruitment challenges and the delays to recruitment following the approval of the study in July 2023. The participants could therefore be ≥ 24 weeks pregnant, have a two-year old, six-year old or an eight-year old, and this provided variation across this time span. The women may have more than one child, and they did not have to have parental custody of their children. The participants needed to be registered in the one of the Trust's Substance Misuse Services and to have initiated OST.

Table 3: ***Participant Inclusion and Exclusion Criteria***

	Inclusion Criteria	**Exclusion Criteria**
	Female and/or capable of pregnancy	Comorbid with a serious mental health condition e.g., bipolar disorder or Psychosis
	Age 18+ years old	
	Pregnant at ≥24 weeks to 8 years post birth	
	Diagnosis of OUD[1] (illicit)	Other forms of sole substance abuse e.g., alcohol
	Initiated OST[2] or recently completed OST	Not initiated on OST
	Sufficient understanding of English in order to be able to engage in the study	Lack of child custody not an exclusion criterion
	Custody of children is not an inclusion criterion (i.e., mothers may have babies in care or be subject to care proceedings).	

Key: 1 Opioid Use Disorder involving illicit use of opioids e.g., heroin 2. Opioid Replacement Therapy

5.5.2.1 Sampling Method

A number of factors were considered as part of the sampling design. The study was bound by several factors: a study timeframe, recruitment sites within defined NHS Trust boroughs, and specific inclusion criteria were sought for a population with specific characteristics. Savin-Badin & Howell Major (2013) describe purposeful sampling as a sampling method allowing 'careful selection of members of the community'. (p.315). Purposeful sampling was adopted with key goals in mind, specifically as a means to identify and recruit cases which were representative of the healthcare journey i.e. across a time frame, which captured heterogeneity amongst the women, and allowed the consideration of theory, difference and similarities to be studied. Various approaches of purposeful sampling exist in qualitative research, and criterion sampling was used to allow for the identification of relevant and particular criteria (Savin-Badin & Howell Major, 2013). These inclusion and exclusion criteria are set out in Table 2. These criteria defined clearly the attributes of the participants. A further factor taken into account in the sampling, was the aim to recruit a heterogeneous sample representing the diversity (ethnic and socio-economic) of the population of women with OUD, registered within NHS Substance Misuse Services, to improve the coherence, validity and generalisability of the study.

5.5.2.2 Number of Participants

The Research protocol submitted to the NHS Ethics Committee sought approval for twelve participants. However, six to eight participants are frequently cited as an appropriate number for a qualitative study using TA. (Braun & Clarke, 2016; Guest et al., 2020; Hennink et al., 2017). In this study, five participants were recruited from a hard to reach population, with a specific profile defined in the Inclusion Criteria (Table 3). Malterud et al., (2016) propose a model of information power in which attributes of the data gained from a sample can lower the amount of participants needed for the study. A sample of five participants fulfilled key criteria in this model including the specificity of the sample, and that the interviews were data rich and provided a quality of dialogue providing insight and information which answered the research question. The sample of five participants was therefore considered a robust sample for the study, and allowed for the identification of patterns in the data patterns to be identified.

5.5.3 Patient and Public Involvement (PPI)

Involving patients and the public in healthcare research has become embedded in much research in the UK since 2006 when the Department of Health published its recommendations on involving patients and the public in UK healthcare. A recent analysis estimates 44.5% of health care research papers included a form of PPI in their method which suggests it plays a consistent and important role in UK health care research (Lang et al., 2022). PPI is considered to extend

knowledge production by honouring experience and participation and makes research more democratic, with research being done by people rather than simply to them (Heron & Reason, 2008). In addition to the theoretical and practical contribution underpinning PPI, I thought it would enhance the research method and findings, by bringing in other women's real experiences, feelings and thoughts.

The early study design included the PPI recruitment of two women with older children and who may still be receiving ORT, or in recovery. This was amended to include the option of the PPI contribution coming from a women's recovery group. The aim was for the PPI to contribute to three distinct areas at different stages. Firstly, I sought input towards the development of the interview topic guide, in a second phase towards the themes and results, and thirdly towards the dissemination of findings.

I attended a women's recovery group in one of the Islington clinics which included six women, some of whom were in recovery from alcohol, some from non-opioid substances, and two in recovery from heroin who were on ORT. I explained the aims of the research and ran through the topic guide. This opened a rich and lively discussion about their own experiences of addiction, recovery and motherhood which helped inform the topic guide. The women felt that the topic guide was focussing on the right areas, but they wanted to highlight aspects of their own lived experience; this included, whether the GP was helpful or not and had the time to help them; the idea of hitting rock bottom being the turning point, rather than pregnancy being the motivating factor; the notion of a fun identity being associated with substance use, and a dull identify being associated with sobriety and abstinence, though this was particularly associated with alcohol use. There was an interesting sense of division in the room, towards the women who had been on methadone at the point of becoming pregnant, as they had the benefit of being ''within the system already'' whereas the women who had alcohol problems were ''not in the system'' and they felt they had a lesser health status. I sensed, during the discussions, that there was a limited awareness and understanding about the impact of substances on the foetus. The opinions of how helpful social workers were varied greatly. The discussion on violent and abusive relationships, and the regret of not leaving them earlier was common to the women in the room. All the women seemed to concur that having supportive family was key to their recovery and managing to become a mother and parent of a child. The meeting felt energetic, dynamic and rich, and for the first time, I felt connected to the essence of my research. The recovery worker who led the women's group felt the group was unexpectedly animated and she heard them talk about aspects of their stories for the first time.

No specific changes to the Topic Guide were made as a result of the Patient and Public Involvement. However, the women drew my attention to specific aspects of their experience. The presence or absence of familial support was a key aspect of the women's experience. The women's recovery group emphasised the importance of having a supportive family. In the current study, the presence of supportive family members was key to practical support in the form of kinship care, and in how the women's evolving identity and sense of self was reflected back by family members. The women's recovery group also spoke of the variation in interactions with social workers, GP's and mid-wives. This was consistent with findings in the current study. The PPI field work played an important role in serving to validate the study's findings.

PPI: Reflexive Notes

I found attending the Women's group uplifting. They were all in recovery and gave me some useful insights but most of all, I loved the sense of camaraderie and honesty amongst them. There was a dynamic exchange between them about having an alcohol problem versus a heroin problem, with the latter being easier as 'you've always got methadone'. I felt as if I was being included in a private and an incredibly unique conversation. It was moments like this that I felt energised.

5.6 Amendments

A series of non-substantial amendment were made, during the first six months of the study, of which three types of amendment are described here (Appendix R). The first set of amendments included changes to the inclusion criteria to include women up to eight years post the birth of their child which afforded a larger population of women to screen and recruit. A further amendment was made to extend the inclusion criteria to women who had successfully ceased to take ORT (e.g. methadone) and illicit heroin during their pregnancy. A third key amendment was made to afford women the opportunity to participate in a group interview if this felt more comfortable. No group interviews were undertaken, though it was useful to have the option available. A fourth key amendment was made to the PPI, to allow the contribution to be made by a Women's Recovery group. I felt these amendments were consistent with the design, supported the research aims and were helpful to the study's timeframe.

5.7 Research Procedures and Materials

5.7.1 Recruitment Channels

All clinics invited me to present the research at the weekly MDT meeting and the interest in the study was high. Three recruitment methods were used within the substance misuse services

(SMS) to build a short-list of potential interviewees: clinical records; referral from clinical teams or direct response from the women themselves in response to a poster (See Figure 4).

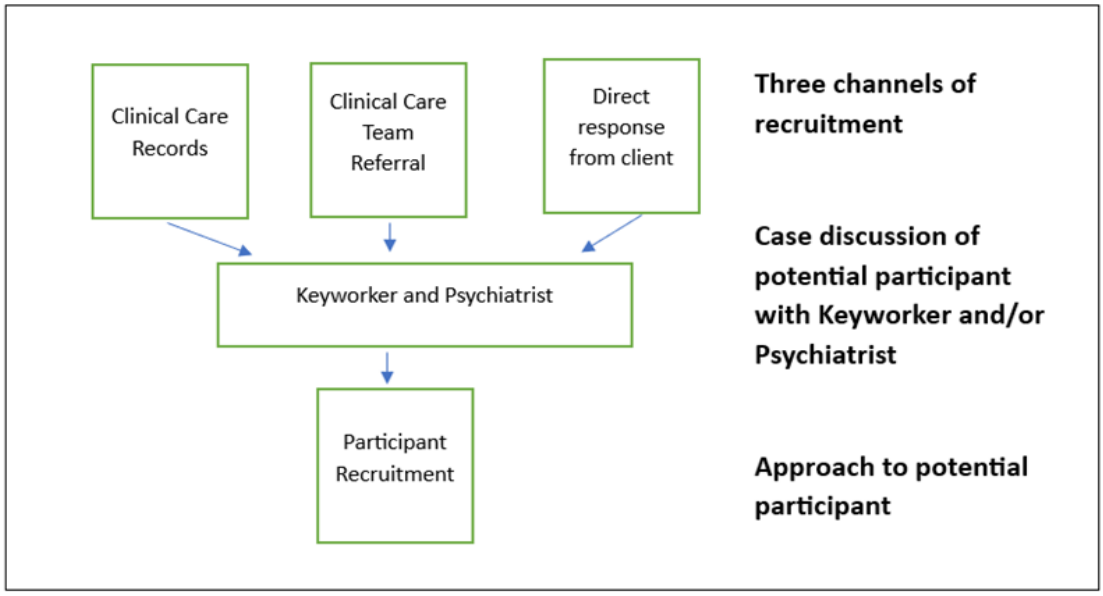


Figure 4: ***Diagram To Show Three Routes To Identify And Recruit Participants***

5.7.1.1 Direct Participant Marketing

The research was advertised in reception areas for clients of the clinic. The poster invited interested participants to contact the researcher whose contact information was included (Appendix A).

5.7.1.2 Care Team Referral.

Posters were also placed within the office area and information boards to capture the attention of the Clinical Care Team who were invited to refer potential candidates to the researcher. Any referral was followed up by the researcher by sending an introductory letter and the Participation Information Sheet (PIS) (Appendices M and N). Care Team Referrals were also sought through routine attendance in the MDT meetings where the research was presented.

5.7.1.3 Clinical Records

The NHS uses many software packages to maintain clinical records e.g. RIO and Illy Carepath. Two substance misuse services ran data reports, extracted from the clinical care records with a summary of all women with OUD. Each report yielded a list of ~160 women registered for opiate treatment. These reports indicated key data fields, notably gender, date of birth, primary substance use, opiate treatment and parental status. Examples of redacted reports are attached (Appendix J and K). In RIO, a commonly used NHS patient record software system, a woman might be listed as having 'no parental responsibility' in the primary patient record. This woman may have had a baby very recently who was being fostered, or who had been adopted. Each data report had to be interrogated further through multiple forms and through key word searches in the women's patient notes to establish if the women had ever been pregnant, had a child, or children. A short list was made of potential candidates and any potential participation was discussed with the Keyworker and, or Psychiatrist before proceeding to send information to the women.

5.7.1.4 Recruitment and Screening

The population group of the study is vulnerable. In one case, a woman had had four children who had all been adopted, and in another case, the women had just had a baby, who was being fostered and she had controlled access. My recruitment approach was cautious and careful. I only followed up with each potential participant after a discussion with the clinical team and having sent the introductory letter and PIS. In some cases, the KW had already introduced the study in a key working session and had given a copy of the poster to the potential participant.

In the majority of cases, the women I approached responded with questions as to why I was doing it, and I was careful to explain that it was entirely voluntary, confidential and would take place in the clinic with which they were familiar. The PIS is a six page detailed document, and I ensured that they understood key it, especially their rights to anonymity, that their GP would be informed of their participation and the right to withdraw. In the cases, where the women responded positively to the invitation to participate, the interview was booked within the following two weeks.

In one case a Keyworker introduced the topic of the research to a potential participant who declined to participate once she had received the PIS and introductory letter. In another case, a participant appeared to engage and did not appear for the interview, on two agreed consecutive appointments. In another case, a participant, did not appear for the first booked interview but attended when it was booked the second time. In two cases, two women were pregnant, and, following discussion with the Keyworker and the women themselves, it was agreed we would postpone participation until a later date, post birth.

In all cases, I verified that the women fulfilled the inclusion criteria. A number of women were excluded for having a clinical diagnosis of schizophrenia or bipolar disorder. In some cases, I could see from the current clinical records that the women were too vulnerable, particularly in relation to housing issues or being victims of domestic violence and did not make an approach.

5.8 The Participants

Five women were interviewed, and all fulfilled the inclusion criteria. At the time of the interviews, the age range of the women was 27 years to 45 years. All women had given birth, and the age of children ranged from 6 weeks to 8 years old. Two women had more than one child, with the older children ranging from 13 years old to 27 years old. All women had started using heroin between the ages of 15 to 21 years old. Four women described being in relationships with substance-using partners when they initiated heroin use. Two of the women described sex-working during early heroin use and one referred to high levels of ‘criminality’. Four of the women gave birth within the Trusts where recruitment had taken place, and one of them had her baby in another region of England and moved to London during the year following birth. All participants have been assigned pseudonyms, all locations de-identified and any locations including the clinics given a generic number in the analysis.

Table 4: Participant Descriptive Data

Participant	P1	P2	P3	P4	P5
Pseudonym	Megan	Elizabeth	Gail	Linda	Janet
Ethnicity	White European	White British	Ethnic British	White European	Black British
Age	38	27	45	30	43
Age of first substance use	16	18	15	16	17
Age of first heroin use	16	21	15	20	17
Opioid replacement therapy	Methadone	Subutex, Buvidal	Methadone	Methadone, Buprenorphine	Methadone
No of children	1	1	4	1	2
Age of child/youngest child	36 months	24 months	8 years old	6 weeks	8 years old
Parental responsibility / Access/Arrangements	Yes	No. Has access rights. Kinship arrangements	No. Has access through Contact centre. Foster care	Yes	No. Has access rights. Kinship arrangements
Attended Tier 4 Service : Mother and Baby Unit or Rehab	No	Yes; Mother and Baby Unit	Yes; rehab	No	Yes; Mother and Baby Unit

5.8.1 Data Collection - the Interviews

The five women were interviewed for durations ranging from twenty-six minutes to fifty-six minutes, with the mean duration, thirty-eight minutes. The interviews were designed to explore the lived experience of the health care journey through substance use, pregnancy and motherhood. The first questionnaire aimed to identify demographic data including age of first drug use. The main part of the interview was carried out using the topic guide which aimed to explore the experiences and feelings covering the pre-pregnancy period, the discovery of pregnancy, pregnancy and the post birth period. There were no questions about the family origin, socio-economic status, ethnicity, race or cultural background, or employment status. Ethnicity was taken from clinical records. There were no specific probes to explore personal and developmental histories or underlying reasons for drug use, though this was frequently shared without prompt. For the two women with older children, accounts focussed at times on the older children, prior to describing experiences with the younger children.

The interviews were held on site and each participant was interviewed once, lasting about fifty minutes. Each interview followed the same stages (see Table 3). The main part of the interview was spent on the semi-structured topic guide which probed key stages of the journey and healthcare as well as the meanings and feelings associated with pregnancy, birth and motherhood.

Table 5: ***Stages Of Participant Interview***

Stage	Description of stage	Documentation	Appendix
1	Participants were met at reception and warmly welcomed and taken to the reserved room. They were invited to ask questions about the Participant Information Sheet to ensure understanding, and to sign a Participant Consent Form.	Participant Consent From	L
2	Demographic, clinical, and psychosocial characteristics were taken via a semi structured questionnaire for descriptive participant data.	Demographic characteristics	O
3	Interviews were conducted following a topic guide / semi-structured schedule of questions.	Interview topic guide	P
4	Participants were invited to keep a 3-week journal following the interview, debriefed, thanked for their participation and provided with a £25 voucher by way of compensation for their time.	Notebook; Voucher	
5	A call was made to the participant 24 hours post the interview to ensure that the interviewee was well.	Follow up Wellbeing call	

The semi-structured interview was selected as the method to gather data in order to answer the research question. Willig (2013) proposes that the semi-structured interview is non-directive, yet the researcher drives the interview to obtain data that will answer the research question. It provided a structured approach to investigate the lived experience at different stages of each participant's journey yet allowed for conversation and 'novel insights' (p 29) to develop in areas of personal significance for each woman. The design included a cross-section of lived experience of participants over an eight year period following birth. Through purposeful sampling, there was variation in the sample, with children of aged from six weeks to eight years old (See Figure 3). The semi-structured approach importantly allowed me to investigate for patterns as well as to go off script and probe for unique experiences, or differences.

The women were also invited to keep a journal in the following three weeks with any further thoughts that they may have after the interview. Guidelines were given as to how notes might be completed, and it was explained that it was not a daily requirement. It was aimed to capture any further thoughts in relation to the topics we had been covering in the interview. One of the women asked if she could text or email me with any thoughts which I accepted. Instructions as to how to return the notes were given.

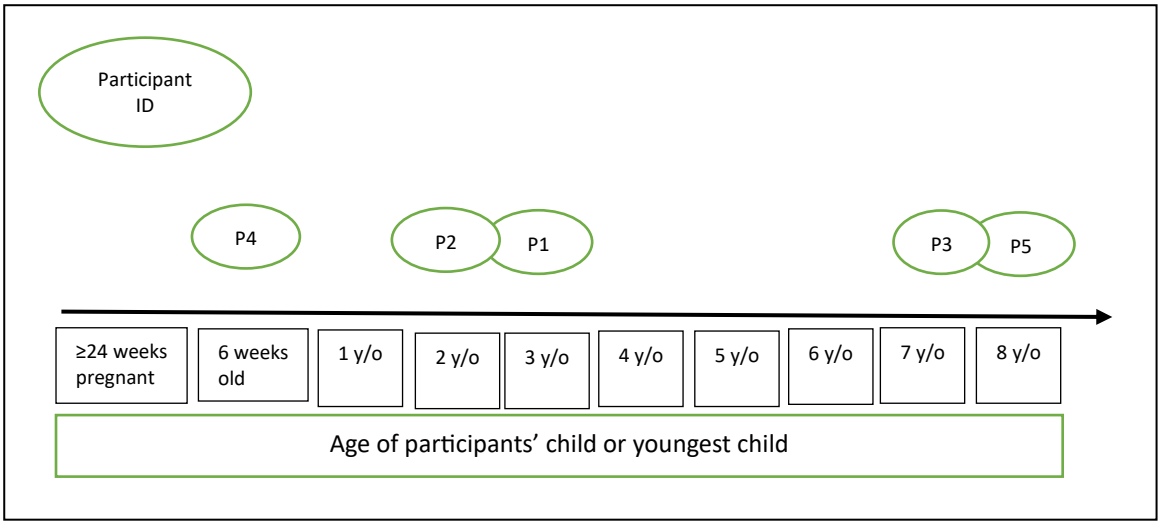


Figure 5: ***Illustration to Show Variation and Distribution of the Participant's (Youngest) Child.***

Savin-Baden & Howell-Major (2013) recommend the semi-structured approach when there is only one interview, in that it allowed me to use the limited time available and keep the interaction focussed. The interview comprised two different topic guides. The first gathered demographic information such as the age of first drug use to situate the sample (Appendix O). It also provided a useful time for us just to start talking together, and to put the women at ease. The semi-structured guide was designed to move forward in time e.g. feelings about being pregnant and backwards again, experience of being pregnant and taking methadone at the same time (Appendix P). The questions were designed to be answerable, straightforward and open and sought to follow some do's and dont's of interview questions advised by King & Hugh-Jones, (2018).

5.8.2 Payments to Participants

At the end of the interview, each participant received a voucher of £25 plus reasonable and validated travel expenses. During the initial screening process and discussion of the PIS, some women told me that they were 'not doing it' for the money and I responded to say that it was in recognition of the time and effort they were contributing to the research. I wanted them to understand that it was useful and that their time and effort was valuable. I felt the voucher helped set out a difference between their interactions with other staff at the clinic and myself, in that I was not trying to 'do' something to them e.g. a blood or urine test. The vouchers were purchased at the post office and were redeemable in retail high street outlets. The voucher was provided at the end of the interview and was included on the PIS. No mention was made on the study poster at the request of the REC. It was fully explained at the start of the interview and on the PIS that receipt of the voucher did not diminish the participants' right to withdraw from the study. Funding for the vouchers was sought and approved by City, the Sponsor. The voucher and validated expenses are considered to be fair compensation for the time taken to participate and does not represent a coercive inducement. It may also reduce any misunderstanding that the time spent with the researcher is any form of therapy. The National Institute of Health & Care Research

(NIHR, 2022) publishes guidelines on payments to participants and the voucher rate of £25 complied with their recommendation.

5.8.3 Consent

The requirement to sign a consent form was included on all marketing material and was explained during the initial contact. Consent forms were signed prior to all face-to-face interviews as well as the implications of signing the Consent form and the right to withdraw. The Consent form was in hard copy and two copies were signed, so the participant and researcher each retained a copy. The Consent form included the name of the participant and was kept separately from all other research materials. The researcher entrusted the Consent forms to the University to be kept securely on site as part of the research materials (Appendix L).

5.9 Participants' Wellbeing, Safeguarding and Risk Management

The study relied on the recruitment of a vulnerable population. The use of opioids and substances may relate to coping mechanisms in order to cope with, or 'block out', what is happening to them, or trauma memories. Participants' use of opioids which act as pain killers may make acknowledgment of risk and abuse difficult for the women to recognise accurately. The women may have been victims of domestic abuse forced into drug or alcohol misuse by their abuser in order to intensify control, or they may be drawn into sex working or other high-risk activity to pay for access to drugs or alcohol. I recognised that Adult Safeguarding was a primary concern to this study. I adopted procedures in three key areas, relating to the monitoring for adverse events, safeguarding, and risk to myself.

It was also important to acknowledge that women of black, Asian and minority ethnic origin (BAME) may be particularly vulnerable in the study population. There is an under-reporting of domestic abuse by people from (BAME) communities in the general population, and there may be additional barriers to women with OUD bringing attention to their abuse or reporting it. Particular attention was paid to how women may manifest signs of abuse.

A summary of risks, adverse events and steps to minimize risk was developed to cover a range of possible needs and adverse events. Examples of these are given below. A detailed plan to mitigate risk and take appropriate action was developed to meet levels of risk (Appendix Q). I also called each participant within 24 hours of the interview to ensure participants were well and not experiencing any sense of being unwell.

5.9.1 Discomfort and Appropriate Facilities.

Women may find pregnancy physically uncomfortable, e.g., to sit for an hour for any interview and they may also require facilities for an infant. They may not wish to attend an

interview with an infant or while pregnant in a substance misuse service or walk any great distance to an interview room. I worked with each site to ensure that the interview room was comfortable and discreet, and they did not need to be in the main clinical area. It was agreed that each participant's GP would be informed of the intention to participate and that the Duty Manager of each site would be informed on the day of the interview.

5.9.2 The Recall of Difficult Memories

It is possible that participants might recall difficult memories associated with their experience e.g., childbirth pain either during or after the interview. I allowed time for difficult memories to be empathetically supported, with the option for referral to therapeutic support. I was careful to monitor the participant throughout the interview and had agreed to inform the site Duty Manager, Keyworker or GP if any sign of distress emerged.

5.9.3 Adverse Events

I considered the possibility of adverse events occurring during the interview, for example, the participants requiring urgent perinatal clinical attention. I actively monitored participants throughout the interview for any signs of distress. I was also ready to offer the participant the right to withdraw at any time or choose to postpone an interview.

5.9.4 Safeguarding

I was aware that I was working with a population of vulnerable women often with histories of intimate partner violence (IPV) and that the participants may have children and wider family who are implicated and impacted by abuse. Safeguarding is underpinned in UK law, and the activity of safeguarding had to be operationalised in my research activity. I thought carefully about how to comply with the Statutory Guidance issued under the Care Act (2014) that states that adult safeguarding 'means protecting an adult's right to live in safety, free from abuse and neglect' (Section 14.7). The two NHS Trusts had Safeguarding protocols, and I recognised that the interview process itself and all my interactions with the participants needed to include safeguarding activity from me.

I operationalised this by actively monitoring each participant throughout all the study procedures and interactions, for signs of physical abuse, domestic violence, sexual abuse, or psychological abuse. I was also alert to other signs of abuse including financial or material abuse, modern slavery, self-neglect, whether caused deliberately or unintentionally. This included being alert to harms either to or from the participants' children, dependents, grandparents (or other adults or family members living or not living with them). I had a formal procedure to follow in the event that I observed any signs of abuse where any participant was the subject of abuse, and this

included information relating to children living with or exposed to abuse, even if not physically harmed.

I had previously worked in one of the clinics. There was no obligation or invitation to any client (e.g. by the Keyworker) with whom I had previously worked with to participate in the research, and I made no approach to a previous client.

5.10 Risk to the Researcher

I committed to follow the Trusts' protocol for reporting abuse and harm from patients and / or Service Users and agree to report any incident of abusive behaviour in writing and to follow all NHS operational procedures when working on site. I had worked for two years in placement in one of the clinics, so I was familiar with operating procedures, such as alarms within meeting rooms. I did not feel under threat at any time.

5.11 Data Analysis

The data analysis followed Braun and Clarke's (2006; 2022) guidelines for six phases of TA – familiarisation, coding, generating initial themes, reviewing themes, defining and naming themes and writing results. The original TA method described in 2006, was clarified iteratively and named Reflexive Thematic Analysis (RTA) by Braun and Clark to refine and clarify the TA approach (2006; 2019). Two important refinements include the focus given to the values of organic and recursive coding processes, and the importance of deep reflection on, and engagement with, data, and the emphasis on the generation of themes, rather than the retrieval of themes. The following sets out my approach to the RTA procedures.

5.11.1 Transcribing and Familiarisation

Initial transcripts were produced using transcription software, with multiple iterations and corrections to provide verbatim versions. English was not the first language for one participant, and whilst her English was excellent, the audio required significantly more time to transcribe comprehensively. Familiarisation was undertaken through listening to the audio and repeated readings of the transcripts. Having listened to each audio multiple times, I simply read each transcript, many times over, to immerse myself in it without making notes, and to just think about the content, until I could hear it in my head.

5.11.2 My Analytical Framework

During familiarisation and immersion, I developed an analytical framework and pushed myself, before coding, to look at both semantic and latent meanings to develop my own analytical sensibility. Braun and Clarke (2013) refer to this as the ability to look beyond surface meaning, provide insights and meaning making, to see connections between theory, context and research.

My analytical framework involved different building blocks. These included reflexivity about my feelings towards the interview material and participants, flexibility about thoughts on possible meanings, and a focus on both surface level and deeper meanings.

I wrote notes about each participant and how I situated myself in relation to each participant to encourage my own reflexivity (Appendix S). I noticed that I was moved by some interviews more than others. I developed questions to ask myself as I considered each new transcript (Appendix T) and I produced each transcript on a landscape document, with three columns to allow for the collecting of ideas, queries and questions to prompt my thinking about my exploratory thoughts about the data (Appendix U). I looked at words or phrases which seemed to sit on the surface, and which easily demanded my attention, as well as phrases which seemed to hold greater depth. I had many queries about the meaning of a particular phrase and noted these. The purpose was to identify surface level or semantic meanings prior to starting the coding. My analytical framework was flexible, in that I remained open to evolving thoughts and reactions to the data; I looked at semantic meaning first, and asked questions about the words, without attempting to answer them all. I listened to the audio tapes again many times, as this helped me reflect iteratively on nuances and meanings I was starting to identify.

5.11.3 Coding

The purpose of coding in RTA is to identify segments of data which appear relevant to the research question, and which are capable of capturing a single concept (Braun & Clarke, 2022). The code label aims to reflect the concept and can be coded at a semantic or latent level. Following many weeks of reading and annotating each transcript, I started to embark on coding. The familiarisation and coding of each transcript took approximately five weeks.

Initially, I took an inductively orientated approach to the coding process, as I was interested in the experiences of the women as expressed by them. The women seemed to have quite different experiences and accompanying thought processes, though I could see the potential for connections and patterns. I aimed to stay very focussed on the research question. An example of this is how the women talked about their early heroin use. I was not researching the circumstances and experiences of early substance use, aged 16 years old, but I was interested in the psychological processes they were using to manage OUD through pregnancy and motherhood, and if and how they reflected on their past and their experiences of pregnancy and transition to recovery, or not. Two women referred to their past histories e.g. in sex work or criminal work, though once again, I was interested in the development of their thoughts towards the past in the context of their current circumstances. It felt important to hold in mind, in tandem, the unique experience and

meaning making of each woman, as well as their experiences along different stages of the healthcare journey. I developed maps to organise the codes visually along an evolving timeline which represented their journey (Appendix T). At a later stage, I considered some of the data using a deductive approach, and this was especially useful in terms of stigma theory, as to how stigma is internalised and felt (Scambler, 2009). The coding felt messy at times, yet creative.

5.12 Theme Development

My approach was to explore and parse meaning from the codes, with the aim of developing as patterns of 'shared meaning underpinned by a central organising concept' (Braun & Clarke, 2022; p 230). This was a deliberate approach distinct from a process of identifying themes in the dataset. RTA involves the researcher subjectively in the development of themes, rather than simply identifying them.

I developed an initial set of themes relating to distinct periods of the journey but realised that this was simply clustering codes around time periods e.g. early substance use, pregnancy, or post pregnancy, and was failing to capture broader meanings and psychological processes over time (Appendix U). I also reverted to the research question, as to what was useful to know, and what would help answer the research question. This led me to focus on the concepts linking the women's lived experience in their multiple and complex interactions, and what meanings they assigned to these processes. I could see that there was considerable change and development in the women's thinking, and feelings about themselves, and that this was a continual process, not a single final event. I also liked the clarity of expression of what the women felt may have helped them. I could also see how many processes were experienced as threatening e.g. reports and meetings, and the ability of one agency to inform another agency, of the pregnancy.

5.13 Writing Results

I have aimed to give the reader a good preview of what to expect in the Analyses and used diagrams to present the four main themes clearly. I have also aimed to tell an overall story of the women's lived experience, as well as reflect the similarities and differences. I have aimed to represent the women in a balanced way across themes and demonstrate the linking concepts between themes. Braun & Clark (2022) recommend the importance of providing a 50/50 balance of analytic narrative and data extracts. I have deliberately kept the Results chapter focussed on the themes and the data extracts, and not developed extensive connections with the literature. I have retained this for the Discussion chapter.

5.14 Data Management

5.14.1 Confidentiality During Data Collection

The key operating principle underlying data management throughout the research was confidentiality. The collection of identifiable data was kept to a minimum, with interview materials assigned a study ID, unrelated to personal information. Data management was carefully considered on site, within NHS premises, and in a second stage, in relation to the University who acted as Data Custodian for the study. A summary of procedures undertaken in the early stage of data collection is summarised in Table 6.

Table 6: ***Steps To Protect Participant Confidentiality***

Recruitment	The researcher will solely use personal data such as name and contact details to make contact about the research study, as necessary.
The minimum data set	The minimum set of personal information will be used in the process of identifying potential participants.
Storage	The researcher will not store any personal information on any personal device at any time. An NHS Trust laptop is being provided for the purposes of recording and transferring data to the secure sponsor site.
Transfer of data from the NHS	The researcher will not use or transfer any personal information off NHS sites during the process of identifying participants.
Informing the participant of their personal records	The key step to inform participants of the potential use of their personal records is set out in the Patient Information Sheet (PIS) which will be provided early in the recruitment process.

Permission to retain personal records	The PIS will also explain that if the participant wishes to receive the results of the study, contact details will also be kept for this purpose.
Access to identifiable data	The only person who will have access to identifiable information will be the researcher.
Storage of personal data	The identifiable personal data of any potential participant who does not wish to participate, or who becomes ineligible will not be retained.
The use of a study ID	All participants will be assigned a study ID, and this will be kept in a separate file which cannot be linked to any personal data.
De-identifying research materials	Interview recordings and transcripts and journals will be de-identified, and labelled with this Study ID.
Transfer to sponsor	Research materials will be transferred electronically to secure University storage facilities, and password protected.

5.14.2 City University as Data Custodian

City, University of London acted as the sponsor and the data controller of the research. This meant that City as Sponsor was and continues to be responsible for looking after the personal data of the participants and for using it properly. The legal basis under which this data was processed and stored is City's public task. To safeguard the participant's data, a series of steps was adopted for the later stages of transferring to City the research materials and for their onward storage. City ensured that the study complies with the provisions of the Data Protection Act (1998) and provides transparent information as to how it handles data at https://www.city.ac.uk/about/governance/legal. The Information Commissioner's Office (IOC) https://ico.org.uk. A summary of procedures undertaken in the earlier stage of data collection is summarised in Table 7.

Table 7: *The Transfer and Storage of Research Materials*

Transfer and storage	Research materials will be transferred electronically to secure University storage facilities, and password protected. If any personal identifying data is used during the interview, this will be deleted by the researcher. No data e.g., a direct quotation would be assignable to a respondent. Personal data will be transferred directly to the University secure site, expressly set up for research purposes and the storage of confidential data.
Consent forms	Consent forms will be held at a University secure site, separate from research materials.

Access to materials	The academic supervisor will have access to the data (recordings and transcripts) on a University OneDrive site.
Duration of personal data	Personal data will be kept for a period of up to 3 years. This is to allow contact with participants who may wish to receive the results after the study end.
Duration of research materials	Results and recordings are kept for 10 years by the University.
Safeguarding by City	If any indication of violence, abuse, self-inflicted harm, harm to others, criminal activity, are revealed the researcher would be obliged to report this to a relevant NHS Duty Manager, or Supervisor

5.15 Reflexivity

Lincoln and Guba (1985) refer to qualitative researchers as human instruments (p.107) which have an immense opportunity to be maximised as research tools, rather than curtailed through some 'magical methodology' (p.107) of objectivity, which they state as being unattainable, and without value. They propose a set of steps which can help ensure checks and balances to support balance and fairness without being able to guarantee it. One of these is the use of 'reflexive journals' (p.109) that helps to capture the researcher's thinking and decision-making process. Finlay (2002) describes the personal dimension of the qualitative researcher as a resource to be celebrated and levered in order to enhance the process of analysing data (Finlay, 2002). I recognised during the research project over two years that my feelings towards it constantly evolved, and it has been valuable to notice the flow and ebbs of my thoughts and feelings about my study and participants.

5.15.1 Reflexivity as a Trainee Counselling Psychologists

Reflexivity is actively encouraged and developed in Counselling Psychology Doctoral programmes. We are encouraged to think of it as a corner stone of our therapeutic practice and way of thinking. In qualitative research, Willig (2019b) makes the distinction between personal reflexivity and epistemological reflexivity. The former not only relates to how we are implicated in the research process and its findings, but how our own reactions to data and the research process make new insights possible, as a form of countertransference. Epistemological reflexivity in this context refers to how we think and theorise, and what sort of psychologists we aim to be. I found it useful to think about reflexivity in these two ways. Apart from the practice of reflexive processes in this research, the engagement with reflexivity has helped me think about my orientation as a therapist, my beliefs and has contributed towards my development as a Counselling Psychologist.

5.15.2 Reflexive Practice in my Research

Reflexive practice in my research has felt at times over-whelming, as if it was dominating the research versus other tasks. Was I doing enough? Was there too much of me in this research, and was it helping interpret the experience of my participants? What is the perfect model to follow? Reflexivity has felt messy, disorganised at times and limitless. Finlay & Gough (2003) refers to 'reflexivities' (p.22) and states that it is a contested term and there are multiple ways of practising it. Differences in approach stem partly from theoretical epistemological positions e.g. realist and social constructionist and the claims that can be made from the data. I have positioned my research within a critical realist approach, and therefore have been thoughtful and curious as to how I make claims about my findings.

Finlay (2002) refers to intersubjective reflexivity. Some of the interviews were quite emotional for both the participant and me, and I felt myself wanting to provide therapeutic support, at times, outside of the interview process itself. The interviews felt emotionally draining. The risk procedures required me to call the participant within 24 hours which I willingly undertook. I found it useful to write notes about each participant to help me recognise and process the transference of the interview encounter. I also have sought to embed reflexive practices throughout the research process, as part of RTA, referred to below. It occurs to me that I started practising reflexivity in different ways.

Reflexive Notes

I was naïve about the role of reflexivity in our Counselling Psychology training at the outset and indeed only partially aware of its importance in qualitative research. I had just completed a MSc in Clinical Mental Health in the Department of Psychiatry at UCL prior to commencing the Doctorate at City, and do not recall a single mention of reflexivity in the two years at UCL! I found the constant practice of it early in Term 1 at City, quite irritating and thought it was a filler exercise instead of theory and academic teaching and logged this with my Year 1 Personal Tutor. I believe I have travelled a long way since that first Term in 2021 at City.

5.16 Methodological Challenges

I encountered a number of methodological challenges at different stages of the research.

5.16.1 Data Collection and Recruitment Challenges

Savin-Baden & Howell-Major (2013) refer to the challenges posed to outside researchers by having to convince potential interviewees to participate and that sites may have a gatekeeper who may have varying degrees of control over invitations. I was employed by both Trusts within the Psychology team, and therefore had full daily access to sites, clinical records and participated in team meetings, and was therefore not an outsider.

The main recruitment challenge was in relation to the role of gatekeeping. Eliciting responses from Keyworkers as to whether I could make the initial approach to the interviewee was time consuming and hard. I was present in most of the clinics weekly and attended regular team meetings and I got to know some of the Keyworkers very well. Keyworkers are overstretched with large caseloads; the work is complex and challenging. In one clinic, there was a significant turnover of staff and caseloads were often being reorganised and in constant flux. Sometimes a Keyworker had only just taken on a case and was not familiar with the history or was handing the client over to a colleague. In another case, I made an approach to a Keyworker via email several times without response. The Keyworker then went on sick leave and then subsequently left the clinic, leaving the case load unallocated.

To a certain extent, the researcher adds to the Keyworkers' workload. The women I spoke to tended to respond and engage positively with the recruitment process. There were also women I never managed to reach by telephone and who did not respond to invitation letters. No women responded to the poster directly. Reception areas in clinics promote a significant amount of information about time and dates of recovery and wellbeing groups, or the availability of foodbanks, crisis numbers, warnings about the circulation of adulterated illicit drugs, or information about Naloxone. It was difficult to achieve standout on most notice boards.

5.16.2 Secondary Data Collection

My design included a secondary data collection from journals or notes which I asked each participant to contribute after three weeks. All were enthusiastic to this request, and some spoke of diaries or journals they already kept. Yet only one participant returned any secondary data.

5.16.3 Evaluation of the Research

How this study and its findings are evaluated and accepted by the reader has preoccupied me throughout. The healthcare journey of my participants is delivered in clinical settings informed by research based on empirical and positivist paradigms which include addiction psychiatry, perinatal obstetrics, behavioural psychology and legal and social care frameworks. This qualitative research uses methods of researcher interpretation and reflexivity to produce knowledge aimed to be useful in those same clinical settings. Willig (2019) stresses that all forms of qualitative psychological research not only aim to use recognised methodical, systematic and transparent processes to produce knowledge, but also endeavour to ground new ideas and findings in evidence that is open to examination and scrutiny from other researchers. This allows qualitative research to be considered as empirical. This point feels especially important to the objectives of my research, namely that its empiricism should enhance its goal of making to make a contribution

to in a clinical setting. The following sections on quality, originality and generalisability are aimed at demonstrating how I have sought to embed transparency and quality in the process of knowledge production.

5.17 Quality

The increased use of qualitative methods in the last thirty years has seen the development of markers and criteria by which qualitative research can be evaluated. Established frameworks include Henwood & Pidgeon's (1992) seven criteria and Yardley's (2008) four quality criteria. I have focussed in particular on the following markers of quality.

5.17.1 A Framework For Quality For RTA

Braun & Clarke developed a 15-point quality checklist (2006), and republished it, with an emphasis on the importance of 'time as a key resource for reflexive TA' (2022; p.268), and the development of strategies to keep fresh perspectives on the data e.g. gaining insights from others and reflexive journaling. Particular attention has been paid by me to the creation of time for the coding and thematic process, focusing on answering the research question, and the coherence between what was done, the described method and the reported analysis. I took care to provide an explanatory framework on the basis of the most important themes and the patterns in the data. I have found the Braun and Clarke framework useful as it is embedding good practice throughout all the stages of RTA.

5.17.1.1 Owning One's Perspective.

I particularly like the evolving guidelines produced by Elliot et al., (1999) for the clarity and examples given of good and poor practice in qualitative research. I found the framework helpful. Two guidelines resonated with me in particular, 'providing credibility checks', and the emphasis on 'owning one's perspective'. I sought clarification or additional information or validation on some data in order to triangulate findings or compare findings between cases. These examples are included in the results section. I have also sought to own my perspective, including a felt sense of risk and vulnerability of doing so.

5.17.1.2 The Coherence of the Design Framework and Research Question

Madill et al., (2000) stress the importance of qualitative researchers stating their epistemological approach so that readers can assess objectivity and reliability in order to place the findings within the researcher's framework. As outlined, the ontological-epistemological design framework of this study is critical realism and phenomenological, and it uses RTA as a method of analysis. It aims to produce insights from participant data drawn from the lived experience of a specialised healthcare journey in order to improve outcomes of that healthcare journey in the future. A key measure of quality for me is Madill's 'bottom line appeal of the research' and

whether the study helps facilitate the phenomenon of interest and 'productive action' (2000; p.13).

5.17.1.3 Originality

My interest in this research came from my work in a substance misuse clinic during my first trainee placement which started in the Autumn of 2021 in NHS Mental Health Trust Barnet, Enfield, Haringey; this work included two cases of women with OUD who were advanced in their pregnancy.

In March 2022, during our first year as Psychology Trainees we were required by City to submit a literature review supporting our doctoral research. My literature review was based on *'Women With An Opioid Substance Abuse Disorder (OUD) Who Become Pregnant: An Investigation Of The Lived Experience Of Their Health Care Journey From The Peri To Post-Natal Stages'.* During this stage, I identified a UK based, NHS supported research project 'The Stepping Stones Study' investigating the clinical guidelines of perinatal care of women who use substances (Radcliffe et al., 2024). The study had four sites in UK, multiple research questions and was well funded with a grant of £1.123 m by the National Institute for Health Research (NIHR 130619).

Enthusiastically, I wrote to Polly Radcliffe, the Principal Investigator and Senior Research Fellow at Kings College and asked if I could run a small qualitative study under the wider umbrella of this approved study and I sent her a proposal. Polly explained that their study was advanced and that it already had four UK sites. Polly very generously invited me instead to join the newly formed Expert Advisory and Co-production Group (EACG) which has met three times a year since spring 2022, to contribute the research aims and objectives at its different stages. It has been incredibly interesting to participate in the EACG and to be close to a large-scale research project, close to my own research interest. I was also somewhat overwhelmed at being on the same Teams call with the authors of some papers that I had reviewed in my literature search and felt rather self-conscious at not being to contribute sufficiently to the discussions, though my confidence grew over time. The study has now reported (April 2024) and its finding are published and included in this thesis as part of the literature review.

The declaration of my participation in the Stepping Stones EACG is deliberate and aims to be transparent. The methodological approach of the Stepping Stones study include significant differences to my own study. I have focussed my findings on my data, rather than on topics which emerged in the discussions over the last eighteen months and have aimed to reflect the patterns emerging from my participants authentically and fully show my commitment to originality.

5.17.2 Generalisability

Generalisation can be understood as the possibility of 'applicability to far more cases beyond the data or the study (Robertson & Norris, 2001, p. 303). It is an important yet debated attribute of qualitative research. Quantitative research relies on design features which include random sampling, comparison with controls, reliability and validity, in order to make inferences about its sample to a wider population whereas qualitative research is characterised by the investigation of a small number of participants or data set which might represent a small sample of a complex context (Roald et al., 2021). The case for the capacity of qualitative methods to make generalisations has been built significantly over twenty years and qualitative research is recognised as having a role to play in contributing knowledge, to a wider population and settings beyond those included in the original qualitative design, especially in healthcare settings (Carminati, 2018; Osbeck & Antczak, 2021; Willig & Borcsa, 2021).

Individual case studies have been argued to make significant contributions to scientific knowledge and theory, and the value of studying a small number of cases to understand a phenomenon of interest in a wider setting is widely recognised as a strength of qualitative methodologies. In mental health research, Willig & Borcsa, (2021) point specifically to what qualitative research needs to include to enable the researcher to provide insight and answer specific research questions. This includes providing systematic and transparent procedures to the research processes and analysis of the data.

I have sought throughout the data analysis to extrapolate insights from the data set to the wider prescribed healthcare model for women with OUD. The capacity of this research to make generalisations beyond the study setting is an overarching goal of the study and has motivated me to drive the research forward through its many challenging phases. Slaney & Tafreshi,(2021) propose three main types of generalisation amenable to qualitative researchers - naturalistic, analytic and transferability. I am motivated by my research's transferability. I have adopted some methodological features which I believe support this goal. Firstly, the research has a specific research question, aims to contribute towards a body of knowledge and has a transparent and stated methodology (Willig and Borcsa, 2021). I have taken 'terminological precautions' by declaring the philosophical roots underpinning the study (Carminati, 2018; p 2099). My epistemology is phenomenological, and I have set out to investigate unique and individual lived experience and identify patterns which may relate or differ to the cohort as a whole and general aspects of the experience. I am therefore moving from an individual data set to a data set from five participants to findings at a more general level which help me answer the research question. I have aimed for situated generalisation which includes human subjectivity, context and

interconnections of phenomena and set out to produce knowledge though the generalisation of the subjective (Schraube & Højholt, 2019).

I have engaged actively in reflexivity throughout and to describe these processes. I also view my findings with a critical eye and acknowledge that generalisations may form working hypotheses (Slaney & Tafreshi, 2021). I also acknowledge that the generalisability and transferability of the research findings rests ultimately with the reader(s). It is with the clinicians in the NHS Trusts where the research took place, and agencies involved in the healthcare journey of women with OUD who play a key role in embracing or accepting any potential generalisability and transferability to help inform improved healthcare models.

5.18 Appraisal of Reflexive Thematic Analysis

There are four main reasons for which the choice of RTA has felt like the best fit for this research.

5.18.1 RTA as a Qualitative Approach Method

RTA is frequently described as being a method of qualitative analysis independent of a particular ontological and epistemological approach (Terry et al., 2017; Willig, 2013). At the outset of the research, it felt important to keep the experience of the women at the heart of the research, yet also consider the complex context of their lived experience. The selection of RTA is coherent with an epistemological stance, notably a phenomenological approach, within a critical realist frame. It allows me to recognise the biological and environmental reality of the women's complex healthcare journey but also acknowledge that their experiences are unique and mediated by an interplay of science, biology, embedded healthcare structures, and societal factors including attitudes to motherhood and women and mothers using substances, especially illicit heroin.

5.18.2 RTA Within NHS Settings

I also considered an aim of the research within an NHS setting. Qualitative research has started to play an important role in contributing towards mental health research alongside quantitative methods and its eminent cousin, the Randomly Controlled Trial (RCT) (Peters, 2010). Within the qualitative approaches, RTA is known amongst many NHS Clinical communities. This was not a primary reason – but it did contribute to my choice of RTA as a qualitative method.

5.18.3 Coding Framework

RTA allows for a degree of flexibility in the coding approach. I wanted to capture the experience of the women, and therefore the primary approach to coding was inductively led i.e. to look at meaning in the data and for patterns in the women's experience (Braun & Clarke, 2022). However, having worked within substance misuse for a year prior to formalising the research, it felt useful to understand the women's experience at greater depth, by taking account of theory

relevant to the field of healthcare and substance misuse. This has felt especially relevant in terms of the experience of stigma, powerlessness and power which is recognised in healthcare settings (Scambler, 2009; Stangl et al, 2019) or theories relating to Neonatal Abstinence Syndrome (NAS) (Boardman et al., 2022; Grossman & Berkwitt, 2019). The ability to develop a coding approach which captured inductive and deductive meanings and patterns has felt useful.

5.18.4 Iterative Levels of Understanding Through Second Sources of Information

As the coding progressed, my understanding of differences in the experience of the participants was enhanced by discussion with co-workers and professionals. For example, these allowed for a better understanding of why some women's prescription of opioid replacement therapy (ORT) was rapidly reduced post birth, whilst for others it was retained for several years post birth. There were stark variances in the accounts which felt important to understand, in order to make sense of them and interpret them. Another query was why some women were prescribed one form of ORT e.g. methadone, whilst another Subutex. Secondary sources of information included professionals who are expert in the topic e.g. addiction psychiatrists, or senior social workers. This information enabled me to contextualise and interpret data and use the iterative nature of RTA analysis which provided deeper understanding of the data before organising themes.

5.18.5 Reflexivity as a Creative Resource and (Personal) Container

All qualitative methods require reflexive involvement from researchers and Finlay (2002) describes this as the defining feature of qualitative research. I felt motivated to use myself as a resource within the data analysis. I was aware at how hard it had been just to get to the starting block of receiving ethical approval, and realised I was thinking about it extensively. I liked the potential positioning as an active and reflexive agent in knowledge production (Finlay & Gough, 2003; Trainor & Bundon, 2021). I thought RTA would help structure my relationship to the topic which had developed over two years.

I like Coyle's description of developing a 'speaking position' which is made up of theoretical commitments, personal understandings and personal experiences (Lyons & Coyle, 2021, p.20). I also deemed it would be useful to recognise types of reflexivity and I wanted to understand as I progressed the influence on analysis and interpretation. Finlay (2002) proposes a map of five different forms of reflexivity, and I focussed on three in particular e.g. introspection reflexivity, intersubjective reflection and social critique. My engagement with reflexivity was different for each of these. For introspection, I considered my personal journey as a researcher and Trainee was only interesting within the research, if it could contribute towards an understanding of meaning in the data. The intersubjectivity between the participants and myself felt as if it was at the centre of my

reflexivity. In terms of social critique, it seemed important to think not only of the issues of power but also the age difference which might confer an authority or a maternal role on me. RTA felt relevant personally, in that it provided an approach in which my proximity to the topic could be both levered, acknowledged and contained, and reflexivity was key to this.

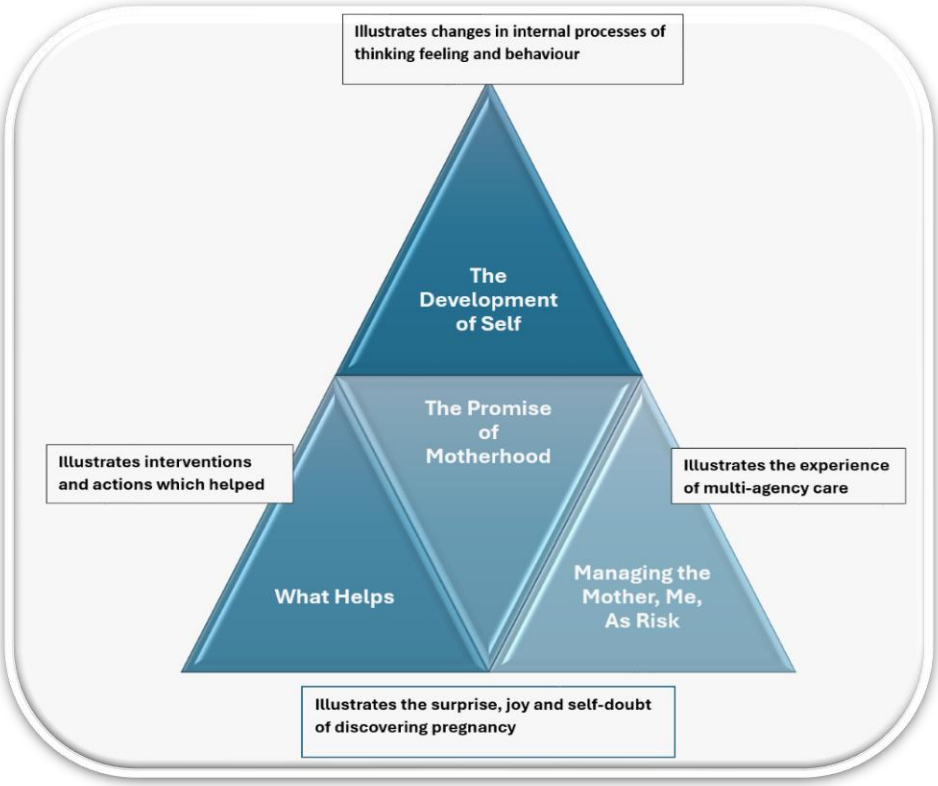
6 CHAPTER 6 Analysis

6.1 Introduction to Themes and Sub-themes

The analysis generated four main themes which are presented as an overview in Figure 6. The main themes link a series of sub-themes which are presented in Table 8, followed by a narrative account with illustrative samples of the data.

The analysis shows journeys of immense personal challenge, at the end of which two women have custody of their children, two have kinship arrangements where the women's parents have legal guardianship, and one woman has her youngest two children in foster care. Prior to pregnancy, four of the women had a relationship with the substance misuse clinics though two of the women were ambivalent about maintaining OST and two of them were consistent in adhering to their methadone prescription. Three of the women describe relapsing within two years following the birth of their child and four were on OST at the point of the interview. The women showed high levels of emotional bonding and attachment to their children, whether they had custody or not. They all described aspects of their healthcare experiences from pregnancy to motherhood as difficult and challenging, portraying journeys of immense personal change as to how they viewed themselves and how they managed their substance use and motherhood. All of the women spoke openly about interactions with the agencies involved in their healthcare, and all of the women described some interventions and behaviour from others which they found helpful.

Figure 6: ***Overview of Main Themes***



The first theme, *The Promise of Motherhood*, seeks to show the early experiences of surprise, joy and self-doubt on discovering pregnancy, which was characterised by the sense of being viewed differently by others. *Managing the Mother, ME, as Risk*, portrays the difficult experiences of the women in multi-agency healthcare through pregnancy, and the programme of tests and monitoring. Many of these experiences resulted in feelings of fear and shame. The third theme *What Helps* illustrates the varied ways the women felt supported, by structures, processes and interactions. Table 8 illustrates each main theme with its sub-themes. The fourth theme *The Development of Self* shows the women starting to think about themselves differently, moving from one of self -harm to one of motivation to re-engage in OST, to change or adapt substance use patterns on behalf of the baby and themselves.

Table 8: *Themes and Sub-Themes*

	Themes	Sub-Themes
1	**The Promise of Motherhood**	• Surprise, joy and self-doubt • Being seen differently: sharing the news • Engaging in new beginnings • Meanings of pregnancy
2	**Managing the Mother, Me, as Risk**	• Instruments of power • The case against me • Judgement and stigma • An unnatural act: child removal
3	**What Helps**	• Understanding my journey • Yes, to information. • I'm glad they are there: Substance Misuse Services • Social Connection • Loss & Healing
4	**The Development of Self**	• Ambivalence to engagement • Agency for two • Non-linear recovery paths • Evolving identities

6.1.1 Theme 1: The Promise of Motherhood

The first theme, ***The Promise of Motherhood***, aims to capture the elusive nature of a promise and the women's belief in the potential of motherhood to bring change and better things. It captures the early experiences of surprise and joy on discovering pregnancy, marking a shift in a pre-pregnancy ambivalence to engage with services and treatment.

6.1.1.1 Surprise, Joy and Self-doubt

All women expressed positive emotions on discovering they were pregnant, describing their pregnancies as unexpected and unplanned, with at least two women admitting doubt that they could get pregnant. All of the women were in relationships at the point of discovering their pregnancies, with two of these relationships stable and ongoing at the point of the interview. One of these was with a substance using partner and one with partner who was non-using. The discovery of pregnancy saw a change in how the women saw themselves.

Gail had four children and had started using heroin at the age of fifteen; she had her first child aged fifteen. Here she describes her feelings on discovery of being pregnant with her third child at the age of 34 years old. She was in a relationship and had described the pregnancy as something which both herself and her partner wanted.

''I was so happy. The first time I found out I was pregnant…I went straight to the hospital… I just wanted them to confirm (it) with me. And… they took me for a scan. And they done the pregnancy shot, and they said, yeah, yeah, you' re pregnant''.[Gail]

Gails' positive emotions were also marked by disbelief in her own fertility ability to get pregnant due to the use of substances. She talked about how she had started to give up trying to get pregnant, believing that she no longer could.

Megan had started using heroin when she was sixteen-years old and was on methadone at the point of becoming pregnant. Similarly, Megan's disbelief in her own fertility was marked by self-doubt in a potential role as a mother, and this lack of confidence was related directly to her heroin use and the way she saw herself living.

''I was in love with the children, but because of my world…I never think I'm gonna be a good mom… Because.. the way I was living...I was needing…you know the heroin... I never done something bad to someone else. I was doing something bad to myself like….. I was still going on that road. I was good with the children. But I never thought I was going to have one by myself, because of the way I was living.'' [Megan]

Megan appears to be clear about the self-harm she recognised she inflicted on herself. She seemed to suggest that she could not imagine a life very different from the one she was living, as a user of heroin, or that she could ever become a mother, even though she had a concept of a 'good mom'. Megan had been using heroin for twenty years at the point of becoming pregnant and did not seem to be able to imagine herself in a mother role, prior to pregnancy. Her joy was marked with self-doubt about assuming the 'good mom' role. She seemed to see others in this role e.g. her sisters but could did not believe she could assume it.

6.1.1.2 Being Seen Differently: Sharing the News

All women described how they shared the discovery of pregnancy with close family members, especially mothers and sisters. Communicating pregnancy news with family members demonstrates not only the importance of bonding with family members but also how pregnancy and the arrival of a baby allows family members to fulfil future and expected roles as grandmothers, uncles or aunts. The news was also shared with close friends who did not always know of the substance use history. The women's accounts suggested that the interactions were positive and contributed to how the women started to view themselves and this supported the development of belief in change, new identities and roles in the family.

Linda had a close relationship with her parents, her mother especially. Her account of sharing the news with her mother suggests she was fulfilling a normative role as daughter, and that she was meeting an expectation to have children. This bonding between Linda and mother is likely to have contributed to Linda's commitment to move forward with the pregnancy and to step into a new role.

''I told my Mum straightway I think when I found out I was pregnant. And …we discussed what I'm going do, and my Mum always spoke about children, and she's been waiting for children. And I said yeah, I'm going to have it…''. [Linda]

Megan came to the UK from another European country, and she had no childhood friends or family members in the UK. Her account of communicating with her friends in her country of origin who were not aware of her heroin use suggested a new way of bonding with close friends, and a new way of being seen by them. She communicates that they were happy for her, in her new role as expectant mum and voiced the doubt they likely had for her as becoming a mum due to her 'crazy' life and being too old. Megan seemed tentative, almost shy of how she now might be seen by them and the positive affirmation she has received as a result of sharing the news.

''That was feeling good. Not all of them knew that I was on methadone, my closest friends, they know…but some of favourite friends, they didn't know… I told them and they were happy because they never thought I was never gonna be a mum…because my life was, you know, a little crazy, ….And they never think I gonna be a mother because I got pregnant later when I was 35''. [Megan]

In the examples provided by Megan and Linda, it is the communication with family members which help confer and strengthen beliefs in change. Identity theory suggests that interactions with others would help confirm or deny the development of a new identity (Stets & Serpe, 2013). These early positive affirmations with family members and experiences of being seen differently may have helped both women think about themselves differently, with a nascent identity as a mother. This is likely to have helped them forego their long-held attachment to being a substance user.

6.1.1.3 Engaging In New Beginnings

The research did not seek to investigate the underlying reasons for substance use. The theme of ***Engaging in New Beginnings*** aims to provide context of the women's experience and journeys. Here, I show the patterns of substance use at the start of pregnancy. All the women described embedded use over long periods ranging from six to twenty-five years. The women revealed rapid progression to heroin use, the use of crack and heroin together, experiences of dependency, and experiences of spiralling out of control. The women were all aged between fifteen to twenty-one years old when the heroin use started; they showed a lack of awareness over the risks, and development of their dependency. The women, in hindsight, recognised points at which they felt their dependency was developing and the sense of losing control. Elizabeth described the speed at which she felt she was dependent on heroin, and the need to combine crack and heroin.

''It just completely spiralled out of control..You…you just completely lose track of time, you lose who you are, you lose everything. You just think about that drug. And then the crack cocaine and heroin goes hand in hand.. most people can't take the crack without taking the heroin. So, then the heroin addiction started… straight, straight away, to be honest, about two days in from starting to take crack''. [Elizabeth]

Heroin and crack have different effects on the brain's reward circuit, with contrasting effects of euphoria and relaxation versus intense stimulation to feeling distressed. The rapid adoption of using both by Elizabeth would likely be to balance the contrasting effects of each drug. Elizabeth described trying to get hold of cocaine from her dealer and using heroin without understanding what she was taking. Elizabeth was the youngest participant and her description of her first use of heroin was the most recent. At the point of discovering pregnancy, Elizabeth was the only participant who had had no contact with substance misuse services.

Prior to discovering pregnancy, the remaining four women, Gail, Linda, Janet and Megan had been in contact with services, and all four of them intermittently combined OST with heroin and crack. Janet had been in contact with services in the past, before her second pregnancy. At this stage, they would all have been routinely tested for illicit opioids, if they were collecting a prescription of OST. What is notable in the four women's accounts is the shift in readiness to talk to their keyworker in the substance misuse services where they were registered, to re-engage in OST and undertake recovery work.

'' I don't think I was registered in a clinic at the time; then after I found out I was pregnant, I went to Clinic 2, to get on a script. They were helpful. I was with a lady called Sally; she was a

really good Keyworker at the time; I was actually trying to do lots of groups, once I got back on my script and I found out I was pregnant, I was actually trying to really engage, and I was doing lots of groups and things like that''. [Janet]

Janet did not express any doubt or sense of hesitancy about renewing contact with the substance misuse service which she previously knew. The readiness to reach out to SMS clinics at an early stage of pregnancy is important to the women's journeys. Elizabeth was in another city when she discovered she was pregnant and in active heroin use. She described having had no contact with services prior to this point and contacted an NHS substance misuse service and she described the support as helpful.

6.1.1.4 Meanings of Pregnancy

The meaning of pregnancy varied for the five women who show variations in the motivations for the pregnancy and what motherhood might mean to each of them. In Elizabeth's account, she identified pregnancy as a reason not to be an addict, suggesting that the pregnancy was a means to end her addiction and to support recovery. Elizabeth's account suggests she identified as a 'drug addict' and that pregnancy provided a reason to shed this identity, as if the state of being an expectant mother and an addict were mutually exclusive. It also suggests that Elzabeth identified pregnancy as an external reason to change, as a way out. Her emphasis was less on becoming a mother, more on a not being an addict.

''I was in active addiction when I discovered I was pregnant… about two months in… I was happy because I saw it as a way out of my addiction. …Right! I have a reason now…not …to be a drug addict. This is my reason to give up drugs now.'' [Elizabeth].

Megan described a strong motivation to engage in training, enrolling herself in an online course, suggesting that pregnancy promoted thinking about the future, engagement in structure and an interest in personal development.

''The moment I find I'm pregnant, I signed myself as a student in a college, so …. in the time when I was pregnant… I was in college.''[Megan]

In three cases, the meaning of pregnancy related to the relationship with the partner, two of who were substance users. In Linda's case, the discussion of the pregnancy with the substance using partner presented them both with the possibility of change, and both of them engaged with the clinic, OST and abstinence.

''When I got pregnant… my partner, he's a user as well, so he went to the clinic, and I was using at that time … he said it makes sense if we both join as a couple.'' [Linda]

All of the women shared thoughts and feelings about the involvement of romantic partners in their pregnancies and lives. The women described them as substance using or non-substance using, and the contribution towards positive outcomes for the women is mixed. In Gail's case, she felt her pregnancy consolidated her love for her partner, who she believed was non-substance using at the time. He had started using heroin after her third baby was two, and Gail started to use heroin again too.

''And then she just came up out of the blue... It was so great! When I found out that I was pregnant, with her, it was just so nice. I was so in love with her Dad, and all I wanted was to have a baby with him, and I knew that's all he wanted.'' [Gail]

There is variation in the meanings of pregnancy for the women though all of the women saw pregnancy as a harbinger of change for themselves.

6.1.2 Theme 2: Managing the Mother, Me, as Risk

Prior to pregnancy, Elizabeth had had no contact with substance misuse services. Gail and Megan were accessing OST at a clinic, and Linda and Janet had had contact with services in the past but recent attendance had lapsed. All five of the women were actively using heroin and crack. The women's main relationship with the NHS at this point had been with their GP, the addiction psychiatrist, recovery workers, their keyworker. The women's pregnancy initiates a multi-agency health care model with different teams, in different locations across the footprint of the Trust, notably with perinatal services and social services. At this point, the women experience a significant increase in attention from the NHS and social services, as well as interactions with individuals who they were likely meeting for the first time. The women's initial early joy on discovering pregnancy evolves into experiences of anxiety, anger and fear, as they interact with many different healthcare practitioners across different services. Their accounts relate to a process in which they are managed as a risk to the developing foetus.

6.1.2.1 Instruments of Power

The significant number of processes and devices which make up the multi-agency healthcare were largely experienced as negative and frightening by the women. These included inter-agency information sharing, meetings, reports, and tests. These processes facilitate the functioning of multi-agency protocols and are procedures embedded within structures within the healthcare system and the healthcare journey which the women start to take. *Instruments of Power* illustrates how the women experience these instruments which they do not hold, the processes which they could not control, and from which they could not withdraw without risk. The consequences of not participating in meetings or processes was not clear for the women.

Linda had renewed her relationship with the substance misuse clinic and discussed alternatives for managing OST during pregnancy with the addiction psychiatrist in a constructive way. Agencies are obliged to make referrals where a child safeguarding case exists. Linda described how she learned about the involvement of other services and professionals. The sharing of information between clinical teams, agencies and services was experienced as frightening by Linda and she withdrew from contact from services.

''The first time I knew of social services involvement was when my social worker called and introduced herself …she said that my midwife would've told me that she's passing the matter on to the social services. I explained to her that I wasn't aware, no one had told me anything. I also spoke to my key worker at Clinic 2 and… said to her that I feel the midwife was too quick to report me as getting clean is a process, my keyworker said 'oh I've reported you too'…I'm not sure whether legally they were meant to tell me or not, but it was quite a shock and scary. It made me afraid to work with social services and I didn't engage with them for a month whilst going to my Mums …to get clean.'' [Linda]

The involvement of a new agency, unannounced to Linda would likely have felt as if the system has power and authority to convene her and become involve in her recently discovered pregnancy, without her knowledge or consent. The multi-agency model increased the numbers of interactions and appointment she was required to have with services and individuals who she did not know. The reporting of the midwife stemmed from Linda continuing to show unclear tests, after she had ceased to use any substances which is not unusual. This led her to feel the process of getting clean was not understood by the midwife. In Linda's case, the discovery that a new agency had become involved, had her mobile number and had the right to contact her was experienced as scary. Linda's reaction was to withdraw from contact, as she was trying to come off all substances, as well as OST, and had a family she could turn to for refuge. The challenge of abstaining from both

OST and substance use would have been a difficult period and any additional stress or sense of threat would likely have been difficult to manage. In Linda's case, she had parent who were supportive and interested in her pregnancy though for many women, family support may not have been available. and moments of feeling under threat, risk women withdrawing from services.

In Elizabeth's case, she described meetings with her social worker as not reflecting her understanding of what had happened in the meetings in follow up letters and reports

''She befriended me, you know, pretended that she was my friend by asking certain questions and saying, oh, yeah, I can help you with this, I can help you with that. And then a week later, you'd get a report about our meeting. And it says a completely different thing to what actually happened in our meeting.'' **[Elizabeth]**

Elizabeth also felt the written communication did not reflect the friendly tone which existed at the meetings, and that the friendliness served an ulterior motive to get information from her. This damaged her trust in the individual and the process. Once again, Elizabeth did not feel that the production of a report and its content was available for her to influence or use. These tools were only available to one party. At a later date, Elizabeth expressed the view that she would record all meetings if presented with the same situation in the future.

The use of tests and monitoring was another process experienced as threatening. It is usual to test new-borns in the Neo-natal Care Unit (NCU) who have been opioid exposed for Neonatal Abstinence Syndrome, (NAS). The process of NAS testing was experienced as extremely difficult by several women, with the feeling of the baby being interfered with, or the tests being withheld from the mother who was not trusted to be in the know. Gail described her baby being taken away for tests in the NCU, and her conversations with a doctor on finding NAS paperwork which she felt was being deliberately hidden from her.

''Furthermore, you took my daughter under the pretence that she had a cough, and I found this withdrawal sheet under her mattress.. with zero, zero, zero on it. '' ***[Gail]***

These processes of inter-agency referral and information sharing, reports, and tests were experienced as threatening by the women and disempowering. A factor common to many of these processes was the lack of information about the process or event. There were many more examples to illustrate this theme.

6.1.2.2 The Case against Me.

The obligation for the women to engage with individuals from different teams and clinicians from different disciplines was experienced as difficult by all five women. The women expressed feelings

that they were expected to fail and were not trusted. Elizabeth experienced it as a case being mounted against her as an unfit mother, which would result in child removal.

''As soon as I met my social worker, she wasn't there to help me at all. She was there to build a case… straight away. She weren't there to help me. All she was doing was building the case straight away. So yeah…Where the social worker would just say to me up front, blank, 'I'm taking your baby, we know you're not going to be able to do it, your baby's getting taken. So, you might as well just give up now'. You know what I mean?'' [Elizabeth].

Janet similarly felt the weight of engagement with multi-agency care and described this as being under attack. She also felt that what she was saying was not being represented accurately, and that she was being set up to fail. Failure would result in child removal.

''And they were trying to make me do all these different things, that were like difficult, whilst trying to be on a script, going to my appointments at hospital, being pregnant for the first time, not expecting to be pregnant, not being in a stable relationship, it was just a lot. They were trying to get me to engage with all these different agencies. I just felt like I was being attacked. And they were going to take away my child, my first child, without giving me a chance. That's exactly what I felt…and doing all those hair tests. And FDAC. And all these different social workers, and whatever I was telling them, it was kind of like getting changed. I felt like they were waiting for me to fail basically. Setting me up to fail. I still feel like that.'' [Janet]

My understanding from Janet was that she knew what failure would look like, and would result in her child being taken away, but did not know what the criteria for success looked like. She felt the multiple interactions with different socials workers resulted in what she was saying and doing as being reported inconsistently and differently, and that it was assigned meanings in contexts with which she was not familiar. The sense of a case being made against the women created a sense for the women that even engagement and compliance in processes was not sufficiently good enough in itself.

6.1.2.3 Judgement and Stigma

All the women gave examples of feeling stigmatised by being pregnant and a mother, with a diagnosis of OUD. The experiences of stigma varied, as to whether it stemmed directly from an interaction with a healthcare worker, or whether it stemmed from an internalised sense of shame. Elizabeth was angry throughout her description of her time in a MBU, where she recounted feeling very ill and being forced off, within three weeks following birth, Subutex, the OST medication

prescribed by the substance misuse service. In her comparison with her relationship with the substance misuse service, she felt both the social worker and midwife told her directly that she was being written off by them, and would not be able to become clean, or that she would retain custody of her child.

''…Where the social worker would just say to me up front, blank, 'I'm taking your baby, we know you're not going to be able to do it, your baby's getting taken. So, you might as well just give up now'. You know what I mean?'' [Elizabeth][2]

[2][The interaction between Elizabeth, the midwife and social worker did not take place in the participating Trusts of this study and Elizabeth's place in the MBU was not commissioned by them].

The women were required to attend appointments with perinatal services during pregnancy which is routine practice for all women during pregnancy. Linda described difficulties in meetings with perinatal services where she would routinely meet a new midwife and would need to explain her particular circumstances, unique to her. In Linda's case she managed to come off all illicit drugs as well as buprenorphine under the guidance of the addiction psychiatrist during the pregnancy. She was required to ask mid-wives for toxicology tests, and was obliged each time to explain her personal history of substance use and tell them that she had used heroin and crack in the early phase of pregnancy.

''…Can I have a toxicology test? Then you have to explain yourself and, say… at the beginning there was substance use. Like one midwife... when I saw her, my blood pressure would go up... So, then she sent me for an extra scan to check the baby…and they said the baby is fine, the baby is big, is growing… I just felt like ...there might be a bit of judgement … just because I've told her…there was a bit of use, especially maybe the type of drug, as they know what I'm taking.''[Linda]

Linda felt judged, not only because of substance use, but because she had named the heroin and crack as the substance she had been taking at the start of pregnancy. Her internalised sense of shame may have come from non-verbal cues from the midwife and being sent for another scan.

Janet internalised societal judgements and a sense of disappointment and futility, as to how she has ended up as a person she , herself also views negatively.

''Well, I didn't want to be using drugs…nobody wants to be a drug user and having a baby, and I always, I remember, I used to be judging people who were like pregnant and using drugs…I never thought I'd end up being that person.''[Janet]

Stigma theory in healthcare settings is defined by Scambler (2009) as a social process whereby a person with a health condition or problem experiences rejection, blame or devaluation, or some form of discriminatory and adverse judgement or behaviour. These are examples from Elizabeth, Linda and Janet and there were other examples in the accounts.

6.1.2.4 An Unnatural act

Four women described the experience or threat of child removal. Three of the five women described having had their babies removed, with two women using parents as legal guardians and one having her two youngest children placed in foster care, a year after birth. The experience was felt viscerally by the women. Elizabeth compares the feelings to what a wild animal might feel like, when a baby is removed.

"Even when you see animals in the wild, when you see their babies getting removed, and how they react, you can't just take someone's baby, for some reason like that! If I was mentally unfit or unfit as a parent with a low IQ, fair enough, take my child." [Elizabeth]

The women did not seem to expect child removal or seem to understand the conditions under which it might happen. Janet appeared to have little understanding that she would not leave hospital with her baby. She described the difficulty of returning home without the baby and family and friends asking her where the baby was, and how this contributed to relapse.

"**At the time, I didn't think they were just going to be able to just take my daughter away like that. ..after they took my daughter away, they told me to express some milk... I had all the baby stuff. I went home to my house, I had all the cot and everything there, so that was really traumatic.'' [Janet].**

The post-birth period and child removal was particularly difficult and associated with relapse. Janet went on to describe how she started using again to cope with the loss of her child, and the start of unfamiliar court proceedings.

6.1.3 Theme 3: What Helps

During the interviews, I asked the women what they felt would have been helpful or unhelpful in relation to their experiences and what they had been describing. All the women gave examples of what they thought would have helped them and these related to different stages of

their journeys and interactions with different departments. They represented examples of themes which are manifest in the data. I also identified themes which I interpreted in the data which were not specifically named by the women.

6.1.3.1 Understanding my Journey

Janet had a positive experience of spending time in a mother and baby unit (MBU) with her second baby and she made comparisons between the experiences of having her first and second child. For her second child, she felt the structure offered by being in the MBU was positive and she identified as being a mother, though her interactions with others. She participated in groups, was not in her neighbourhood associated with access to substances, and valued the trust placed in her to be a mother. The absence of threat from baby removal was highly valued, and she felt as if she was better known and understood by social services and supported appropriately.

''What was helpful, was having my son, and being able to be a mother, going to the groups, I felt positive. I'd been to the mother and baby unit. You know, I had time alone with my son, I had time not using, I felt secure. I had lots of structure [which]….came from being able to have my son, and him not being able to be ripped away from me. And not the pressure of thinking that he was going to be taken away, I put in the work, I had the opportunity to put in the work. They hadn't put me in a mother and baby unit with my first child. And they hadn't given me the opportunity, considering that I'd worked as a teaching assistant, I'd always worked with kids, children with autism. That I hadn't been given that support or opportunity with my daughter, so the fact that they gave me that with my son, that made me feel like I could be trusted.'' [Janet]

Janet assigns importance to being supported and trusted. There is a five year difference between the two ages of her children, suggesting that services had evolved and her experience of them was much better. Not all experiences in the MBU and Tier 4[2] rehabilitation centres were positive. What is interesting is that Janet felt as if she was better understood and supported with the right intervention the second time.

Linda provided contrasting examples of her experiences with mid-wives where she felt the changes in mid-wives resulted in a lack of consistency and different reactions to her substance use history. Linda valued the recognition and encouragement given to her by some mid-wives who had experience of substance use and the encouragement was highly valued by Linda. The switching between mid-wives required her to provide an explanation about her substance use history, with the risk of judgement. She felt a greater exchange of information between mid-wives, or ideally a team or midwife familiar with substance use and her unique history of it would help.

''It would make sense, to have one midwife in general assigned to your case…or at least if they update each other on your case… Because I just felt there was no consistency…and some of them felt … really cold. But some of them have been great. I had a couple of midwives who said, you should be really proud of yourself, not a lot of women manage to get through this. But I just think as if it makes sense to have some kind of team, or a midwife is assigned to you who can see your progress, that you haven't got to explain yourself constantly and be judged. And that they are skilled in that area, and they understand the substance use, the struggles and the journey.'' [Linda]

Linda pointed to the struggles and the journey that she had taken and wanted that to be recognised by mid-wives. In both examples, the women indicate that what would help is being understood. For Linda, what is interesting is that she called for mid-wives to recognise the progress being made, and be 'skilled in that area', as if it requires training.

[2][Tier 4 services are specialised residential alcohol and rehabilitation services]

6.1.3.2 Yes to Information

There was variation in the women's accounts of what information they had received, and when, and whether it had been clear. The four of the women who had had contact with substance misuse services prior to pregnancy would likely have received information about the impact of substances on themselves during their time with the clinics. This is routine for NHS substance misuse services to provide. It is likely they would have attended therapy, workshops and received psychoeducation. Yet, it was not clear from the accounts if and how the women received new information about the use of heroin, or the impact of opioids in relation to their new status of being pregnant, and the impact on the foetus.

Two of the women stepped forward to ask questions about the impact of methadone on pregnancy. None of them spoke of experiences of psychoeducation at the point in the early stages of pregnancy. This was a point when the women appeared to be open to new learning.

In Elizabeth's case, she described learning about a syndrome called Alcohol Foetal Syndrome (AFS) in the mother and baby unit in which she had spent time in, in another Trust. What is curious about Elizabeth's words is her reference to AFS which is a syndrome usually used specifically for babies exposed to alcohol. Elizabeth's account includes descriptions of babies with AFS in the MBU, but does not use the term NAS, or any other term, for which her baby would likely have been tested.

..''In the rehab, I've actually learned of something called AFS -alcohol, foetal syndrome - where your baby can actually have deformities from taking drugs and drinking alcohol. But no, no one told me anything like that! There was no information around that at all.'' [Elizabeth]

Earlier in her account, she felt threatened by the social worker's references to the possibility of her baby being sick and describes not having any information about the risks of alcohol and drugs to her baby. It is also possible that Elizabeth did not take the information in, due to the fractious relationship with her Social worker.

Linda provides an interesting account about the information and advice she had been given by social services which she appeared to be holding in mind, at the appropriate point. The information concerned the use of crack with an infant present, and how to separate the baby from the environment and to wipe down the gear, to avoid the crack particles being ingested or reaching the infant.

''…The things I've learnt being with the service about the particles…Just like getting the gear out, it gets into their system, you know, it all gets passed on to them…that [information] was through social services…because they said, you know, there might be some use, as you are still at early days whatever, and they just want you to be doing it safely…they just taught us about how to keep her locked away safely, and to wipe down the gear.''[Linda]

Linda's recall of it suggests she found it useful and that it was given in a non-judgemental way and was recalling it at the point of the interview when the baby was 6 weeks old. This suggests that the information was communicated and retained in a constructive way. Linda also recalled that she had been warned by social services that her baby would be deformed if she continued to use drugs and would need monitoring in hospital. Linda therefore asked questions once in hospital though she referred to not having received any information about tests from Midwives – just from social services.

Gail suggested that she had never really been made to understand the severity of drugs, and that she had come from a family which did not talk about drugs at all.

''That's why I didn't think it [*drug use*]was so bad because, it didn't get addressed. It didn't get talked about…I wasn't made to understand the severity of my drugs…of what I'd done… I don't know; maybe if they had done something with me, maybe like maybe go to courses or classes or something.'' [Gail]

The information flow towards the women appeared inconsistent, with some feeling they lacked information and in hindsight would have liked more, or recalled information, suggesting

that it was retained and useful. The variation in the women's account raises the question of role of information in the healthcare journey, and where responsibility lies between agencies to provide the right level of information.

6.1.3.3 I'm Glad They are There: NHS Substance Misuse Services

There were expressions of gratitude for the presence of NHS SMS services. This related to periods pre-pregnancy, during pregnancy and post pregnancy, suggesting that the relationship the women had with the NHS substance misuse services lasted many years and was valued. Linda expressed gratitude for the presence of substance misuse services, for being able to see someone or get medication, making comparisons with other places, which I understood to be her European country of origin, where substance misuse services might not be available.

''I think just having the services in general, that you can go to, and that you can meet, or be given some sort of medication or some help, or able to see someone, that alone is helpful. In other places, you might not get that… It's something to be grateful for.''[Linda]

Elizabeth's description suggested she valued the relationship with the staff at the NHS substance misuse service she contacted, on discovering pregnancy, for the sense of being cared for, and the sense of re-assurance provided by her contact at the clinic. Elizabeth described a particularly fractious relationship with her social worker who she did not trust and a midwife in the MBU and draws comparisons with her relationship with the substance misuse clinic staff.

''They were just more supportive …and more like… caring. And they were there for you more, especially being pregnant, they just helped you more like and… told you like, things will be okay.'' [Elizabeth]

NHS substance misuse services can apply for funding for Tier 4[(i)] Services for clients. In Gail's case, she was given the opportunity to attend residential rehab after her third and fourth child were taken into care, and her eviction from her council home, when she was living on the streets.

[i][Tier 4 services are specialised residential alcohol and rehabilitation services]

''They were the one that put me in the rehab. There is a lot more they could do. They never made contact me when I was in the rehab, they just put me in the rehab, that was it…I didn't hear nothing from them again until I came back…. But people.. when they think you're off, you just become a nobody.''

Gail seemed to experience the organisation of rehab by the clinic as rejection and a rupture in the relationship as a familial bond, suggesting the attachment to the services is familial,

underpinned by an emotional bond. She experienced the lack of visits and contact with them as a rejection and felt diminished by the lack of interaction with the NHS service she knew very well.

In all the descriptions of interactions with the NHS substance misuse services, the women used first names of their keyworker, suggesting there was a close relationship, and they trusted this person. There is a singular lack of references to first names in all accounts with any service outside of the substance misuse services, with the notable exception of one senior social worker named by Linda. The relationship with the substance misuse services may have lasted many years and seemed to form a key part of the fabric of the women's lives.

6.1.3.4 Social Connection

Connection with other parents, or a wider community of neighbours in the post birth period provided women with new relationships, sources of information, friendships and resources. It suggested that becoming a mother fostered new relationships. Megan valued the contact with parents she met in the park and found social interaction meant she belonged to social groups which provided useful resources. It suggests that the contact provided a new community, outside a substance using community where her history was not known, and she could continue to develop in her new role as a mother

''So, when you are outside, when you are around the parents… in the park, you get information from everyone. Here is a group, there is a play-day, and when you go to that kind of group, you always get everything you need because there is always a person you know, and other young mothers; also, people … to help you …to connect to connect you to where you need to, or to what you want to. That's how I became to know – I'm gonna' become a teacher.'' [Megan].

6.1.3.5 Loss and Healing

For the women who had their children removed, there was an acute sense of loss, and sense of difficulty ahead, with an unclear legal process to face. These are acute moments of risk and relapse for mothers. Janet acknowledged that her recourse to comfort herself was to start using again.

''Obviously for me, my coping mechanism was to use, even though they tell you not, because you are trying to get your baby back. But going home to that environment, and everyone is like, where is the baby? And stuff like that…all the neighbours, your family and that. I had no one to talk to." [Janet].

For Elizabeth she expressed a sense of loss of her former life, with the relationship with social services experienced as a trauma, and the intensity of change required in rehab. She referenced

several times during the interview, a sense of loss of her former life and a lack of therapeutic support to come through it all.

''Maybe if I had some support with my mental health…or maybe in the rehab, if I had had some support for my mental health like counselling or therapy, on drugs-work but I was just coming off the street from XXX as a full-blown addict… I've left a whole life behind…all my friends, my ex-partner, all my associates…the trauma I had been through with social services…I wasn't doing well as I was missing my old life.'' [Elizabeth].

Elizabeth's parents took legal custody of her child which she felt was the best option for her and her child, and she acknowledged that she needed to heal and continued recovery from relapse in the post birth period. Elizabeth felt the interview had been a form of therapy for her, and it was the first time she had been listened to and talked about her experiences.

6.1.4 Theme 4: The Development of Self

The interviews show changes in how the women think and talk about themselves, and in their descriptions of thoughts, feelings and behaviours over the course of the months and years of pregnancy to the post birth years. All of the women shared descriptions of their lives prior to becoming pregnant, illustrating patterns of chronic heroin and crack use and a sense of chaos. Two of the women described being involved in sex work providing cash and access to drugs. The starting points of their pregnancy journeys were marked by chronic use and ambivalence to abstinence from heroin and consistent engagement with OST.

6.1.4.1 Ambivalence to Engagement

Prior to pregnancy, four of the women had contact with substance misuse services and started prescriptions for opioid substitution therapy (OST). One of the women started OST in an EU country before coming to the UK, where she continued with Clinic 1 on OST. All the women showed high levels of ambivalence to engage fully in recovery and continued to use crack and heroin, along with methadone. The reasons for this lack of engagement were not fully investigated in the interviews yet the women revealed that their ambivalence to OST stemmed from a lack of belief that methadone would work as a substitution for heroin and that factors maintaining use had not changed.

''I was 27-28, I start with the methadone… I was thinking.. it cannot help me to run from the heroin; I know, it's very bad to use them together…but I was still enjoying it.''[Megan]

The ambivalence to weave heroin use, with intermittent methadone scripts pervaded four women's accounts, suggesting that the initial contact with NHS substance misuse services was an important first step, but neither were the women committed to abstinence, or understood the risk and implications of combining methadone and heroin.

'' I'd been on and off of it; it wasn't a thing where I didn't want to be on a script, it is just that I hadn't bothered.'' [Janet]

The women would have been tested routinely for the presence of illicit heroin by the clinics, if they were prescribed OST. The ambivalence to fully engage in recovery suggests that underlying reasons to maintain substance use had not been addressed.

In Elizabeth's case, she had not been in contact with any substance misuse services prior to becoming pregnant. There is a sense of her being caught in a complex and vicious circle where she felt she had access to cash through sex work, which gave her a sense of control, yet, with the availability of cash to buy drugs as a means to cope with the sex work. Elizabeth would have been younger than twenty-four years old at this point, appeared highly vulnerable. She describes being without a familial network and being at a distance from support, as risk factors in becoming involved in sex work. She also described a sense of shame of her substance use and managed to keep it hidden as long she kept a distance from her parents and family network in her home town.

'' ***And I think to deal with that kind of line of work and the amount of cash… you have around you, ….you just end up spending it on drugs to be able to deal with the fact what you're doing. And you've got so much cash, what do I spend it on? You end up spending it on drugs.'' [Elizabeth]***

6.1.4.2 Agency for Two

All the women showed patterns of change in their thinking early in pregnancy. An example of this is the expressions of interest in how OST and heroin might impact the baby. Megan described a motivation and interest in wanting to understand the impact of methadone on the foetus and set out to gain more information from clinic 1 where she was registered.

''I have only one question that I ask people who were more informed. What should I do? Do I need to stop it now? Or what? …I think I was on 20 ml (of methadone). So, they say we just need to keep you on it until the end of the pregnancy…because …I may go through that … but the baby doesn't understand what's going on, so they say…they say better keep, better keep the methadone.'' [Megan]

All women described how they started to think and act on behalf of two, themselves and the baby. Janet described an important shift in thinking about the impact of illicit heroin on the foetus, and how methadone caused her to think differently, causing her to change how she set out to procure street drugs. Janet's description points to a sense of self-disapproval of being out scoring drugs with her pregnant 'belly', as if she is aware of how she would be observed and would even disapprove herself of a pregnant woman taking street drugs.

'' I felt more relaxed, always not having to go out and score. Or trying to get money whilst being pregnant. Also, I felt about the child, about me using the street drugs whilst being pregnant as well, like going to score with my belly and all that kind of stuff, and so it was easier when I was on the methadone.''[Janet]

A pattern in the women's accounts is that they seem to develop a sense of awareness of care for themselves, and agency in pregnancy. This is shown in their steps to gain knowledge about OST and to adapt and change their embedded usage patterns.

6.1.4.3 Non-linear Recovery paths

There are variations in the women's recovery paths in the post birth years. Linda and Megan described abstinence from substance use, with Megan continuing on a low dose of methadone (15 ml) from her regular clinic. Linda who had had her baby the most recently was abstinent and was no longer taking OST at the point of the interview. Gail and Elizabeth relapsed in the first- year post birth, and Janet described continued and current substance use at weekends. Gail became homeless and lived on the street for several months, with her youngest two taken into foster care. Gail attended a rehab unit and was eventually rehoused by the same Council who had evicted her, two years earlier.

Elizabeth reached abstinence later in the post birth year and showed a sense of regret of not having managed it earlier, and even a sense of futility of becoming clean. She uses the word clean to denote no substance use or OST. Elizabeth described her stay in the MBU as brutal, describing being forced off OST within three weeks post birth, only to relapse again, within months of leaving the MBU.

''Why couldn't I have been clean when I had everything to lose? I have nothing to lose…There are days when I think …what's the point in being clean? I've got nothing to lose now…you know.'' [Elizabeth]

Elizabeth had returned home to live with her parents and her baby. She describes this as being very difficult and, as a result of her relapses, her parents were assigned custody as

guardians, with Elizabeth having visitation rights. She contacted a Trust's SMS and was stabilised on Subutex. She was required to leave the family home, and at the time of the interview was living in a hostel with a non-substance using boyfriend, looking for work.

Megan had retained custody of her child and continued to receive a low dose of methadone. She described her continued use of OST as a young mother as part of routine medication, similar to blood pressure medication. She was careful to explain that she was not ready to cease OST yet.

''It's the same like people who take medication for blood pressure…You wake up, you need to take your medication, I take my medication and then ..go home…It's starting what… makes you go on your normal day… I know there will be a day where I have to stop it. I don't want to push it because I'm not ready.'' [Megan]

6.1.4.4 Evolving Identities

The women described their chronic heroin and crack use and an ambivalence to change. As they talked about their journeys of healthcare, they all reflected on their past, present and future which seemed to show personal growth and changes in how they thought about themselves, their identities and roles as mothers. Motherhood was enacted in different ways, which partly related to the legal status of custody of their children. The women managed their substance use in different ways, with four of the women describing not using substances at all, and one of them electing to use heroin at weekends, with her mother acting as guardian.

For Linda, she desired what she saw as normative identities, structures and goals such as 'being a mum', 'leading a normal life' and her child 'starting school.' Linda's vision of a future indicates a desire to move forward with 'how things are supposed to be.'

''I'm just generally looking forward to going back to work and just being a mum and like leading a normal life. Just how you are supposed to and how it should be. I'm looking forward to seeing xxx grow…and starting school and all those milestones.'' [Linda].

Gail expressed a desire to share her experience in schools as if recognising that her knowledge and experience might serve a wider societal purpose, which she wanted to contribute. This thinking suggests that she valued her accumulation of experience and knowledge, however difficult her experiences had been, and she wanted to share this with a younger generation, girls especially.

''I'd like to …get a little portfolio together of all my daughters' pictures…when she was born… and I'd like to go around to schools and talk to the children and girls about prostitution, about drugs and about what can happen to their baby if they take drugs when they're pregnant.''[Gail]

Janet described continued heroin use which she felt she had organised safely, in such a way that she was still assuming a role of a mother. Her mother had become the legal guardian of her children, and she remained active in their care. She recognised that being a user was not what her family expected or wanted of her, but it was a chosen path.

''As long as they are not around it and no one is coming to their environment, and putting them in danger, they are with my Mum, they are at home, and they get to school; that is as much as I can do. ..They've got mentors; social services are involved as much as they can be aware of what they are doing. It might not fit into everybody's else ideal. They always say, I've got so much potential, I'm always there for everyone else. They just don't understand why I can't give up the drugs for my children. I think that everyone feels like that.'' [Janet]

The experiences of the women show journeys of great personal challenge and difficulty, with variations in how they managed their substance use and reached a state of motherhood, where they retained legal custody of their children, or had access to their children through kinship or foster arrangements. The women show the development of internal processes as they reflect on their experiences of multi-agency care.

7 CHAPTER 7 Discussion

7.1 Introduction

This chapter summarises the findings from the analysis and reviews convergences and divergences with existing literature. I review the extent to which the analysis answers the research questions and consider the implications for clinical practice and Counselling Psychology.

The research explored the lived experience of the healthcare journeys of women diagnosed with OUD who become pregnant and give birth, and in the following post birth years. I approached this work as a critical realist, positioning the study on the continuum between positivism and relativism (Bhaskar, 1975; Bhaskar & Hartwig, 2010). This has allowed me to acknowledge the complex healthcare model, OUD diagnosis, interventions and multi-agency model experienced by the women in a specific context. I have aimed to explore the real world faced by the women and their meaning making of the structures, layers of realities and interrelated processes encountered during the healthcare journey (e.g. healthcare guidelines, attitudes towards motherhood and

addiction, attitudes towards them). Throughout this, the biological aspects of the context have been ever present and I have explored the subjective experience of being pregnant and being opioid dependent.

Five women, diagnosed with OUD, with children aged between six weeks to eight years old were recruited and interviewed in NHS substance misuse services using a semi-structured topic guide. The interviews were transcribed verbatim and analysed using Reflexive Thematic Analysis (RTA) (Braun & Clarke, 2022) from which four main themes were identified: ***The Promise of Motherhood; Managing the Mother, Me, as Risk; What Helps; The Development of Self.*** From the four themes and sub-themes, I have selected the following key findings for discussion.

7.1.1 Findings

7.1.1.1 Pregnancy as a Potential Pathway to Change

The analysis shows that pregnancy represents for the women a moment of change in how they view themselves, and this leads to a change in their patterns of substance use. All the women saw the potential of change in their circumstances, and the potential of a different version of themselves. All the pregnancies were described as unplanned and unexpected, and the news was shared with close family members at the outset. These interactions were described positively, allowing the women to experience positive emotions and to be seen differently within a known familial network. The women assigned different meanings to their pregnancies, according to individual contexts and status of personal relationships.

The notion of change is important in substance use work, and tiny imperceptible steps towards starting to think about change is involved in many approaches in substance misuse therapy (Prochaska et al., 2013). What is key here is the motivation to change. The change is guided by the personal awareness and understanding that the present behaviour is not aligned with personal goals (Mitcheson & Grellier , 2011). For the women, the current status of substance use is inconsistent with the promise or goal of motherhood in the future. All of the women described prior entrenched patterns of chronic heroin and crack use, starting between the ages of fifteen to twenty-one years old, and all described changes towards their substance use, with four women re-engaging in recovery work, OST and abstinence from heroin. One woman contacted an NHS Substance Misuse Service for the first time. The change brought by pregnancy promises motherhood and enables the women to see a different version of themselves, as mothers. When this is reflected back by close friends and family it confirms and strengthens this nascent identity and possibility of change.

I also saw self-doubt pervading the accounts of discovery of pregnancy (***Megan: 'because of my world…I never think I'm gonna be a good mom')*** and thought it was important to capture this sense of doubt, within the theme of ***Joy and Self-doubt***. Megan's words *s*uggest feelings of exclusion, the assimilation of the identity as substance user as being outside the cultural and accepted societal norm for motherhood. This self-doubt was countered by others reacting to her news who greet her status of pregnancy positively and support the potential of change for her. The important role of family in reflecting back the potential identity of motherhood was important for several women. It raises the question of how this is reflected in cases where women with OUD do not have a family or social network.

7.1.1.2 The safety of the children born, or unborn

The outcomes for the babies and children of women with OUD, (born or unborn) are key to this study. All the women demonstrated interest in the health of the unborn foetus, and appeared ready to engage in OST which they understood was less harmful to the developing foetus. Some of the women engaged in proceedings which they understood would offer the child a more stable environment than keeping them in their own care e.g. kinship care. The women demonstrated difficulties yet some understanding that their baby's wellbeing versus their own wellbeing were severable, and that they may take different trajectories however challenging this may have felt. This raises the question as to how to harness and balance the safety of both mother and baby in the cases where the pathway to optimum outcomes for the mother and infant differ.

7.1.1.3 Attachment to NHS Substance Misuse Services

A third finding is the high level of attachment the women displayed towards the NHS substance misuse clinics. The women described interactions with their respective substance misuse clinics before pregnancy, during pregnancy and in the following years, suggesting an enduring relationship characterised by a therapeutic alliance and trust. The therapeutic alliance can be described as the bond between client and therapist which evolves during the process of therapy (Horvath et al., 2011). The women are of course receiving an OST prescription from the NHS substance misuse services, but the accounts suggest something more enduring and profound than that.

Elizabeth reached out to substance misuse services for the first time on discovery of her pregnancy, finding them helpful, responsive and reassuring. On moving back to her home city, she was struggling with relapse and contacted a community-based NHS substance misuse services. She described the relationship with a new Keyworker as highly supportive and non-judgemental at a time when she felt was failing. Linda described co-constructing a plan with the addiction

psychiatrist to manage her reduction from OST during the last three months of pregnancy and found the discussion of options tailored for her as incredibly helpful. The clinic supported Megan and her partner to work towards abstinence, and this recognition of the couple as a unit seeking help was experienced as helpful. Both Linda and Megan made comparisons with other places which lack services, a likely reference to their European countries of origin. Megan continued to discuss her OST prescription and her feelings about how she was coping with her Keyworker, three years after the birth of her child. The women all used first names to describe their contacts at the substance misuse services as opposed to professional or clinical titles.

The importance of this relationship at the heart of the lived experience suggests that substance misuse services are likely exhibiting non-judgmental behaviours and offering practical support. They have an important and underutilised role to play in supporting the women through the complex healthcare journey, with other NHS teams, and the potential to contribute greater value in the healthcare model. This is discussed further in the clinical implications.

7.1.1.4 An Object of Risk in the Multi-Agency Care Model

A fourth finding is how the women experienced the multi-agency care model in which they find themselves objectified as a risk in their own pregnancy. This sense of being managed as a risk created anxiety, fear and anger in the women, and appears to have been exacerbated by two factors. The experience of being a risk clouds the nascent sense of potentially being a mother which the women may have experienced very early in their pregnancy.

The sub-theme *'Instruments of Power'* suggests that the experience of unfamiliar and opaque process was threatening. It is through this that the women perceive that they were considered a risk by others. Meetings and reports and intra agency processes were experienced as opaque instruments to be used in the assessment of women as potential mothers. Elizabeth described a feeling of needing to record everything that was said in meetings as the report that followed did not reflect her understanding of what had taken place.

Information plays a role here. The women seemed to lack information as to who, when and why an agency would become involved or contact them, particularly social services. The experience of receiving a call from social services and learning that one agency is informing another was particularly egregious and threatening for Linda who described herself as unaware that this was happening. She wondered whether the midwife had the rights to alert social services of her case. It is likely that the women would have signed consent for information sharing on registration at the service in previous years. In the context of being pregnant and diagnosed with OUD, the experience of teams exchanging information was threatening.

The sense of a case being developed against themselves was expressed by the women directly and overtly. The multi-agency care model in which social services, perinatal services and the substance misuse clinic assessed risk in different ways made Janet feel as if she was '*under attack'*. Elizabeth felt that her social worker was '*building the case straightway'*. All clients registered in NHS substance misuse services are routinely tested for illicit substances, and this would have been known and experienced many times by the women prior to pregnancy. In the context of being pregnant, the meaning of a testing regime evolved into a threatening anxiety-provoking cloud, eclipsing the promise of motherhood. Linda gave up all OST and illicit use during pregnancy, under careful advice from an addiction psychiatrist. This is the best outcome amongst the women. Even Linda, struggled with the processes and withdraw from contact entirely prompting more attention that she was not engaging. The healthcare journey remained significantly difficult for Linda throughout, with the threat of child removal constant.

The origin of the women's substance misuse was not investigated as part of this study. My hypothesis is that the women's chronic dependency on heroin and crack use was likely an adaptive coping response to earlier circumstances of pain, threat and or trauma. This is based on the principles of the PTMF framework which proposes that mental distress and health developed in the context of adversity, power and threat (Johnstone & Boyle, 2018). For the women, their healthcare journey is, operationalised by processes the women needed to follow; they feel threatened, if they do not engage. The women lack the resources to complain, object or seek redress, and this is partly due to their 'risk' status as mothers with OUD. The healthcare journey likely uses the women's significant resources of survival, rather than enhance and develop the women's personal agency and confidence to achieve change.

7.1.1.5 Stigma and Judgement

Threat and power are closely linked to the judgement the women feel. One component of how stigmatisation operates is power (Link & Phelan 2006). All of the women gave examples of internalising shame and stigma, not just for substance use, but for being a mother, being pregnant and for using drugs, for '*being that person'*. The women's accounts can be viewed in the context of Scambler's (2012) dimensions of stigma which help dissect the mechanisms by which stigma is communicated and experienced. Elizabeth's understanding of the interaction with her social worker might be regarded as enacted stigma where discrimination by others for being deviant and failing a social norm is communicated to her. Janet's reference to '*being that person'* suggests an internalised sense of shame gained from deviating from societal norms and criteria which Janet believes she fulfils, i.e. a mother who takes substances. Linda's words, '*they know what I'm taking'*

suggests internalised shame as she senses the opprobrium her status as a substance using mother attracts from a midwife. Linda experienced this in the Autumn of 2023.

Scambler (2012) suggests that felt stigma can be as damaging to people's lives as enacted stigma, in that it is conveyed non-verbally, is difficult to respond to, internalised and carried by the women. It certainly would lead to diminished self-worth. Linda was required herself to advise the midwife of her substance use. Up to that point, her prior history of substance use was invisible. As soon as Linda volunteers the information, she felt disqualified by the midwife for social acceptance. Linda talked about her focus on keeping her spirits up during this phase of pregnancy. Link and Phelan (2001) emphasise how power dynamics play a key role in stigmatisation, leading amongst other experiences to a loss of status by the stigmatised person. For the women, many aspects of their healthcare journey are characterised by differences in the power held between themselves and the individuals and teams with whom they are interacting.

7.1.1.6 Information and Psychoeducation

The important role and impact of information and psychoeducation runs through the women's accounts. I have used the labels information as well as psychoeducation, to cover a broader conceptualisation of information. Psychoeducation is typically a structured intervention which helps clients develop coping skills and understand expected treatment and risks. There is good evidence for its use in a number of approaches including substance use therapy, PTSD and Bipolar Disorder (Cho et al., 2016).

There are examples of women having received and having used information by reflecting or acting on it, examples of the women seeking more information, and examples of the women not having enough information. Linda seeks to ask questions about her methadone on discovering she was pregnant and what she should do next. *'I have only one question that I ask people who were more informed. What should I do? Do I need to stop it now? Or what?'.* It suggests that she understood the physiological impact of heroin and methadone on herself but now needed to understand the information in a different way. The safety of the unborn infant could turn on the level of understanding which the mother gains at an early stage of pregnancy. The women's account suggest that they would have been open to more information, than they were receiving, and this is likely to serve the infant, coupled with the evolution of psychological processes taking place. Gail felt that she had been brought up in a house where there was no discussion or awareness of drugs, and that she lacked information about the severity of drugs from a young age, contributing to her motivation to take on a role in schools to provide more information to younger girls.

Crack, also known as crack cocaine, is a solid form of cocaine which is produced by heating with an ingredient such as baking powder and water. It makes a crackling sound when it is smoked, giving rise to its name (UKAT, 2024). The production may leave residue on surfaces, pipes and utensils. Linda recalls this piece of information given to her by social services, notably that crack residue may stay within the environment and the baby risk being exposed to it. Linda recalls this, together with their advice that Linda may continue to use (' *there might be some use'*). The way Linda recalls this advice suggests that she is does not feel judged by it, and that she found it useful. It causes Linda to reflect on how using crack made her feel anxious and that she would not want to use around the baby. This recall and reflection on information would likely help Linda adhere to a behaviour change.

Information from the women on how the multi-agency model works, who might be involved, the names of people, processes and timing of their involvement is sparse and appears lacking in a number of accounts. There is variation in the women's accounts of NAS, how and when it might be tested. This suggests that the information about NAS may not have been provided in a way that all the women could retain or use. Megan and Linda's accounts imply that they were expecting tests on the newly born infant, and found the process of testing difficult, whereas Gail's accounts give the impression that she knew about the tests but was not informed that neonatal staff were actually testing for them. This suggests that the information about the testing for NAS may have been provided in an earlier phase, but that the implementation of testing procedures was not communicated by clinical staff or was communicated ineffectively. Similarly, the role of social services and the process of the family courts does not seem fully explained or understood by the women.

7.1.1.7 Non-Linear Recovery Paths and a Window of Opportunity

The women's accounts illustrate a variability in outcomes and recovery paths, with three women relapsing in the post birth years, two women assuming full parenting roles, and three with their babies in care or with grandparents acting as guardians. The present study did not seek to identify specifically the factors associated with relapse though it is impossible to ignore the variation in the women's experience in the post birth years, and to reflect on how their lived experience contributed to relapse. Women with OUD are understood to be vulnerable to relapse in the post birth period and a qualitative studies have identified factors which may contribute to the risk of relapse including a lack of social support, mother-infant attachment and mental health (Renbarger et al., 2020).

Gail's relapse seemed to be linked to her partner starting to use heroin again, and her eviction by her local Council. Elizabeth described not being able to breast feed or experience skin to skin contact with her baby and having ongoing mental health difficulties in the aftermath of stopping all medication in the mother and baby unit three weeks post birth. There is evidence to suggest that skin to skin contact and breastfeeding supports the development of maternal-infant bonding, the release of the hormone oxytocin and responsiveness from the mother (Scatliffe et al., 2019). High levels of anxiety were present in the women's accounts in the post birth period, as they grappled with a complex set of factors including understanding and participating in the legal process of the family courts. It raises the question as to whether the post birth year represents a window of opportunity for better structured and tailored care.

7.1.1.8 Being Clean

There is variation in the accounts as to the meaning of being ''clean''. Elizabeth had an extremely tough time being required to stop Subutex rapidly in MBU, during her three weeks post birth and described feeling ill for ten days, with Paracetamol to help, and feeling as if she could not bear having anyone, including her baby touch her skin. She relapsed in the following months and contacted another substance misuse service and was prescribed Buvidal from she found it easier to taper down and cease use entirely. Megan, on the other hand, described continued use of methadone as a mother of a three-year-old, and described a distant future point at which she felt she would reduce use further. It is possible that the variation in accounts is due to tailored plans, though my sense is that there was an expectation from three of the women that being clean of OST supported their cases of being assigned custody. There remains an open query in the accounts as to what being clean means: does it mean the cessation of illicit heroin, or does it also mean the cessation of OST, or both?

7.1.2 Findings Converging with Existing Literature

7.1.2.1 Pregnancy as a Catalyst for Change

Two of the primary findings reflect similar results from qualitative studies investigating experiences of pregnant women and mothers with OUD. The theme of pregnancy as a catalyst for change and personal recovery is reported in a number of qualitative studies where the discovery of pregnancy is a catalyst for change and transformational journeys of recovery (Peacock et al., 2021; Shadowen et al., 2022). ***The Meanings of Pregnancy*** seeks to capture the variation across the participants in the meanings and values they assigned to the initial discovery of pregnancy. The meanings included viewing motherhood as a motivation to stop being an addict, or a desire to enhance and build a normalised romantic relationship as a family unit. A number of studies report

the meanings of motherhood as a motivator for change and engagement in treatment which is experienced as denied or invalidated in the perinatal, or postnatal stages though interactions in complex healthcare journeys (Shadowen et al., 2022; Schiff et al., 2022).

I wanted to capture the nuances at the earliest stage of pregnancy discovery, under ***The Promise of Motherhood***, before this potential of a different future becomes clouded by interactions with the healthcare system. My focus in the research has been on the lived experience, which allows feelings and meaning making to be expressed. The change of feelings expressed during the interview as we travelled through different stages, provides important information about the healthcare journey. The importance of the changes extracted from the data, leads me to query whether the experience of NICE Guidelines (NICE, 2017) promotes or impairs the women's early steps in motivation to change.

7.1.2.2 Stigma

Experiences of judgement and stigma are one of the most widely reported findings in qualitative studies with pregnant women and mothers using substances in UK (Chandler at al., 2013) and the US (Bakos-Block et al., 2024), especially women using illicit opioids These experiences stem from the pregnant mother being defined and managed as the risk to the foetus (Stengel, 2014) and viewed as having deviated from accepted norms of motherhood (Radcliff, 2011; Nichols et al., 2021). Neale et al., (2021) reported results illustrating how power is experienced by women on OST who are accessing contraception through interlinked processes, including access to information and relationships with professionals. For example, women felt that the possible side effects of taking OST, and the oral contraception were poorly explained by the pharmacist and their GP, with one woman reporting feeling suicidal. The lack of information leading to lack of empowerment over contraception and choice. The women also reported negative attitudes from professional towards them and women ceased to seek out contraception advice. Stigma in mental healthcare settings is pervasive, recognised, researched and reported on, yet continues to be exceptionally difficult to resolve (Thornicroft et al., 2024).

7.1.3 Findings Diverging with the Existing Literature

7.1.3.1 The Absence of Barriers to Substance Misuse Services

There are divergences with existing literature. The sub-theme ***'Engaging in New Beginnings'*** illustrates how the women moved from entrenched use of heroin and crack to re-engagement with NHS Substance Misuse Services. This readiness to re-engage with substance misuse services at the early stages of pregnancy suggests prior knowledge of OST, an awareness of services and an ability to access services. This finding indicates that the psychoeducation, access

and presence of community services is important and relevant to younger women at this stage. This is somewhat different from US findings which suggest that pregnant women even at the early stage of pregnancy are fearful of seeking prenatal OST treatment due to state and federal laws about pregnancy and substance misuse, the fear of social services and actions following disclosure to healthcare providers. A number of US studies report systematic barriers to accessing treatment and this stems from the marked differences in healthcare systems, and legal obligations on healthcare providers in the treatment of pregnant women using substances (Leiner et al., 2021; O'Rourke-Suchoff et al., 2020; Apsley et al., 2024).

7.1.3.2 Absence of Issues Relating to Birth, Labour and Pain Management

The participants were not asked directly about their experience of labour but were asked if there was anything helpful or unhelpful they experienced at any point of pregnancy and birth. There was an absence in the women's accounts of issues relating to difficult labour and pain management. US qualitative research suggests that women with OUD described increased sensitivity to pain because of a history of opioid use and described feeling as if they were offered limited pain management options, expressing heightened feelings of fear of pain during birth (Nowakowski et al., 2023). O'Rourke-Suchoff et al., (2020) reported that participants taking methadone or buprenorphine felt they had greater understanding and knowledge of the pharmacological effects of medications and felt at times that they were more knowledgeable of the physiological effects that these were likely to have, than their healthcare providers. The women in this study did not describe difficult experiences in relation to child birth, purely in relation to the post birth period, NAS testing and abstaining from OST.

7.2 Methodological considerations

The following sets out some of the methodological strengths and limitations in conducting this research.

7.2.1 Strengths

The study design focussed on a precise profile of women who have used illicit heroin and received a diagnosis of OUD within the NHS. All of the women were engaged in OST or had recently stopped OST within the previous three months. All women were registered at the point of the interview within NHS Substance Misuse Services, and four of five had had their baby within a similar geographical footprint served by four major hospitals. The ethical considerations were given much thought in the preparation and there were no adverse events. The decision to focus on women with OUD, rather than other substances such as cocaine or benzodiazepines provides some similarities of lived experience in the sample which has facilitated the analysis process. Heroin is

extremely difficult to quit. All the women demonstrated a long-term relationship to heroin and OST, allowing for an in-depth investigation of patterns and variances from a small homogenous group.

Language can be used to represent experience and reality in different ways (Hall, 1997). For example, language can act like a mirror to reflect the truth of things, suggesting there is a material reality independent of language. Alternatively, constructionist approaches treat language as a means to create reality rather than reflect it. English was not the first language for all women, and the decision to use Reflexive Thematic Analysis has allowed patterns to be examined without the differences in use of language amongst the women to delimit findings. In this way, RTA has allowed me to accept the women's language as a window on to their world.

Many qualitative studies look for precise data points such as barriers and facilitators to recovery or engagement with OST. The lived experience has allowed the women to speak quite freely, albeit following a semi-structured topic guide. The use of a cross-sectional design, where the women were at different stages of their journey from pregnancy to motherhood, provided valuable insights of change over time. The initial design included recruitment criteria of women between twenty-four weeks pregnant to twenty-four months post birth. The extension to recruit women up to eight years post birth felt as if it enriched the data collected of the women's journey and experiences over time.

The recruitment setting of NHS substance misuse clinics were known to the women. All the interviews were conducted in the same clinics familiar to the women, and this I believe assisted in putting them at their ease during the interview process. The women were not known to me prior to recruitment, therefore I came to listen to their lived experiences with an open mind, without prior knowledge, though I had accessed clinical notes to ensure eligibility.

As a qualitative researcher who has worked in substance misuse services, I have aimed to pay attention to issues of power, education and privilege between the women and myself, the ethical issues attached to their participation and above all to seeking to reflect the women's perspectives, by acknowledging my role, not as a neutral researcher but at times positioning myself as an insider in collaboration with other insiders, and at times as an outsider (Yardley, 2000; Herr & Anderson, 2014). An example of a piece of data, illustrated in the sub-theme '***Instruments of Power'*** in were the accounts of having one agency inform another of the pregnancy. This resonated acutely with me. Clients in therapy earlier in my Substance Misuse Clinic placement had told me what it felt like to have one department in the NHS inform another about their 'condition', i.e. the OUD, and how undermining it felt to have their substance misuse history publicised. I felt my clients' discomfort

when they told me how this made them feel. Their 'condition' always preceded them. I too have had one department in the NHS inform another department about a conversation I had had, which I felt was personal and private. I know it may be important for NHS departments to share information, but I saw this very much from the women's point of view. This is an example of interpreting the data as insider, with the women. An example of positioning myself as an outsider in relation to the data, might be '***Evolving Identities'*** where I saw the women evolving differently and in different ways. I did not relate very much to any of their identities, due to my Social Graaces (Burnham, 2018) which are uniquely differently, though I could see the immense transition and change they described during the interview.

7.2.2 Limitations

The research is marked by limitations, and these relate mainly to the recruitment challenges. The thesis is based on the analysis of data from interviews with five participants. Ideally, six participants as a minimum would have recruited. Yet the data from the participants was rich and allowed for an analysis of the topic.

The interviews were conducted with women who fulfilled a number of key inclusion criteria e.g. being on OST. A number of potential candidates who appeared to fulfil criteria and who I approached did not attend interviews as planned, or did not respond at all, even when they expressed interest to their Keyworker. There were also many women registered within the clinics who had had children in the last eight years but who were intermittently relapsing, not consistent with OST or who were just too unwell. My research focussed therefore on women with OUD who were responsive to the treatment and interventions, but did not include women with untreated OUD. The findings therefore are drawn from data from interviews with women who were engaging and choosing to respond to participation in the research. It is possible that the lived experience of women who were pregnant or had children and who continued to struggle with illicit opioid use, may have revealed insights not captured in the interviews with the women included here.

The initial research proposal was to recruit from a wider range of NHS substance misuse services. During the preparation phase, 50% of the NHS substance misuse services in one the Trusts was passed to a charity, Change Grow Live (CGL). CGL was not covered by my NHS Ethics approval. This diminished the potential pool of participants prior to starting the recruitment. Furthermore, the setting from which I could recruit was where I was employed, as part of the clinical care team. This was a request of the NHS Ethics Committee, and my recruitment was focussed therefore on the substance misuse clinics where I was employed. It is possible that there were women with OUD coming though perinatal services of whom I was not aware, and who were

not registered in the substance misuse services where I was based. This may have led to a few cases being missed.

Many of the women had used heroin for many years and the research did not probe specifically the full personal histories of the women during earlier time periods e.g. childhood and adolescence. I would have liked to have had more of the participants' earlier lived experience to provide context to the immense changes and challenges presented by pregnancy and motherhood. The limits were set by me, in order to focus on the research questions relating to their healthcare journeys though at times, I felt we had missed part of their stories. It is possible that Grounded Theory (GT) (Glaser & Strauss, 2017) as a method on the same data would provide different insights on the same model of healthcare. The interview data could have been analysed concurrently with ongoing interviews and allowed insights on how social, and psychological mediate the healthcare model. For example, I have referred to two women who came from within the EU and who seemed to fare better through the healthcare journey. I felt this may be due to their sense of having very few services in their country of origin, and possibly being grateful, or compliant within the healthcare model. GT may have provided a more explanatory model of differences between the experiences of the women.

7.3 Clinical Implications

7.3.1 Counselling Psychology

Counselling Psychologists are employed in the NHS across a range of settings such as substance misuse services or perinatal services where they assess and provide psychosocial therapy for women who may be substance users. They are required to understand and work using models which relate to individuals' adaptive responses to difficult life contexts (HCPC, 2024). Counselling Psychologists may work with women with OUD who become pregnant, are mothers or who have had motherhood curtailed through enforced adoption and removal. Counselling Psychology is imbued with an approach to suffering and distress which marks it out distinctly from other clinical disciplines. This includes a holistic and integrative approach which has the power to respond to each woman in a highly individualized way, at whatever stage of their journey they may be.

Women with OUD face many personal challenges. Where a woman's children have been taken into care, feelings of loss, bereavement, trauma, and shame often form part of the presentation. Counselling Psychologists have a role to play in contributing to the mental wellbeing and recovery of women in whatever service they present, though these are likely to be NHS substance misuse services. Counselling Psychology can play an important role in providing

information iteratively throughout the healthcare journey, as the woman's thinking and feelings about her status as a pregnant woman evolves. The understanding of information about the use of illicit opioids during pregnancy may evolve, but the information can be provided in a way without objectifying the pregnant woman as a risk in her own pregnancy.

Counselling Psychology, with its holistic approach can draw on theories to help frame and understand the use of illicit heroin as a coping mechanism for trauma and fear, as well as respect the physiological impact of opioids and the difficult steps to gain recovery. Working with other disciplines within the NHS, Counselling Psychology has the capacity to respect different theoretical models which seek to explain and account for the physiological symptomatology of illicit opioids yet give time and space to support the women to find their ways of working towards motherhood and their own recovery. OUD as a diagnosis has the power to enact stigma in healthcare settings where the use of a diagnosis may contribute to feelings of shame, deviance and blame (Scambler, 2009). Counselling Psychologists who work within NHS settings where formal diagnosis is the pathway to interventions such as OST, can provide therapy tailored to a female client with OUD. The healthcare system through which the women travel, and on which they are crucially dependent, may perpetuate multiple social systems which reflect and sustain complex inequalities from the women's own lives (Grzanka et al.,2017). Counselling Psychology has an important role to play to issues of intersectionality faced by the women, and their experience of societal views on substances using women and motherhood.

7.3.2 Recommendations Within the Multi-Agency Healthcare Model

A number of recommendations are proposed from the findings which relate to the multi-agency model, and these are set out below.

7.3.2.1 Repositioning the Healthcare Journey as A Pathway Of Potential Change

The findings suggest that the journey into motherhood is a powerful pathway of potential change for women with OUD who become pregnant and mothers and this pathway to recovery is non-linear. The current approach creates fear, anxiety, and a sense for the woman 'of being a problem and risk'. There is a potential opportunity for creating a shift in how the multi-agency healthcare journey is conceived within the NHS and experienced by women with OUD.

This shift might involve a repositioning in a series of micro-processes of interactions between healthcare staff and women with OUD. This repositioning might include the expression of greater positivity from NHS staff especially in the early stages of the pregnancy journey. This might include words of congratulations and discussion on feelings about motherhood, and any physical and material needs which could be met. Shifting the current approach to one in which the women's

first report of pregnancy is celebrated, supporting self-efficacy, personal agency and ability to see themselves differently. This may be about how the current model is delivered rather than changing its component parts. The healthcare model could aim to focus on enhancing the woman's confidence to see herself differently, to encourage use of information at the right times and to develop agency for both her and baby.

This agency might also extend to the mother being engaged in decisions about the safety of her and outcome for her child, prior to legal proceedings stepping in to remove a baby. Providing tailored support, especially in the post birth phase where risk of relapse is heightened, especially during periods following rapid OST detox. Another difficult phase is the social care and legal process which may lead to the loss of the baby. For women whose babies are taken into care or even into kinship arrangements, bereavement and loss counselling is important to provide. The absence of support for women whose babies have been removed is a similar key finding by Gilmour et al., (2024) in their recent review of two hundred clinical guidelines in the UK.

7.3.2.2 Information

It would be helpful to produce and provide a booklet with detailed and accessible information about the stages of the healthcare journey and what the women might expect. The aim would be to empower the women with access to information in an accessible way. This might include information about pregnancy, the impact of opioids on the developing foetus, and which different teams and departments with whom a pregnant woman would expect to meet and when. This could be co-produced by the agencies and disciplines involved in the provision of care. As the woman progresses, through the healthcare journey, sections could be discussed and explained in more detail, as they become relevant to the key stage. The explanation that different agencies are involved from the outset, and will be in contact with each other, should be clearly set out, as well as the involvement of social services, and processes used by the Family and Drug Alcohol Court.

7.3.2.3 A Greater Role for NHS Substance Misuse Services

NHS Substance Misuse Services often have a client relationship with women with OUD before, during and after the pregnancy and birth. It is likely this relationship lasts for many years. As prescriber of the OST, clinics could take a lead in explaining to the women the impact of OST and illicit opioids on the foetus. The NHS SMS could also take a greater responsibility in ensuring that other agencies are appropriately trained in substance use, as a form of interprofessional education (IPE). IPE in an NHS setting comprises two or more professionals learn with and from each other to improve the quality of care (NHS, 2024). The substance misuse teams could provide

training models to perinatal services on the range of substances presenting amongst female registered service, and how to work with substance using women pre and post birth.

7.3.2.4 Specialist Midwife Teams

It would be helpful if women with OUD could meet with a specialist midwife team, that was familiar and had received training in substance misuse, especially the background and context of beneficial use (e.g. trauma histories, childhood neglect, intimate partner violence, sex work). It would also be beneficial if the mid-wives were familiar with the woman's case history. This would reduce the need for the women to feel they had to explain during routine appointments their history of use, and why they needed toxicology tests. This would reduce the likelihood of a midwife hearing of heroin and crack use at the appointment for the first time, and allow the midwife to absorb this information, reflect and take a non-judgemental stance.

7.3.2.5 Stigma Training

Addressing stigma is fundamental to delivering quality healthcare and achieving optimal outcomes. Training in the impact of stigma is key. A recent systematic review of fifteen stigma interventions for providers who treat individuals with SUD reports interventions using motivational interviewing as being one of the highest quality studies (Bielenberg et al., 2021). An understanding of how stigma undermines treatment, and successful health outcomes remains an important recommendation for everyone involved in the women's healthcare journey. This recommendation is found in other studies yet remains very much part of the findings of the present study. Examples of feeling judged by midwives in 2023 were clear and present in the current study.

Not all illnesses are stigmatised in the same way. Women who use substances are judged more harshly than men, and women with OUD who become pregnant, and mothers receive social opprobrium for being both a user of heroin, as well as for becoming a mother, the two states being judged as mutually exclusive by society (Radcliffe, 2011). The challenge of addressing the stigma in healthcare settings is complex to address. Substance misuse is one of seven health conditions identified as attracting stigma: HIV, tuberculosis (TB), mental health conditions, substance abuse, diabetes, leprosy, and cancer (Nyblade et al., 2019). Approaches to reduce stigmatisation associated with these illnesses might be used in substance misuse such as employing women with OUD as trainers, or speakers at workshops in order to convey personal histories and what might be perceived as stigmatising e.g. non-verbal communication.

7.3.2.6 Wider Social and Policy Considerations

There is great scope for continued drugs education in schools, especially directed at young girls, as well as to provide awareness-raising with the general public especially about the alarming

rate that illicit opioids can create dependency. The use of social media, and preferred digital communication channels for young adults can be used to promote information and dissemination.

7.4 Responding to the Research Questions

The study focussed on three research questions and each of these are taken in turn.

7.4.1 Question 1

To gain an understanding of how women with OUD who become pregnant experience and understand the complex journey of peri-natal and post-natal healthcare.

Five women diagnosed with OUD, and who had children ranging from six weeks old to eight years old were interviewed about their lived experience of peri-natal and post-natal healthcare. The analysis of the interview data suggest that the women start to communicate and think about themselves differently at the start of pregnancy, which leads to small yet perceptible changes in their thinking and behaviour. This early stage is marked by hope and positive emotions yet is challenged by multiple interactions with different departments including NHS substance misuse services, perinatal and NCU teams, as well as social services. These specialist teams collectively form a multi-agency healthcare journey for pregnant women with OUD, following NICE guidelines (DoH, 2017; NICE, 2010).

Research question one has been met in three key areas. Firstly, our understanding is improved by data which indicate the women are acutely aware that, as heroin users diagnosed with OUD, they are operating outside an accepted societal norm, with examples of internalised stigma and shame present throughout their accounts. The women show that they start to think differently about themselves, as potential mothers, with the promise of motherhood ahead, with responsibility for a child. This important psychological process can be validated and enhanced, or challenged and rejected during the healthcare journey, with the women remaining highly vulnerable to relapse or sustained heroin use in the post birth years. The car system has an opportunity to enhance this process of change. Secondly, the data provides an understanding of how demanding the healthcare journey is for the women to engage with. This is not simply due to maternity and motherhood being challenging in itself, but due to the complexity of healthcare processes and structures with which the women must engage. The women's feelings of being treated as a persistent risk to their unborn or born child, even in the face of efforts to abstain from illicit heroin use or cease OST is a valuable insight. The healthcare processes appear to be opaque to the women; they do not seem to be clear about them, or the extent to which information is shared between agencies, and standard operating procedures are experienced as threatening. Processes vary across many sites where they need to attend meetings. The sense of having a case

built and made against them is acutely experienced by the women in certain interactions, provoking anxiety, even in the face of their efforts to abstain or achieve recovery. The lived experience suggests that their journey is not consistent in supporting the women's nascent self-belief and agency, but rather undermines a fragile opportunity for change. Thirdly, our understanding of the women's experience suggests that there is an attachment to NHS Substance Misuse Services and that this could be used to greater effect in the multi-agency model.

7.4.2 Question 2

To contribute towards clinicians' understanding of factors which impair, or which promote better outcomes for mother and infant (e.g., adherence to opioid substitution therapy (OST); engagement in psychosocial support and recovery from substance use).

The research indicates that a number of factors can impair or promote better outcomes for the mother and infant. Firstly, the women showed evidence of learning, seeking out and using information at key points. For example, all women appeared aware of the importance of OST at the point of discovering their pregnancy. This indicates that the dissemination of information provided to women prior to pregnancy, about the importance of OST during pregnancy is currently retained by the women, and they act on it, implying that the use of information is effective. This therefore suggests that communicating to all women with OUD, whether pregnant or not, is a useful step in achieving commitment to OST at the start of pregnancy. Secondly, factors which strengthen the women's sense of agency are important, and these include greater information about the agencies, testing regime and processes used by social services and FDAC. Thirdly, supportive encouragement by all healthcare workers remains key to nurturing the women's self-belief in change and identity. Fourthly, a greater understanding amongst the midwifery community of OUD is key, as well as the use of specialist midwifery teams. Fifthly, psychosocial support during and post birth to develop self-efficacy and agency, including group work with other women appeared to be valued by the women and remains important.

Factors which impair outcomes include interactions from healthcare professionals experienced as anxiety provoking (e.g. a midwife's negative reaction to discovery that the pregnant woman is on OST; the discovery of NAS testing). Moments of stress and activation of fear networks all create risk for relapse. The variations in approach to the continued use of OST in the post-labour weeks was striking. It suggests that suggesting that there is a marked inconsistency between MBU's insisting on the cessation of OST such as buprenorphine and methadone versus community NHS Substance Misuse Clinics continuing to prescribe in the post birth years. The

theoretical generalisation from the small sample in the current study suggests the latter had a better outcome.

7.4.3 Question 3

To inform current practice, interventions and services aimed at supporting young adult female population with OUD

Findings from the research suggest that information about the effect of opioids on pregnancy is important to maintain, though the women may choose to act on it at moments of their choosing. A greater use of peer support, including by women with lived experience talking about their experiences of recovery with younger women is recommended, as well as mentoring.

7.4.4 Suggestions for Future Research

The research focussed on five women whose OUD was managed and being treated. Suggestions for future qualitative research includes three areas. Firstly, it would be useful to investigate within the Trust the lived experience of Keyworkers, midwife teams and social workers working with women with OUD who become pregnant. This would provide a fuller picture of healthcare workers experiences and feelings about working with women with OUD who become pregnant.

Secondly, many women with OUD registered within the Trusts' Substance Misuse Services fell outside the inclusion criteria of the current study and were therefore excluded. Reasons for exclusion included comorbidities with other serious illness, and mental health conditions or non-engagement with OST. The population of women with poor OST engagement and untreated OUD not approached in this study has the potential to contribute to our understanding of what facilitates engagement and recovery, though this requires resources, especially recruitment time, and resources to follow up with a highly vulnerable group.

A third area of potential research is to investigate psychological therapies for women who have had their babies removed, to identify the best approaches, and how Substance Misuse Services might commission or deliver these interventions. The experience of birth parents who have had their babies compulsorily removed is under-researched in UK, though two recent papers have provided some focus on the experiences of birth parents and their experiences of psychosocial therapies following the loss of a child to adoption (Morgan et al., 2019; Wright et al.,2022). Substance Misuse Services provide therapies tailored to the individual, though therapy for mothers bereaved through the removal of a child may be distinct from other therapies. Clinical notes list mothers whose baby has been removed as 'having no parental responsibility'. Several screens of information may obscure the experience of the loss a woman has experienced.

7.4.5 Overall Reflections of Research Process

The overall research process of this study has taken three years. My interest in the area developed in my first year as a trainee from early therapeutic work, with a 33-year-old women with OUD who was eight months pregnant at the start of therapy which lasted for six months. Since that early clinical work, my understanding of my ontological and epistemological position as a Counselling Psychologist has developed throughout the research process.

I can see how evidence-based theory builds formal NICE guidelines made up of structures and processes, which are opaque or even invisible to the women they are designed to support. These are the generative mechanisms which cause real experiences and events for the women; these may result in the real event of a baby being removed. The lived experience has allowed me to understand the women's experience of a healthcare journey which is extremely challenging.

I have experienced a wealth of emotions during the research process. At times, I have felt doggedly focussed on the task of writing and developing the proposal and the initial literature review. At other times, I have felt emotionally drained. My determination to keep going through the longwinded NHS Ethics process was weakened by the lengthy NHS Ethics process. I have asked myself how research in the NHS ever gets undertaken. I felt irritated when quizzed by the NHS Ethics Committee with odd questions, such as how would I mitigate the risk of being stabbed by one of my participants. The question carried judgement and an inappropriate way of assessing risk to the researcher. I experienced great joy in discussing the research with the women's group, before the interviews. I found myself becoming tearful during the interviews with the women which were deeply moving at times. I have found supervision with Professor Willig immensely helpful in navigating what has felt like a long and slow research process and rollercoaster of emotions. Reaching the interviews felt enriching and nourishing again. Far from being a mere template to follow, the research process, thesis structure and process of undertaking RTA, have provided me with forward momentum and a structure in which emotions have felt contained and calmed.

The women I interviewed contributed richly, describing their experiences and insights. There was anger too in their accounts, as well as tearfulness at the experience of recounting many difficult years. My immersion in the audio and transcripts in the analysis process has made me feel as if I know the women intimately. I would like to know more about them, especially how they are getting on now. It is an intimacy which is not mutual, on which I have reflected. As a qualitive researcher, it feels privileged to be able to conduct such research, to dip into someone's life when they know so little about me, and I have thought many times about the earlier reading I have done

on the ethics and the power in the relationships between the researcher and participant. I also reflect on the women who I could not interview, the ones who did not turn up to an interview or did not return my calls.

This research is dedicated to the women with OUD who participated in this research as well as to all the women who did not.

8 References

Advisory Council on the Misuse of Drugs, (2024); ACMD advice on 2-benzyl benzimidazole and piperidine benzimidazolone opioids (accessible version) - GOV.UK (www.gov.uk) (accessed 23.03.2024).

Agar, M. (1996). *The professional stranger: An informal introduction to ethnography*. 2nd edition, Academic Press: San Diego, United States of America.

Alenezi, A., Yahyouche, A., & Paudyal, V. (2021). Current status of opioid epidemic in the United Kingdom and strategies for treatment optimisation in chronic pain. *International Journal of Clinical Pharmacy*, *43*(2), 318–322. https://doi.org/10.1007/s11096-020-01205-y

American Psychiatric Association. (2013). *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.

Andersson, C., Wincup, E., Best, D., & Irving, J. (2021). Gender and recovery pathways in the UK. *Drugs: Education, Prevention and Policy*, *28*(5), 454–464. https://doi.org/10.1080/09687637.2020.1852180

Apsley, H. B., Brant, K., Brothers, S., Harrison, E., Skogseth, E., Schwartz, R. P., & Jones, A. A. (2024). Pregnancy-and parenting-related barriers to receiving medication for opioid use disorder: A multi-paneled qualitative study of women in treatment, women who terminated treatment, and the professionals who serve them. *Women's Health*, 20, 17455057231224181.

Back, S. E., Lawson, K. M., Singleton, L. M., & Brady, K. T. (2011). Characteristics and correlates of men and women with prescription opioid dependence. *Addictive behaviors*, 36(8), 829–834. https://doi.org/10.1016/j.addbeh.2011.03.013

Bakos-Block, C., Yatsco, A., Cohen, A. S., Vega, F., & Champagne-Langabeer, T. (2024). “My Addiction Doesn’t Define Me”—Experiences of Stigma among Mothers with Opioid Use Disorder. *Pharmacoepidemiology*, 3(1), 57-68.

Bhaskar, R., & Hartwig, M. (2010). *The formation of critical realism: A personal perspective*. Routledge

Bhaskar, R. (1975). Forms of realism. *Philosophica*, 15.

Bielenberg, J., Swisher, G., Lembke, A., & Haug, N. A. (2021). A systematic review of stigma interventions for providers who treat patients with substance use disorders. *Journal of Substance Abuse Treatment*, 131, 108486.

Boardman, J. P., Mactier, H., & Devlin, L. A. (2022). Opioids and the developing brain: Time to rethink perinatal care for infants of opioid-dependent mothers. *Archives of Disease in Childhood: Fetal and Neonatal Edition*, *107*(1), F98–F104. https://doi.org/10.1136/archdischild-2020-320102

Boyatzis, R. (1998). *Transforming qualitative information: Thematic analysis and code development*. Sage.

Brady, K. T., & Lydiard, J. B. (2021). Women and Addiction. In *Textbook of Addiction Treatment* (pp. 1395–1405). Springer International Publishing. https://doi.org/10.1007/978-3-030-36391-8_98

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Braun, V., & Clarke, V. (2016). (Mis)conceptualising themes, thematic analysis, and other problems with Fugard and Potts' (2015) sample-size tool for thematic analysis. In *International Journal of Social Research Methodology* (Vol. 19, Issue 6, pp. 739–743). Routledge. https://doi.org/10.1080/13645579.2016.1195588

Braun, V., & Clarke, V. (2019). Reflecting on reflexive thematic analysis. *Qualitative Research in Sport, Exercise and Health*, *11*(4), 589–597. https://doi.org/10.1080/2159676X.2019.1628806

Braun, V., & Clarke, V. (2021). Can I use TA? Should I use TA? Should I not use TA? Comparing reflexive thematic analysis and other pattern-based qualitative analytic approaches. *Counselling and Psychotherapy Research* 21: 37–47. https://doi.org/10.1002/capr.12360

Braun, V., & Clarke, V. (2022). *Thematic Analysis: A Practical Guide.* SAGE Publications.

Braun, V., & Clarke, V. (2013). *Successful qualitative research: A practical guide for beginners.* London: SAGE

Brinkman,S., & Kvale,S. (2017). Ethics in Psychological Qualitative Research. In Willig, C., & Rogers, W. S. (Eds.). (2017). *The SAGE handbook of qualitative research in psychology*. Sage. Psychotherapy Research, 21(1), 37–47. https://doi.org/10.1002/capr.12360

Britannica (n.d); https://www.britannica.com/summary/positivism

British Psychological Society. Division of Clinical Psychology, Johnstone, L., Boyle, M., & British Psychological Society. (n.d.). *The Power threat meaning framework : overview*.

British Psychological Society. (2018). Code of Ethics and Conduct. *The British Psychological Society*, *July*, 100–102. www.bps.org.uk. (Accessed 01.09.2023)

Burnham, J. (2018). Developments in Social GRRRAAACCEEESSS: visible–invisible and voiced–unvoiced 1. In *Culture and reflexivity in systemic psychotherapy* (pp. 139-160). Routledge.

Burr, V. (2015). *Social constructionism*. Routledge.

Cane, J., O'Connor, D., & Michie, S. (2012). Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science*,7(1), 1–17.https://doi.org/10.1186/1748-5908-7-37

Canfield, M., Norton, S., Downs, J., & Gilchrist, G. (2021). Parental status and characteristics of women in substance use treatment services: Analysis of electronic patient records. *Journal of Substance Abuse Treatment*, *127*. https://doi.org/10.1016/j.jsat.2021.108365

CareAct, 2014 ; https://www.legislation.gov.uk/ukpga/2014/23/ (Accessed 01.09.2023)

Carminati, L. (2018). Generalizability in Qualitative Research: A Tale of Two Traditions. In *Qualitative Health Research* (Vol. 28, Issue 13, pp. 2094–2101). SAGE Publications Inc. https://doi.org/10.1177/1049732318788379

Chandler, A., Whittaker, A., Cunningham-Burley, S., Elliott, L., Midgley, P., & Cooper, S. (2020). Diagnosing uncertainty, producing neonatal abstinence syndrome. *Sociology of Health and Illness*, *42*(S1), 35–50. https://doi.org/10.1111/1467-9566.13000

Chandler, A., Whittaker, A., Cunningham-Burley, S., Williams, N., McGorm, K., & Mathews, G. (2013). Substance, structure and stigma: parents in the UK accounting for opioid substitution therapy during the antenatal and postnatal periods. *International Journal of Drug Policy*, *24*(6), e35-e42.

Charmaz, K. (2000). Grounded theory: Objectivist and constructivist methods. In N. Denzin & Y. Lincoln (Eds.), *Handbook of qualitative research* (2nd ed., pp. 509-535). London: SAGE.

Charmaz, K. (2003). Grounded theory: Objectivist and constructivist methods. In N. K. Denzin & Y. S. Lincoln (Eds.), *Strategies of qualitative inquiry* (2nd ed., pp. 249-291). London: SAGE.

Cho, S. H., Torres-Llenza, V., Budnik, K., & Norris, L. (2016). The integral role of psychoeducation in clinical care. *Psychiatric Annals*, 46(5), 286-292.

ChildrenAct, 1989. Available at https://www.legislation.gov.uk/ukpga/1989/41/resources

Cho, S. H., Torres-Llenza, V., Budnik, K., & Norris, L. (2016). The integral role of psychoeducation in clinical care*. Psychiatric Annals*, 46(5), 286-292.

Crenshaw, K. (1991). Stanford Law Review Mapping the Margins: Intersectionality, Identity Politics, and Violence against Women of. *Source: Stanford Law Review*, *43*(6).

Cromby, J. (2022). Meaning in the Power Threat Meaning Framework. *Journal of Constructivist Psychology*, *35*(1), 41–53. https://doi.org/10.1080/10720537.2020.1773355

Cudjoe, E. (2023). Making Sense of Husserlian Phenomenological Philosophy in Empirical Research. *International Journal of Qualitative Methods*, *22*. https://doi.org/10.1177/16094069231171099

Department of Health, 2017; https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management. (Accessed 01.09.2023)

Dilthey. W., (2010) *Selected Works, Volume IV: Hermeneutics and the Study of History*. Princeton University Press.

Drugwise, 2024:https://www.drugwise.org.uk/synethic+opiods. (Accessed 23.03.24)

Dydyk, A. M., Jain, N. K., & Gupta, M. (2024). Opioid Use Disorder. In *StatPearls*. StatPearls Publishing.

Elliott, R., Fischer, C. T., & Rennie, D. L. (1999). Evolving guidelines for publication of qualitative research studies in psychology and related fields. *British Journal of Clinical Psychology*, *38*(3), 215–229. https://doi.org/10.1348/014466599162782

European Monitoring Centre for Drugs and Drug Addiction (2022); European Drug Report 2022: Trends and Developments; ; https://www.emcdda.europa.eu/publications/edr/trends-developments/2022_en. (Accessed 10.03.2024)

Finlay, L., & Gough, Brendan. (2003). *Reflexivity : a practical guide for researchers in health and social sciences*. Blackwell Science.

Finlay, L. (2002). Negotiating the swamp: the opportunity and challenge of reflexivity in research practice. *Qualitative Research*, 2(2), 209-230. https://doi.org/10.1177/146879410200200205

Finnegan, L. P., Connaughton Jr, J. F., Kron, R. E., & Emich, J. P. (1975). Neonatal abstinence syndrome: assessment and management. *Addictive diseases*, *2*(1-2), 141-158.

Frost, N. (2016). *Practising research: Why you're always part of the research process even when you think you're not*. Palgrave.

Gilchrist, G., Dennis, F., Radcliffe, P., Henderson, J., Howard, L. M., & Gadd, D. (2019). The interplay between substance use and intimate partner violence perpetration: A meta-ethnography. *International Journal of Drug Policy*, 65, 8–23. https://doi.org/10.1016/j.drugpo.2018.12.009

Gilmour, L., Honeybul, L., Lewis, S., Smith, E., Cheyne, H., Aladangady, N., Featherstone, B., Maxwell, M., Neale, J., & Radcliffe, P. (2024). Scoping review: mapping clinical guidelines and policy documents that address the needs of women who are dependent on drugs during the perinatal period. *BMC Pregnancy and Childbirth*, *24*(1). https://doi.org/10.1186/s12884-023-06172-6

Glaser, B., & Strauss, A. (1967). Grounded theory: The discovery of grounded theory. *Sociology the journal of the British sociological association*, *12*(1), 27-49.

Glaser, B., & Strauss, A. (2017). *Discovery of grounded theory: Strategies for qualitative research*. Routledge.

Goodman, D. J., Saunders, E. C., & Wolff, K. B. (2020). In their own words: A qualitative study of factors promoting resilience and recovery among postpartum women with opioid use disorders. *BMC Pregnancy and Childbirth*, *20*(1), 1–10. https://doi.org/10.1186/s12884-020-02872-5

Gilchrist, G., Dennis, F., Radcliffe, P., Henderson, J., Howard, L. M., & Gadd, D. (2019). The interplay between substance use and intimate partner violence perpetration: A meta-ethnography. *International Journal of Drug Policy*, *65*, 8–23. https://doi.org/10.1016/j.drugpo.2018.12.009

Grossman, M., & Berkwitt, A. (2019). Neonatal abstinence syndrome. *Seminars in Perinatology*, *43*(3), 173–186. https://doi.org/10.1053/j.semperi.2019.01.007

Grzanka, P. R., Santos, C. E., & Moradi, B. (2017). Intersectionality research in counseling psychology. *Journal of counseling psychology*, 64(5), 453.

Guba, E. G., & Lincoln, Y. S. (1994). Competing paradigms in qualitative research. *Handbook of qualitative research*, 2(163-194), 105.

Guest, G., Namey, E., & Chen, M. (2020). A simple method to assess and report thematic saturation in qualitative research. *PLoS ONE*, *15*(5). https://doi.org/10.1371/journal.pone.0232076

Hall, S. (1997). The work of representation. In S.Hall *Representation: Cultural representations and signifying practices,* (pp.13-73) LONDON: SAGE

Hammond, A. S., & Chisolm, M. S. (2022). *Co-occurring Mental Health Conditions in Pregnant Women with Opioid Use Disorders*. 27–34.

Health and Care Professions Council. (2016) https://www.hcpc-uk.org/resources/guidance/guidance-on-conduct-and-ethics-for-students. (Accessed 01.09.2022)

Health and Care Professions Council. (2024) https://www.hcpc-uk.org/standards/standards-of-proficiency/practitioner-psychologists. (Accessed 01.09.2024)

Heidegger, M. (1962). Heidegger, *Being and Time*. Harper & Row

Hennink, M. M., Kaiser, B. N., & Marconi, V. C. (2017). Code Saturation Versus Meaning Saturation: How Many Interviews Are Enough? In *Qualitative Health Research* (Vol. 27, Issue 4, pp. 591–608). SAGE Publications Inc. https://doi.org/10.1177/1049732316665344

Henwood, K. L., & Pidgeon, N. F. (1992). Qualitative research and psychological theorizing. *British journal of psychology*, *83*(1), 97-111.

Heron, J., & Reason, P. (2008). Extending epistemology within a co-operative inquiry. *The Sage handbook of action research: Participative inquiry and practice*, *2*, 366-380.

Herr, K. and Anderson, G. L. (2014). *The action research dissertation: A guide for students and faculty*. 2nd edition, Sage: California, United States of America.

Hiersteiner, C. (2004). Narratives of low-income mothers in addiction recovery centers: Motherhood and the treatment experience. *Journal of social work practice in the addictions*, *4*(2), 51-64.

Horvath, A. O., Del Re, A. C., Flückiger, C., & Symonds, D. (2011). Alliance in individual psychotherapy. *Psychotherapy*, 48(1), 9.

Hughes, T., McFadden, A., Whittaker, A., Boardman, J. P., & Marryat, L. (2024). Antenatal care of women who use opioids: a qualitative study of practitioners' perceptions of strengths and challenges of current service provision in Scotland. *BMC pregnancy and childbirth*, *24*(1), 75.

Humphreys, K., Shover, C. L., Andrews, C. M., Bohnert, A. S. B., Brandeau, M. L., Caulkins, J. P., Chen, J. H., Cuéllar, M. F., Hurd, Y. L., Juurlink, D. N., Koh, H. K., Krebs, E. E., Lembke, A., Mackey, S. C., Larrimore Ouellette, L., Suffoletto, B., & Timko, C. (2022). Responding to the opioid crisis in North America and beyond: recommendations of the Stanford–Lancet Commission. *The Lancet*, *399*(10324), 555–604. https://doi.org/10.1016/S0140-6736(21)02252-2

Hunt, J. (2020). Two decades of UK research on kinship care: an overview. *Family Rights Group: London, UK*.

Jansson, L. M., Velez, M., & Harrow, C. (2009). The opioid-exposed newborn: assessment and pharmacologic management. *Journal of opioid management*, 5(1), 47–55.

Johnstone, L. & Boyle, M. with Cromby, J., Dillon, J., Harper, D., Kinderman, P., Longden, E., Pilgrim, D. & Read, J. (2018). *The Power Threat Meaning Framework: Overview*. Leicester: British Psychological Society

Kim, J., Busse, M., Kantrowitz-Gordon, I., & Altman, M. R. (2022). Health Care Experiences during Pregnancy and Parenting with an Opioid Use Disorder. *MCN The American Journal of Maternal/Child Nursing*, *47*(2), 100–106. https://doi.org/10.1097/NMC.0000000000000805

King, N., & Hugh-Jones, S. (2018). The interview in qualitative research. *ng qualitative research in psychology: a practical guide.* Sage, London, 121-144.

Koopmans E, Schiller Dr C. Understanding Causation in Healthcare: An Introduction to Critical Realism. *Qualitative Health Research*. 2022;32(8-9):1207-1214. doi:10.1177/10497323221105737

Lang, I., King, A., Jenkins, G., Boddy, K., Khan, Z., & Liabo, K. (2022). How common is patient and public involvement (PPI)? Cross-sectional analysis of frequency of PPI reporting in health research papers and associations with methods, funding sources and other factors. *BMJ Open*, *12*(5). https://doi.org/10.1136/bmjopen-2022-063356

Larkin, M. and Thompson, A.R. (2011). Interpretative Phenomenological Analysis in Mental Health and Psychotherapy Research. In *Qualitative Research Methods in Mental Health and Psychotherapy* (eds D. Harper and A.R. Thompson). https://doi.org/10.1002/9781119973249.ch8

Leiner, C., Cody, T., Mullins, N., Ramage, M., & Ostrach, B. M. M. (2021). "The elephant in the room;" a qualitative study of perinatal fears in opioid use disorder treatment in Southern Appalachia. *BMC Pregnancy and Childbirth*, *21*(1), 1–13. https://doi.org/10.1186/s12884-021-03596-w

Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic inquiry*. SAGE.

Link, B. G., & Phelan, J. C. (2001a). Conceptualizing stigma. *Annual review of Sociology*, *27*(1), 363-385.

Link, B. G., & Phelan, J. C. (2006). Stigma and its public health implications. *Lancet*, *367*(9509), 528–529. https://doi.org/10.1016/S0140-6736(06)68184-1

Lorman, W. J. (2015). Substance use disorders. In *Psychiatric Nursing Made Incredibly Easy!: Second Edition*.

Lyons, E., & Coyle, A. (Eds.). (2021). *Analysing qualitative data in psychology*. Sage.

Madill, A., & Gough, B. (2008). Qualitative Research and Its Place in Psychological Science. *Psychological Methods*, *13*(3), 254–271. https://doi.org/10.1037/a0013220

Madill, A., Jordan, A., & Shirley, C. (2000). Objectivity and reliability in qualitative analysis: Realist, contextualist and radical constructionist epistemologies. *British Journal of Psychology*, *91*(1), 1–20. https://doi.org/10.1348/000712600161646

Malterud, K. (2016). Theory and interpretation in qualitative studies from general practice: Why and how?. *Scandinavian journal of public health*, 44(2), 120-129. https://doi.org/10.1177/1403494815621181

Martin, C. E., & Parlier-Ahmad, A. B. (2021). Addiction treatment in the postpartum period: an opportunity for evidence-based personalized medicine. *International Review of Psychiatry*, *33*(6), 579-590.

Meyer, J. P., Isaacs, K., El-Shahawy, O., Burlew, A. K., & Wechsberg, W. (2019). Research on women with substance use disorders: Reviewing progress and developing a research and implementation roadmap. *Drug and alcohol dependence*, 197, 158–163. https://doi.org/10.1016/j.drugalcdep.2019.01.017

Michie, S., Van Stralen, M. M., & West, R. (2011). The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implementation Science,6(1), 42.https://doi.org/10.1186/1748-5908-6-42

Miller, P. (Peter G., Strang, John., & Miller, P. M. (Peter M. (2010). *Addiction research methods*. Addiction Press/Blackwell Pub.

Mol, A. (2002) *The Body Multiple: Ontology in Medical Practice*. Durham: Duke University Press

Misuse of Drugs Act 1971. http://www.legislation.gov.uk/ukpga/1971/38/contents; accessed 2.4.2022

Mitcheson, L., & Grellier, B. (2011). Motivation and change. *Principles and Practice of Group Work in Addictions*, 17.

Moran-Santa Maria, M.M., & Brady, K.T. (2015). Women and Addiction. In: el-Guebaly, N., Carrà, G., Galanter, M. (eds) *Textbook of Addiction Treatment: International Perspectives*. Springer, Milano. https://doi.org/10.1007/978-88-470-5322-9_96

Morrison, P. K., Yourish, E., Chang, J. C., Krans, E., & Pallatino-Trevelline, C. (2023). Barriers to Care for Pregnant and Post-Partum Women Experiencing Co-Occurring Intimate Partner Violence and Opioid Use Disorder. *Journal of Family Violence*, *38*(8), 1625–1637. https://doi.org/10.1007/s10896-022-00466-7

Neale, J., Nettleton, S., & Pickering, L. (2014). Gender sameness and difference in recovery from heroin dependence: A qualitative exploration. *International Journal of Drug Policy*, *25*(1), 3-12.

Neale, J., Werthern, H., Alhusein, N., Chater, A., Scott, J., & Family, H. (2021). Contraceptive choice and power amongst women receiving opioid replacement therapy: qualitative study. *Drugs: Education, Prevention and Policy*, *0*(0), 1–12. https://doi.org/10.1080/09687637.2021.1954599

National Health Service, Manchester University Foundation Trust (2024) https://mft.nhs.uk/ipe. (Accessed 09.09.2024)

National Institute on Drug Abuse, 2024; https://nida.nih.gov/publications/research-reports/substance-use-in-women/importance-including-women-in-research (Accessed 01.09.2024)

National Institute for Health and Clinical Excellence. (2010) *Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors* (NICE guideline NG110). https://www.nice.org.uk/guidance/CG110/chapter/1 -Guidance#pregnant-women-who-misuse-substances-alcohol-andor-drugs

National Institute for Health and Clinical Excellence, 2022; https://cks.nice.org.uk/topics/opioid-dependence. (Accessed 16.03.2024).

National Institute for Health and Clinical Excellence, 2022; https://cks.nice.org.uk/topics/opioid-dependence/management/managing-special-circumstances. (Accessed 16.03.2024).

National Institute for Health and Clinical Excellence, 2007; https://www.nice.org.uk/guidance/cg52 (Accessed 01.03.2022)

National Institute for Health and Clinical Excellence, 2017; https://bnfc.nice.org.uk/treatment-summaries/substance-dependence (Accessed 01.03.2022)

National Institute for Health and Clinical Excellence, 2014; https://www.nice.org.uk/guidance/cg192 2014 (Accessed 01.03.2024)

National Institute for Health Research. https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392; (Accessed 01.12.2022).

National Institute for Health Research. https://bnf.nice.org.uk/drugs/buprenorphine/ (Accessed 08.09.2024)

Neale, J., Werthern, H., Alhusein, N., Chater, A., Scott, J., & Family, H. (2021). Contraceptive choice and power amongst women receiving opioid replacement therapy: qualitative study. *Drugs: Education, Prevention and Policy*, *0*(0), 1–12. https://doi.org/10.1080/09687637.2021.1954599

Nichols, T. R., Welborn, A., Gringle, M. R., & Lee, A. (2021). Social Stigma and Perinatal Substance Use Services: Recognizing the Power of the Good Mother Ideal. *Contemporary Drug Problems*, 48(1), 19–37. https://doi.org/10.1177/0091450920969200

Noclor: www.noclor.nhs.uk. (Accessed 01.10.2022)

North Central London Integrated Care System. https://nclhealthandcare.org.uk/ics/ (Accessed 01.06.2024)

Nowakowski, E., Dayananda, S., Morgan, M., Jarvis, O., Altamirano, V., LaSorda, K. R., ... & Lim, G. (2023). Obstetric pain management for pregnant women with opioid use disorder: A qualitative and quantitative comparison of patient and provider perspectives (QUEST study). *Addiction*, *118*(6), 1093-1104.

Nyblade, L., Stockton, M. A., Giger, K., Bond, V., Ekstrand, M. L., Lean, R. M., ... & Wouters, E. (2019). Stigma in health facilities: why it matters and how we can change it. *BMC medicine*, 17, 1-15.

Oates, J., Carpenter, D., Fisher, M., Goodson, S., Hannah, B., Kwiatowski, R., Prutton, K., Reeves, D., & Wainwright, T. (2021). *BPS Code of Human Research Ethics*. https://discovery.dundee.ac.uk/en/publications/bps-code-of-human-research-ethics

Office of National Statistics, 2022; https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsrelatedtodrugpoisoninginenglandandwales/registrations (Accessed 01.03.2023)

Ogden, S. N., Dichter, M. E., & Bazzi, A. R. (2022). Intimate partner violence as a predictor of substance use outcomes among women: A systematic review. *Addictive behaviors*, 127, 107214. https://doi.org/10.1016/j.addbeh.2021.107214

O'Rourke-Suchoff, D., Sobel, L., Holland, E., Perkins, R., Saia, K., & Bell, S. (2020). The labor and birth experience of women with opioid use disorder: A qualitative study. *Women and Birth*, *33*(6), 592–597. https://doi.org/10.1016/j.wombi.2020.01.006

Osbeck, L. M., & Antczak, S. L. (2021). Generalizability and Qualitative Research: A New Look at an Ongoing Controversy. *Qualitative Psychology*, *8*(1), 62–68.

Patton, D. (2024). The Power, Capacity, and Resiliency of Women in Substance Use Disorder Recovery to Overcome Multiple and Complex Housing Transitions. *Social Sciences*, *13*(4), 206.

Peacock-Chambers, E., Paterno, M. T., Kiely, D., Fioroni, T., Byatt, N., & Friedmann, P. D. (2021). Engagement in perinatal outpatient services among women in recovery from opioid use disorders. *Substance Abuse*, *42*(4), 1022–1029. https://doi.org/10.1080/08897077.2021.1904091

Peters, W., Guille, C., & Mittal, L. (2019). Substance use disorders in women. *Neurology and Psychiatry of Women: A Guide to Gender-Based Issues in Evaluation, Diagnosis, and Treatment*, 103–113.

Phillips, H., Warshaw, C., Kaewken, O. (2020). *Literature review: Intimate partner violence, substance use coercion, and the need for integrated service models*. National Center on Domestic Violence, Trauma, and Mental Health (Accessed 01.03.2023)

Prochaska, J. O., Norcross, J. C., & DiClemente, C. C. (2013). Applying the stages of change. *Psychotherapy in Australia*, 19(2), 10–15. https://search.informit.org/doi/10.3316/informit.254435778545597

Proulx, D., & Fantasia, H. C. (2021). The Lived Experience of Postpartum Women Attending Outpatient Substance Treatment for Opioid or Heroin Use. *Journal of Midwifery and Women's Health*, *66*(2), 211–217. https://doi.org/10.1111/JMWH.13165

Public Health England. (2019) United Kingdom drug situation focal point annual report. https://www.gov.uk/government/publications/united-kingdom-drug-situation-focal-point-annual-report/uk-drug-situation-2019-summary (Accessed 01.03.2023)

Potter, J., & Wetherell, M. (1987). *Discourse and social psychology: beyond attitudes and behaviour*. Sage. https://go.exlibris.link/zfZSKgcn

Radcliffe P., et al., (2024) https://www.kcl.ac.uk/research/the-stepping-stones-study (Accessed 09.06.2024)

Radcliffe, P. (2011). Motherhood, pregnancy, and the negotiation of identity: The moral career of drug treatment. *Social Science and Medicine*, 72(6), 984–991. https://doi.org/10.1016/j.socscimed.2011.01.017

Rankin, L., Mendoza, N. S., & Grisham, L. (2023). Unpacking perinatal experiences with opioid use disorder: relapse risk implications. *Clinical social work journal*, *51*(1), 34-45.

Renbarger, K. M., Shieh, C., Moorman, M., Latham-Mintus, K., & Draucker, C. (2020). Health Care Encounters of Pregnant and Postpartum Women with Substance Use Disorders. *Western Journal of Nursing Research*, 42(8), 612–628. https://doi.org/10.1177/0193945919893372

Roberts J.M. (2014) Critical realism, dialectics, and qualitative research methods. *Journal for the Theory of Social Behaviour*, 44(1), 1–23.

Robertson, J. E., & Norris, N. F. J. (2001). Generalization: The linchpin of evidence-based practice? *Educational Action Research*, 9, 303–310.

Roald, T., Koppe, S., Jensen, T. B., Hansen, J. M., & Levin, K. (2021). Why Do We Always Generalize in Qualitative Research? *Qualitative Psychology*, *8*(1), 69–81. https://doi.org/10.1037/qup0000138

Sadler, G. R., Lee, H. C., Lim, R. S. H., & Fullerton, J. (2010). Recruitment of hard-to-reach population subgroups via adaptations of the snowball sampling strategy. *Nursing & health sciences*, *12*(3), 369-374.

Sanders, A. N., Vance, D. E., Dudding, K. M., Shorten, A., & Rice, M. (2022). Maternal-infant bonding for the opioid exposed dyad: A rodgers' evolutionary concept analysis. *Nursing Forum*, 57(1), 165–170. https://doi.org/10.1111/nuf.12663

Savin-Baden, M., & Howell-Major, C. (2013). *Qualitative research: The essential guide to theory and practice*. Routledge.

Scambler, G. (2009), Health-related stigma. *Sociology of Health & Illness*, 31: 441-455. https://doi.org/10.1111/j.1467-9566.2009.01161.x

Scambler, G., & Scambler, S. (2015). Theorizing health inequalities: The untapped potential of dialectical critical realism. *Social Theory and Health*, *13*(3–4), 340–354. https://doi.org/10.1057/sth.2015.14

Scatliffe, N., Casavant, S., Vittner, D., & Cong, X. (2019). Oxytocin and early parent-infant interactions: A systematic review. International Journal of Nursing Sciences, 6(4), 445–453. https://doi.org/10.1016/j.ijnss.2019.09.009

Scambler, G. (2012) https://www.grahamscambler.com/stigma-and-mental-illness/2012 (Accessed 29.07.2024)

Scottish Government, 2018; https://www.gov.scot/binaries/content/documents/govscot/publications/research-and-analysis/2018/06/ drug-related-deaths-women-increasing-scotland/documents/00537476-pdf/00537476-pdf. Accessed 01.03.2023)

Schiff, D. M., Work, E. C., Muftu, S., Partridge, S., MacMillan, K. D. L., Gray, J. R., Hoeppner, B. B., Kelly, J. F., Greenfield, S. F., Jones, H. E., Wilens, T. E., Terplan, M., & Bernstein, J. (2022). "You have to take this medication, but then you get punished for taking it:" lack of agency, choice, and fear of medications to treat opioid use disorder across the perinatal period. *Journal of Substance Abuse Treatment*, 108765. https://doi.org/10.1016/j.jsat.2022.108765

Schiff, D. M., Nielsen, T., Terplan, M., Hood, M., Bernson, D., Diop, H., Bharel, M., Wilens, T. E., LaRochelle, M., Walley, A. Y., & Land, T. (2018). Fatal and nonfatal overdose among pregnant and postpartum women in Massachusetts. *Obstetrics and Gynecology*, 132(2), 466.

Schraube, E., & Højholt, C. (2019). Introduction: Subjectivity and Knowledge – The Formation of Situated Generalization. *Psychological Research* (pp. 1–19). https://doi.org/10.1007/978-3-030-29977-4_1

Shaw, R. M., Howe, J., Beazer, J., & Carr, T. (2020). Ethics and positionality in qualitative research with vulnerable and marginal groups. *Qualitative Research*, *20*(3), 277-293.

Shadowen, C., Jallo, N., Parlier-Ahmad, A. B., Brown, L., Kinser, P., Svikis, D., & Martin, C. E. (2022). What recovery means to postpartum women in treatment for opioid use disorder. *Women's Health Reports*, *3*(1), 93-103.

Simpson, K. A., & Bluthenthal, R. N. (2021). Qualitative Approaches to the Study of Substance and Behavioral Addictions. In *The Cambridge Handbook of Substance and Behavioral Addictions* (pp. 106–118). Cambridge University Press. https://doi.org/10.1017/9781108632591.013

Skogseth, E. M., Brant, K., Harrison, E., Apsley, H. B., Crowley, M., Schwartz, R. P., & Jones, A. A. (2024). Women and treatment for opioid use disorder: contributors to treatment success from the perspectives of women in recovery, women with past attempts in drug treatment, and health and criminal justice professionals. *Substance Use: Research and Treatment*, *18*, 11782218231222339.

Slaney, K. L., & Tafreshi, D. (2021). Scientific Generalization in Psychological Inquiry: A Concept in Need of Clarification. *Qualitative Psychology*, *8*(1), 82–94. https://doi.org/10.1037/qup0000186

Smith, J. A. (1996). Beyond the divide between cognition and discourse: Using interpretative phenomenological analysis in health psychology. *Psychology and health*, 11(2), 261-271.

Smith, J. A. (2017). Interpretative phenomenological analysis: Getting at lived experience. *The journal of positive psychology*, 12(3), 303-304.

Smith, J. A. (2011). Evaluating the contribution of interpretative phenomenological analysis. *Health psychology review*, 5(1), 9-27.

Stangl, A. L., Earnshaw, V. A., Logie, C. H., van Brakel, W., Simbayi, L. C., Barré, I., & Dovidio, J. F. (2019). The Health Stigma and Discrimination Framework: A global, crosscutting framework to inform research, intervention development, and policy on health-related stigmas. *BMC Medicine*, *17*(1), 18–23. https://doi.org/10.1186/s12916-019-1271-3

Staudt, M. (2018). Best practices for enhancing substance abuse treatment retention by pregnant women. *Best Practices in Mental Health: An International Journal*, 14(2), 48–63.

Stengel, C. (2014). The risk of being "too honest": Drug use, stigma and pregnancy. *Health, Risk and Society,* 16(1), 36–50. https://doi.org/10.1080/13698575.2013.868408

Stets, J. E., & Serpe, R. T. (2013). Identity theory. In J. DeLamater & A. Ward (Eds.), Handbook of social psychology (2nd ed., pp. 31–60). Springer Science + Business Media. https://doi.org/10.1007/978-94-007-6772-0_2

Sturgiss, E.A., & Clark, A.M. (2020) Using critical realism in primary care research: an overview of methods, *Family Practice*, Volume 37, Issue 1 (p. 143–145). https://doi.org/10.1093/fampra/cmz084

Sullivan, C., & Forrester, M. A. (Eds.). (2019). *Doing qualitative research in psychology: a practical guide* (2nd ed.). SAGE .

Terplan, M., Kennedy-Hendricks, A., & Chisolm, M. S. (2015). Prenatal substance use: Exploring assumptions of maternal unfitness. Substance Abuse: Research and Treatment, 9, 1–4. https://doi.org/10.4137/SART.S23328

Terry, G., & Braun, V. (2013). "We have friends, for example, and he will not get a vasectomy": Imagining the self in relation to others when talking about sterilization. *Health Psychology*, *32*(1), 100–109. https://doi.org/10.1037/a0029081

Terry, G., Hayfield, N., Clarke, V., & Braun, V. (2017). Thematic Analysis. In *The SAGE Handbook of Qualitative Research in Psychology* (pp. 17–36). SAGE Publications Ltd. https://doi.org/10.4135/9781526405555.n2

Thoburn, J. (2023). Child welfare and child protection services in England. *The Oxford handbook of child protection systems*, 135-155.

Thomson, S., Khalil, A., Hafford, S., & Waterstone, M. (2021). Opioid misuse in pregnancy. *The Obstetrician & Gynaecologist*, 1–8. https://doi.org/10.1111/tog.12779

Thornicroft, G., Sunkel, C., Milenova, M., & Commission Implementation Partnership (2024). How to stop stigma: implementing The Lancet Commission on ending stigma and discrimination in mental health. *The Lancet. Psychiatry*, *11*(2), 88–89. https://doi.org/10.1016/S2215-0366(23)00374-7

Trainor, L. R., & Bundon, A. (2021). Developing the craft: reflexive accounts of doing reflexive thematic analysis. *Qualitative Research in Sport, Exercise and Health*, *13*(5), 705–726. https://doi.org/10.1080/2159676X.2020.1840423

UK Government, 2020; https://www.gov.uk/government/statistics/substance-misuse-treatment-for-adults-statistics-2019-to-2020/adult-substance-misuse-treatment-statistics-2019-to-2020-report. (Accessed 15.03.2024)

UK Government, 2021; https://www.gov.uk/government/publications/from-harm-to-hope-a-10-year-drugs-plan-to-cut-crime-and-save-lives/from-harm-to-hope-a-10-year-drugs-plan-to-cut-crime-and-save-lives. (Accessed 22.03.24)

UK Government, 2006; https://webarchive.nationalarchives.gov.uk/ukgwa/20170807150623/http://www.nta.nhs.uk/uploads/nta_modelsofcare_update_2006_moc3.pdf (accessed 22.03.2024)

UK Treatment Addiction Centres. https://www.ukat.co.uk. (Accessed 01.06.2024)

United Nations Office on Drugs and Crime. (n.d.). World drug report 2015.

Walsh, R. T., Teo, T., & Baydala, A. (2014). *A critical history and philosophy of psychology: Diversity of context, thought, and practice*. Cambridge University Press. https://doi.org/10.1017/CBO9781139046831

Warshaw, C. & Tinnon, E. (2018). Coercion Related to Mental Health and Substance Use in the Context of Intimate Partner Violence: A Toolkit for Screening, Assessment, and Brief Counseling in Primary Care and Behavioral Health Settings. Chicago, IL: National Center on Domestic Violence, Trauma, and Mental Health. Retrieved from: http://www.nationalcenterdvtraumamh. (Accessed 01.09.2023)

Wasserman S, Pattison P, Steinley D.. (2005) Social Networks *Encyclopedia of Statistics in Behavioral Science*. Hoboken, NJ: John Wiley &Sons, 2005

Wetherell, M., Taylor, S., & Yates, S. J. (Eds.). (2001). *Discourse theory and practice: A reader*. Sage.

Whittaker, A., Martin, F., Olsen, A., & Wincup, E. (2020). Governing Parental Drug Use in the UK: What's Hidden in "Hidden Harm?". *Contemporary Drug Problems*, 47(3), 170-187. https://doi.org/10.1177/0091450920941267

Wiggins, S. (2017). *Discursive psychology*. SAGE Publications Ltd., https://doi.org/10.4135/9781473983335

Wilkinson, S., & Kitzinger, C. (Eds.). (1996). *Representing the other: A feminism & psychology reader*. Sage.

Williams, L., Rycroft-Malone, J., & Burton, C. R. (2017). Bringing critical realism to nursing practice: Roy Bhaskar's contribution . In *Nursing philosophy* (Vol. 18, Issue 2). Wiley Subscription Services, Inc . https://doi.org/10.1111/nup.12130

Willig, C. (2019a). What Can Qualitative Psychology Contribute to Psychological Knowledge? *Psychological Methods*, *24*, 796–804. https://doi.org/10.1037/met0000218

Willig, C. (2019b). Ontological and epistemological reflexivity: A core skill for therapists. *Counselling and Psychotherapy Research*, *19*(3), 186–194. https://doi.org/10.1002/capr.12204

Willig, C. (2013). I*ntroducing Qualitative Research in Psychology*. (Fourth Edition). McGraw-Hill Education (UK).

Willig, C., & Borcsa, M. (2021). Conclusion: Qualitative research in mental health: Reflections on research questions, methods and knowledge. In *Qualitative Research Methods in Mental Health: Innovative and Collaborative Approaches* (pp. 251–261). Springer International Publishing. https://doi.org/10.1007/978-3-030-65331-6_11

Willig, C., & Rogers, W. S. (2017). The SAGE Handbook of Qualitative Research in Psychology. In *The SAGE Handbook of Qualitative Research in Psychology*. SAGE Publications Ltd. https://doi.org/10.4135/9781526405555

World Health Organization. (2022). ICD-11: International classification of diseases (11th revision). https://icd.who.int/

Wright, H., Morgan, H. C. M., Forbes, C., & Nolte, L. (2022). 'Someone who's there for you … even in your darkest days': an evaluation of a psychotherapeutic counselling service for birth relatives of adopted children. *Journal of Social Welfare and Family Law*, *44*(3), 283–305. https://doi.org/10.1080/09649069.2022.2102762

Yardley,L. (2008). Demonstrating validity in qualitative psychology. In J.A. Smith (Ed.,) *Qualitative psychology: A practical guide to research methods* (2nd ed.,) London: SAGE

Yardley, L. (2000). Dilemmas in qualitative health research. *Psychology and health*, 15(2), 215-228.

Zaborowski, H. (2011). Heidegger's hermeneutics: Towards a new practice of understanding. In *Interpreting Heidegger: Critical Essays* (pp. 15–41). Cambridge University Press. https://doi.org/10.1017/CBO9780511974465.003

9 Appendices

Appendix A: Research Poster

Appendix B: **Drug Street Pricing Guide (Pending Permission Requested For Use)**

Appendix C: Research Protocol

Appendix D: HRA & HCRW Research Approval

Appendix E: Confirmation of Chief Investigator and Principal Investigator roles

Appendix F: Research Approval by Noclor

Appendix G: Organisation Informational Documents, signed with Noclor

Appendix H: Insurance provided by Sponsor, City University

Appendix I: Clarification of insurance cover for pregnant women

Appendix J: Redacted Data Extract – Clinical Care records (RIO)

Appendix K: Redacted Data Extract – Clinical Care records (ILLY-CAREPATH)

Appendix L: Participant Consent Form

Appendix M: Letter to Potential Participant

Appendix N: Participation information Sheet

Appendix O: Interview Demographic Questionnaire

Appendix P: Interview Topic Guide

Appendix Q: Risk Management Procedures

Appendix R: Summary of Amendments

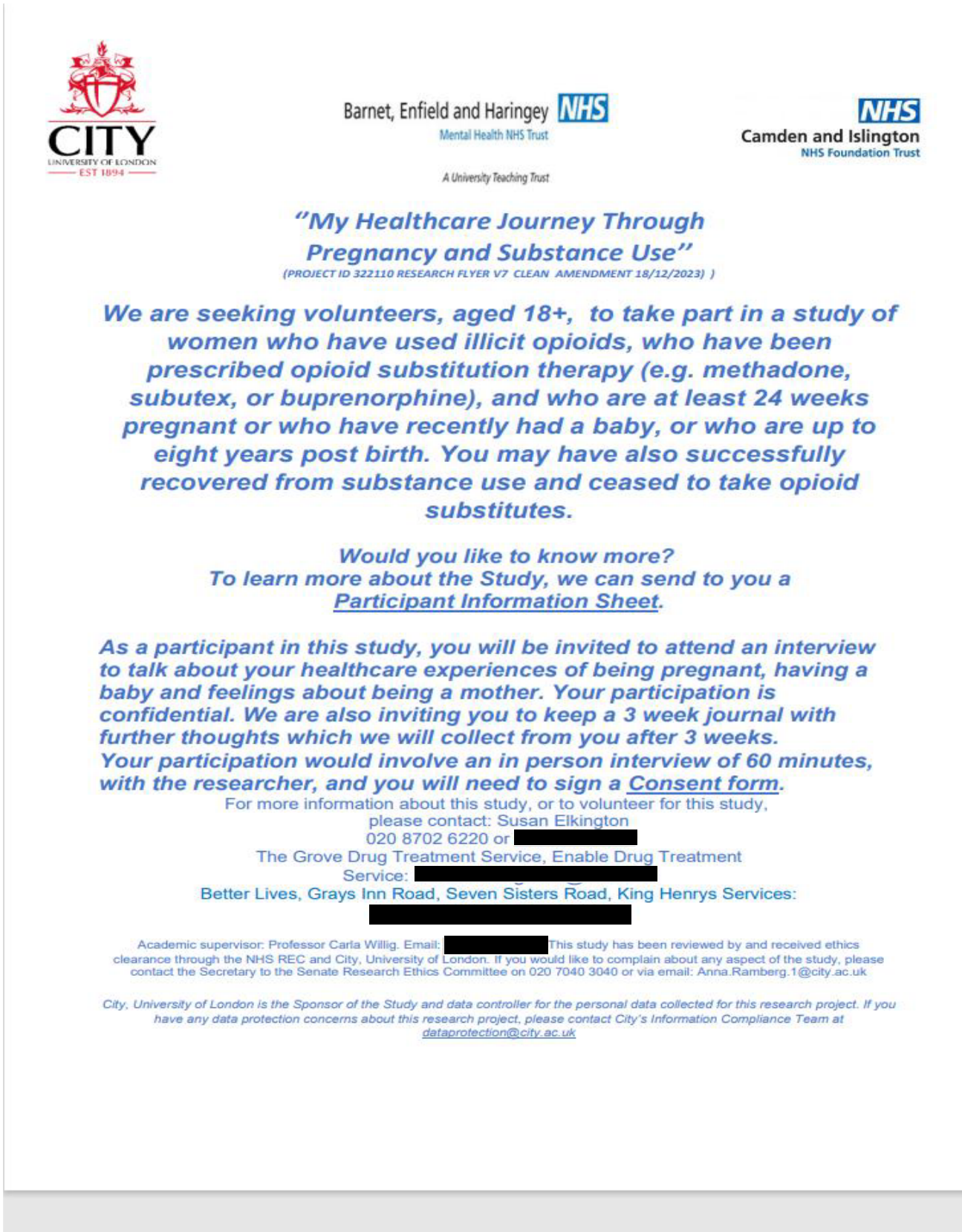
Appendix S: Coding Analysis-Reflexive notes on each participant

Appendix T: Coding Analysis-Example Extract Transcript notes and queries

Appendix U: Coding Analysis-Initial Code Development

Appendix V: Theme Development -Initial Draft

9.1.1 Appendix A: Research Poster



CITY
UNIVERSITY OF LONDON
EST 1894

Barnet, Enfield and Haringey NHS
Mental Health NHS Trust
A University Teaching Trust

NHS
Camden and Islington
NHS Foundation Trust

"My Healthcare Journey Through Pregnancy and Substance Use"

(PROJECT ID 322110 RESEARCH FLYER V7 CLEAN AMENDMENT 18/12/2023))

We are seeking volunteers, aged 18+, to take part in a study of women who have used illicit opioids, who have been prescribed opioid substitution therapy (e.g. methadone, subutex, or buprenorphine), and who are at least 24 weeks pregnant or who have recently had a baby, or who are up to eight years post birth. You may have also successfully recovered from substance use and ceased to take opioid substitutes.

Would you like to know more?
To learn more about the Study, we can send to you a Participant Information Sheet.

As a participant in this study, you will be invited to attend an interview to talk about your healthcare experiences of being pregnant, having a baby and feelings about being a mother. Your participation is confidential. We are also inviting you to keep a 3 week journal with further thoughts which we will collect from you after 3 weeks.
Your participation would involve an in person interview of 60 minutes, with the researcher, and you will need to sign a Consent form.

For more information about this study, or to volunteer for this study, please contact: Susan Elkington
020 8702 6220 or [redacted]
The Grove Drug Treatment Service, Enable Drug Treatment Service: [redacted]
Better Lives, Grays Inn Road, Seven Sisters Road, King Henrys Services: [redacted]

Academic supervisor: Professor Carla Willig. Email: [redacted] This study has been reviewed by and received ethics clearance through the NHS REC and City, University of London. If you would like to complain about any aspect of the study, please contact the Secretary to the Senate Research Ethics Committee on 020 7040 3040 or via email: Anna.Ramberg.1@city.ac.uk

City, University of London is the Sponsor of the Study and data controller for the personal data collected for this research project. If you have any data protection concerns about this research project, please contact City's Information Compliance Team at dataprotection@city.ac.uk

9.1.2 Appendix B: Drug Street Pricing Guide

Independent Drug Expert Alliance

Inclusive Impartial Independent

Quick Reference - Average UK* Drug Price Guide 2023

Substance	0.05g	0.1g	½ g	1g	3.5g 1/8th oz	7g ¼ oz	14g ½ oz	28g 1 oz	125g 1/8th kg	250g ¼ kg	500g ½ kg	1000g 1 kg
Amphetamine	-	-	£5	£10	£15-£20	£30-£40	£60	£80	-	£300	£500	£1k-£3k
Cannabis FFH (UK)	-	-	-	£10	£25-£35	£50-£70	£80-£130	£170-£220	£650-£900	£1.3k-£1.6k	£2k-£3k	£3k-£5k
Cannabis FFH (Cali)	-	-	-	£15-£30	£60-£100	£100-£170	£200-£350	£500-£600	-	-	£4k	£4k-£6k
Cannabis Resin & Herbal Cannabis	-	-	-	£5	£15	£25-£30	-	£80-£150	£300	£450	-	£600-£1k
Cocaine - Adulterated	-	-	£25	£40-£60	£120-£180	£220-£300	£425-£500	£800-£1k	£4.5k	-	£12k-£16k	£20k-£26k
Cocaine - Unadulterated	-	£10 point	£35-£50	£70-£120	£200-£350	£400-£600	£600-£800	£1.1k-£2k	£5.5k	-	£14k-£19k	£28k-£36k
Crack Cocaine[1]	£5	£10	£30-£40	£60-£80	£120-£200	£250-£300	£550-£650	£800-£1.4k	-	-	-	-
Heroin[1]	£5	£10	£30-£40	£60-£80	£120-£200	£250-£300	£550-£650	£750-£1.5k	-	-	-	£18k-£22k
Ketamine	-	-	-	£20-£40	£50-£70	£120-£150	£180-£250	£350-£600	-	-	£3k-£3.5k	£5k-£8k
MDMA (Powder/Crystal)	-	-	-	£20-£40	£50-£60	£110-£130	£180-£200	£300-£600	-	-	£2k-£2.5k	£3k-£8k
MDMA Pills	-	-	-	£5-£10 [2]pp	£20 3 pills	£60 10 pills	£300 50 pills	£550 100 pills	-	-	-	£1k-£1.5k 10,000 pills

*UK does not include Scotland & N.Ireland

[1] Heroin & Crack Cocaine are typically sold on the 'point' (0.1, 0.2 and so on)

[2]pp – Per Pill

Always refer/cross reference to pricing within the case if present e.g., SMS marketing messages containing pricing for specific deal sizes.

If you are able to provide additional, validated, pricing data, please contact us here info@independentdrugexpertalliance.co.uk

(Pending Permission requested for use)

9.1.3 Appendix C: Research Protocol

''My Healthcare Journey Through Pregnancy and Substance Use''.

An Investigation of the Lived Experience of the Healthcare Journeys of Women with Opioid Use Disorder Who Become Pregnant.

This is a qualitative study which investigates the lived experience of women with opioid use disorder (OUD) who become pregnant, and their journey through their journey of peri-natal and post-partum healthcare.

PROTOCOL VERSION NUMBER AND DATE
18/12/2023
PROTOCOL NUMBER: v 6. Redlined

RESEARCH REFERENCE NUMBERS
IRAS NUMBER: 322110
NHS ETHICS REVIEW: NORTH WEST GREATER MANCHESTER WEST REC

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor: Date: Signature: Name (please print): Dr Sebastian Gaigg, Position: Head of Psychology Department, City, University of London.		Date: ...../...../.....
Student and Prin Signature: ..... Name: (please pr Susan Elkington		Date: ...../...../.....

LIST of CONTENTS

KEY STUDY CONTACTS

Student and Principal Investigator	Susan Elkington (MA; MSc; MBPs) Barnet, Enfield and Haringey Mental Health NHS Trust The Grove, 9 Bruce Grove, Tottenham, London N17 6RA T: [redacted] E: [redacted] E: [redacted]
Chief Investigator & Academic Supervisor	Professor Carla Willig (BSc; MPhil; PhD) City University, Rhind Building, City University, Northampton Sq., London Post, EC1V 0HB T: [redacted] E: [redacted]
Sponsor and Head of Psychology Department, School of Health Psychology and Health Sciences	Dr Sebastian Gaigg, , City University, Rhind Building, City University, Northampton Sq., London, EC1V 0HB T: [redacted] E: [redacted]
R&D Team NHS C&I	Thomas Freeth R&D Delivery Team Manager for BEH MHT Barnet Enfield & Haringey Mental Health NHS Trust R&D Office | 1st Floor, Apple Unit – Entrance I (Link Corridor) | St. Ann's Hospital | London | N15 3TH T: [redacted] M: [redacted]
NOCLOR	Robert Pleass R&D Manager. T: [redacted] [redacted]
Psychology lead, the Grove Substance Abuse Clinic, NHS BEH	Dr Charlotte Dent, Psychology Lead Barnet, Enfield and Haringey Mental Health NHS Trust 9 Bruce Grove, Tottenham, London N17 6RA T: [redacted]
Clinical lead, Substance Abuse Services, NHS C&I	Dr Dominic O'Ryan Interim Head of Psychology, Substance Misuse Services and LD Trust, CBT Training Lead Camden & Islington NHS Foundation Trust Margarete Centre, 108 Hampstead Road, London NW1 2LS T: [redacted] E: [redacted]

STUDY SUMMARY

Study Title	**''My Healthcare Journey Through Pregnancy and Substance Use''.** **An Investigation of the Lived Experience of the Healthcare Journeys of Women with Opioid Use Disorder Who Become Pregnant.**
Brief synopsis	This is a qualitative cross-sectional research project which investigates the lived experience of women with opioid use disorder (OUD) who become pregnant, and their lived experience of a complex journey of peri-natal and post-partum healthcare.
Study Design	A qualitative study design based on interviews with a single cohort of women, aged between 18+years old, with opioid use disorder (OUD)who will be between 24 weeks pregnant and up to eight years post birth . The design is cross-sectional, and women will be at different stages of perinatal to post-natal care.
Study Participants	Women, 18+ years old, between 24 weeks pregnant to 8 (eight) years post birth post birth with OUD, who are taking opioid replacement therapy (OST e.g., methadone). Women may also be in recovery or completed opioid substitute therapy.
Planned Size of Sample (if applicable)	N=12
Follow up duration (if applicable)	N/A
Planned Study Period	October 2022-May2025
Research Question/Aim(s)	This research proposal seeks to understand how women aged 18+ years old with an opioid use disorder (OUD) who become pregnant, experience and understand their healthcare journeys from pregnancy to the post-natal stages. The research has three objectives: a) To gain understanding of how women with OUD who become pregnant, experience and understand the complex journey of peri-natal and post-natal healthcare. b) To contribute towards clinicians' understanding of factors which promote better outcomes for mother and infant (e.g., adherence to opioid substitution therapy (OST); engagement in psychosocial support and recovery from substance use). c) To inform current practice, interventions and services aimed at supporting young adult female population with OUD.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**CITY is providing funding up to £500 for the participant and PPI compensation.**

ROLE OF STUDY SPONSOR AND FUNDER

City University is the sponsor of the study and assumes overall responsibility for the initiation and management of the study. The Chief Investigator is a Trainee Counselling Psychologist. City requires doctoral trainees to submit a portfolio of work which includes an original research (50,000 word). The present study is a piece of doctoral research required for submission on October 1st, 2024.

City provides academic supervision, monitoring and teaching in research methods. City has assessed and marked all key stages of the research proposal, including a Research question, Literature Review and Research proposal. City also provides materials for the study such as secure storage, software tools and provides data management.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The PI is the student researcher and is responsible for study set up, implementation and all study tasks and management. The PI has a direct reporting line to the academic supervisor and Chief Investigator and an operational reporting line to the staff within the NHS Trusts. There are no committees.

KEY WORDS:

Opioid use disorder, (OUD)

Methadone

Pregnancy

Substance Use

Perinatal (care)

Postpartum (care)

Maternity (care)

STUDY FLOW CHART

The following diagram provides a schematic overview of the study commencing October 2022. It is estimated the study will be completed in April 2025.

Figure 1: Overview of the study

STUDY PROTOCOL

''My Healthcare Journey Through Pregnancy and Substance Use''.

An Investigation of the Lived Experience of the Healthcare Journeys of Women with Opioid Use Disorder Who Become Pregnant.

1 BACKGROUND

UK has one of the highest opioid misuse rates in Europe and heroin is reported as the most used illicit drug in substance abuse clinics (SUD) clinics. Its purity and availability are understood to have increased since 2016 (European Drug Report, 2019; Point, 2018). Research indicates that women start using illicit opioids at an earlier age and develop use more rapidly than men, with the majority of female opioid users being of childbearing age; this makes them a particularly vulnerable group, with multiple complex health and social care needs (Tarasoff et al., 2018; Unger at al., 2010). In the UK, data indicates that 4.2% of opiate users presenting to substance abuse clinics are pregnant, and 58% of females receiving substance abuse treatment are parents or lived with children (Public Health England, [PHE] 2019). A study of four thousand electronic patient records in the addiction services of South London and Maudsley (SLaM), National Health Services (NHS) Foundation Trust indicates 39.6% of service users were mothers (Canfield et al., 2021). Women with opioid use disorder (OUD) who use illicit drugs such as heroin, and who become pregnant, navigate unique and personal journeys of complex healthcare treatment through pregnancy, birth and the post-natal stages.

Public Health England (2017) and National Institute for Clinical Excellence (NICE 2010) provide clinical guidelines for the treatment of pregnant mothers with an OUD which includes the assessment and treatment of the addiction disorder, initiation of opioid substitution therapy (OST), specialised maternity care, the monitoring for neonatal abstinence syndrome (NAS), as well as psychosocial and onward social support.

The disciplines of psychiatry, pharmacology, substance abuse, midwifery, obstetrics & gynaecology define this health care which provides a model of multi-agency clinical treatment for pregnant women with an OUD (Thomson et al., 2021).

Women with OUD who become pregnant, face difficulties unlike other pregnant women; they tackle a challenging journey during which they receive a concentrated period of healthcare which includes initiation and maintenance of methadone, testing and managing

substance use as well as perinatal care. The women experience the state of being pregnant, often for the first time, and start to grapple with the challenges of motherhood. The proposed study aims to interview women aged 18-45 years old who are taking this journey.

The study aims to inform current practice, interventions and services aimed at supporting women with OUD who become pregnant. Potential findings might include how well the use of illicit drugs is understood on the impact of the foetus attitudes to healthcare, how motherhood and responsibility is perceived, and how recovery is experienced. In addition, we can gain understanding as to what promotes a new relationship with oneself, forgiveness and acceptance, as well as factors which women feel can support them to build a new social network, and to develop resilience to patterns of opioid use.

Literature Search

The literature search was conducted in March and April 2022 including: CINAHL, Medline, PsycINFO via EBSCOhost and Embase, Medline via Ovid Online, PROSPERO, Cochrane Library, and Google Scholar. Individual searches were undertaken in specialised journals covering substance abuse, gynaecology and obstetrics, and UK addiction websites and The Substance Abuse and Mental Health Services Administration (SAMHSA). The search revealed a lean research field, dominated by research undertaken in the US.

Research in the US.

Research by Schiff et al., (2022) investigated factors influencing mothers' (N=26) engagement in opioid substitution therapy (OST) and who were, on average, 10 months post-delivery. The approach uses semi-structured interviews based on models of health behaviour research and Grounded Theory, with questions updated as interviews progressed to allow for development of theory (Gelberg et al., 2000). Themes identified, include the lack of agency and autonomy surrounding medication, hesitation to use medication and methadone clinics not feeling suitable environments for mothers with infants.

A key experience voiced by mothers is the anxiety and uncertainty in the post- partum period whilst waiting for a diagnosis and preparing to care for a baby with potential Neonatal Abstinence Syndrome (NAS) (O'Rourke-Suchoff et al., 2020). New-borns exposed to opioids are at risk of withdrawal, damage to the cardiac, central nervous system (CNS), respiratory and digestive tract following delivery, and are subject to a range of tests and routine scoring using the 10-item Finnegan Neonatal Abstinence Scoring System (sFNAS) (Unger at al., 2012).

Mixed methods research which included recovery questionnaires and semi-structured interviews with women (N=8), aged 28.6 years old (M), recruited from a specialist perinatal addiction clinic 2-6 months post birth yield a theme of transformation in the postpartum period (Shadowen et al., 2022). All participants had taken medication for OUD from pregnancy and were in recovery. Recovery was experienced as a new relationship with oneself of self-love, forgiveness and acceptance and a desire to curate mindfully a new social network, to engage in activities to promote mental and physical health and to develop resilience to past trauma. Transformational development as a mother and woman in recovery emerges as a key concept in several studies where women identify with their ability to meet the challenges of childbirth, healthcare and parenting to regain a sense of self and self-care. The relationship with the women's environment was transformed, though the process of recovery may be non-linear and dynamic (Goodman et al., 2020; Peacock et al., 2021).

Research in the UK.

In the UK, a qualitative study by Chandler et al., (2020) investigated the experience of mothers (N=16) preparing to care for a baby with NAS and were interviewed 1-6 months post birth. Results indicated themes of anxiety, a lack of clarity and consistency in the identification or diagnosis of NAS post birth and scoring. Feelings of powerlessness and exclusion from the care of babies were expressed, with differences across two study sites, with some parents encouraged to use the scoring system, and others, in the semi-rural area and managed by standard maternity services not aware that their baby was being scored at all or had to ask about their baby's score. Parents were sensitive to the scoring of NAS, due to fears of losing custody and being judged as unsuitable, and experienced wide variations in scoring from different clinical staff, adding to anxiety and uncertainties. Chandler et al., (2020) illustrate how anxiety provoking the diagnosis of NAS can be. The authors propose that NAS is a variable clinical diagnosis and can be produced and enacted in diverse ways, making it a controversial diagnostic label and socially constructed, and it would be more constructive to frame NAS as a social diagnosis which recognises the inequalities and hardship faced by many parents. The studies illustrate a complex lived experience through pregnancy with OUD. It suggests that the nascent research field recognises that services vary and that some challenges faced by women are not well understood. These challenges are compounded by experiences of stigma experienced by users and mothers who are using, with recent studies providing evidence of its persistent presence. Stigma theory posits that stigma is a process which is context specific, and which disempowers those with characteristics not acceptable by the society and can be particularly pervasive in healthcare settings (Stangl et al., 2019). The present study has considered current research, especially the US research. In the UK, the proposed research project aims to contribute new knowledge to the healthcare model by investigating the personal journeys of these women as they learn to manage their OUD, and early motherhood

The present study & population of interest

The present study is set within two NHS Healthcare Trusts in north London. It aims to recruit twelve women with OUD, aged 18+ years, diagnosed with OUD who are taking methadone and who are between 24 weeks pregnant to 8 (eight) years post post birth. Women will be drawn from different stages of pregnancy and will be interviewed once. Each woman will be invited to keep a notebook of further thoughts during the following 3 weeks. The data will be transcribed and analysed using thematic analysis (TA). Results will be produced in a research thesis and submitted in October 2024 to City University, the sponsor. Results will also be disseminated within the participating Trusts and publication sought.

2 RATIONALE.

The study aims to address a gap in current research of the population of women as they journey through an intense period of healthcare and interaction with healthcare services. It is a timely area for investigation in UK and seeks to contribute towards clinical practice. Illicit opioids continue to be used amongst women 18+ years old, and who are fertile.

This research proposal investigates the lived experience of women with an opioid use disorder who become pregnant and their healthcare journeys from pregnancy to the post-natal stages.

The research has three aims.

a) To gain an understanding of how women with OUD who become pregnant experience and understand the complex journey of peri-natal and post-natal healthcare.

b) To contribute towards clinicians' understanding of factors which promote better outcomes for mother and infant (e.g., adherence to opioid substitution therapy (OST); engagement in psychosocial support and recovery from substance use).

c) To inform current practice, interventions and services aimed at supporting young adult female population with OUD

3 THEORETICAL FRAMEWORK.

The qualitative research methods of the current study have the potential to generate knowledge grounded in human experience and contribute findings relevant to practice (Sandelowski, 2004). The proposed qualitative method for this study is Thematic Analysis (TA) set within the ontological paradigm of critical realism (Bhaskar & Hartwig, 2010). This allows for understanding of parts of the lived experience to be accepted as true (e.g., the biological condition of pregnancy) yet acknowledges the individual experience of that reality as being an interpretation of experience and therefore subjective (Willig & Stainton-Rogers, 2011).

The epistemological approach for the study is phenomenological. The aim is to interpret the experience of situated realities through data collection and analysis via TA (Braun & Clarke, 2022).

The study aims to work sympathetically with a marginalised population, already within NHS care, and make a relevant contribution to practice by investigating patterns in the data in the form of themes arising from the interviews.

4 RESEARCH QUESTION/AIM(S)

To gain understanding of how women with OUD who become pregnant experience and understand their complex journey of peri-natal and post-natal healthcare.

4.1 Objectives

a) To contribute towards clinicians' understanding of factors which promote better outcomes for mother and infant (e.g., adherence to opioid substitution therapy (OST); engagement in psychosocial support and recovery from substance use).

b) To inform current practice, interventions and services aimed at supporting young adult female population with OUD

c) To contribute findings within healthcare and social care systems to improve pathways and support all women with any substance abuse disorder

4.2 Outcome

Outcomes will be summarised as themes which reflect patterns in the data, as well as less well represented and unique views. It is likely that these will have three dimensions. They may reflect firstly the experience of biological experiences e.g., being pregnant or the experience of labour, or secondly the experience of healthcare interventions e.g., methadone and thirdly personal meaning making of their experiences e.g., becoming a mother, managing substance use.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Study Design

This is a qualitative cross-sectional design project which will recruit twelve women and interview them each once. The women will be invited to continue to make notes in a journal for the following 3 weeks after the interview. The research is being conducted in two London NHS Trusts. Women aged between 18+- old who have received a diagnosis of opioid dependency, adopted opioid substitution therapy (OST) (e.g., methadone) and who are between 24-weeks pregnant to 8 (eight) years post birth, will be eligible to take part. Women may also have completed OST and be in recovery.

Data collection and participant Interviews

Each participant will be interviewed once, and this will last approximately 60 minutes. The interview topic guide will probe keys stages of the journey and healthcare as well as the meanings and feelings associated with pregnancy, birth and motherhood. There are four stages to each interview.

Participants will be invited to ask questions about the Participant Information Sheet to ensure understanding, and to sign a Participant Consent Form.

Demographic, clinical, and psychosocial characteristics will be taken via a questionnaire for descriptive participant data.

Interviews will be conducted following a topic guide / semi-structured schedule of questions.

Participants will be debriefed, thanked for their participation and provided with a £25 voucher by way of compensation for their time.

Participants may elect to participate in a focus group of 2-4 women; the women will be subject to the same recruitment processes and be required to sign a consent form.

The researcher will follow up with the interviewee 24 hours post the interview to ensure that the participant is well.

Data transcription, analysis, coding

Audio interviews will be recorded, transferred for secure data storage to City OneDrive, and deleted from the recording device. The data will be de-identified and each participant assigned a study ID. The interviews will be transcoded using relevant software such as NVivo Pro. The interview data will be analysed by the researcher using Thematic Analysis (T.A). This method has been selected as it allows deep analysis of patterns in the data and keys themes and findings to be summarised in a way that is useful for clinical practice.

Management of data, transferring, access and storage

Personal data will be transferred, processed and stored electronically to a secure University site specifically organised for this purpose. Participant data will be anonymized which means it will not be identifiable and matched to the information provided. The Chief investigator and Academic Supervisor will have sole access to the data through three levels of security. The results will be kept in a secure University system called OneDrive. Results are usually kept for 10 years.

Researcher effects/bias

The researcher has personal experience working therapeutically with women with substance abuse, including pregnant women with OUD in an NHS substance abuse clinic. This ongoing work affords valuable insight into the women's' lived experiences, understandings and reactions to their maternity healthcare. The researcher will maintain a journal and notes to maintain objectivity throughout

STUDY SETTING

Participants will be registered service users within NHS Mental Health Trust Camden and Islington or NHS Trust Barnet, Enfield and Haringey substance abuse services, and, or receiving care from the Trusts' perinatal services. The substance abuse services, and perinatal services will act as the main recruitment pathways. This setting is relevant as substance abuse services and perinatal services are the main secondary and specialist care pathways for women with OUD during pregnancy.

Interviews will be conducted on NHS sites within substance use services premises within the site's normal operating hours. Requirements include a quiet and comfortable room, which may require baby facilities. Room bookings will be made in advance via the normal booking process. The site's Duty Manager will be informed of the date and time of the interview in advance.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

a) Female and/or capable of pregnancy

b) Age 18+

c) Pregnant at ≥24 weeks to 8 (eight) years months post birth

d) Diagnosis of OUD (illicit)

e) Initiated on opioid substitution therapy (OST) (e.g., methadone) and/or completed OST.

f) Sufficient understanding of English to be able to engage in the study

g) Absence of comorbidity with bipolar disorder or psychosis

h) Custody of children not an inclusion criterion (i.e., mothers may have babies in care or be subject to care proceedings).

Exclusion criteria

Diagnosis of bipolar disorder or psychosis, or comorbid with another serious mental health condition

Diagnosis of other forms of sole substance abuse e.g., alcohol

Not initiated on opioid substitution therapy (e.g., methadone)

Lack of custody, post birth, not an exclusion criterion

7.2 Sampling and sampling technique

Participants will be recruited at different stages from a period of 28 months representing, ≥ 24 weeks pregnant to ≤ 8 (eight) years months post birth. 'Criterion sampling' will be adopted as a purposeful sampling methodology (Savin-Badin & Howell Major, 2013).

7.2.1 Size of sample

Twelve participants are considered to be appropriate for a qualitative study using TA. This quantity will allow patterns of data to be investigated as well as unique units of data which differ from the group.

7.3 Recruitment & sample identification

The research will be advertised within Trust sites by posters about the research and distributed to relevant healthcare teams e.g., Perinatal services. Materials and distribution to sites for display will be carried out by the researcher. Participants will be approached and recruited through the following three methods:

Participant: The potential participants respond to a poster/ leaflet directly by contacting the researcher through details on the poster by telephone.

Care Team referral: Information, posters and flyers will be distributed within the Clinical Care Team who may refer potential candidates to the researcher. Potential participants may be referred to the study by a member of the participants' clinical care team (e.g., perinatal team, substance abuse service). The researcher will follow up with any potential candidates by sending a letter and the Participation Information Sheet (PIS).

Clinical records: The researcher identifies a potential participant through clinical records to which the researcher has access within the substance abuse services and contacts the potential participant via a letter, email or telephone call. The researcher is employed by Barnet, Enfield & Haringey, NHS Trust in the Grove Substance Abuse Service and will have access to the active service user base to identify potential participants. In Camden & Islington, the researcher will be provided with an Honorary contract to work on site with an access letter to work within the substance addiction services. The researcher may send a letter to the service users who fulfil the criteria with the PIS inviting them to contact the researcher. The researcher will follow up twice to establish interest.

The researcher takes responsibility for ensuring participants meet the inclusion criteria and for sampling participants.

Payments to participants

Each participant and the two PPI research contributors who have engaged in supporting the research topic guide will each receive a voucher of £25 + reasonable and validated travel expenses. The voucher is redeemable in retail high street outlets. The basis of the compensation is explained on the study materials. The voucher will be provided at the end of the interview.

Receipt of the voucher does not diminish the participants' right to withdraw from the study. This funding has been sought and approved by City, the Sponsor.

The voucher and validated expenses are considered to be fair compensation for the time taken to participate and does not represent a coercive inducement. It may also reduce any misunderstanding that the time spent with the researcher is any form of therapy.

7.3.2 Consent

The researcher takes responsibility for gaining signed consent before all interviews. The requirement for a Consent form to be signed is included on all marketing material; this will also be explained during the initial contact. Thereafter, consent will be obtained directly from each participant by the researcher in the following stages.

Face to face interviews

During the initial contact, the researcher will advise the potential participant that a Consent form will be required to proceed and will send it in advance for reading.

The Consent form will be explained to the participant at the start of the Interview and the opportunity to ask questions. The PI will be careful to take time to consider the alternatives to not taking part and that the purpose of the study is understood.

The Consent form will be signed by the participant at the start of the Interview.

The Consent form will be a non-electronic form.

The researcher will entrust the Consent forms to the University to be kept securely on site as part of the research materials.

Online interviews

For online interviews, the procedure will be slightly different. During the initial contact, the researcher will advise the potential participant that a Consent form will be required to proceed and will send it in advance for reading.

The consent form will be sent to the participant. The interviewer will call the potential participant to ask if there are any queries. A stamped addressed return envelope will be sent.

The interview will be set once the consent form has been returned.

The above process may take place electronically by email.

8 ETHICAL AND REGULATORY CONSIDERATIONS

There is physiological and ethical complexity in recruiting pregnant women in research as it involves vulnerable women navigating pregnancy, substance use, significant life change, as well the rights of an unborn child.

Safety, Confidentiality

The research design has taken into consideration key ethical and regulatory factors. A major consideration is the safety of the foetus, health of the woman pre and post birth. Risks, burdens and a management plan have been considered and are set out below.

The research needs to protect the rights of the future child, in perpetuity as well as the right of the autonomous mother, therefore confidentiality is paramount. The collection of identifiable data will be kept to a minimum, with interview materials assigned a study ID, unrelated to personal information. Personal data will be transferred directly to the University secure site, expressly set up for research purposes and the storage of confidential data.

Additionally, the researcher will adhere to codes of practice from the BPS (2018) and HCPC (2016) and has undertaken NHS training in research.

8.1 Assessment and management of risk

Pregnant women with an OUD are vulnerable and care will need to be taken to ensure that they have full understanding of the research, purpose and anticipated outcomes of the participation (see Appendix 5)

A summary of risks, adverse events and steps to minimise risk include:

The participants are likely to have a busy schedule of perinatal/post-natal maternity care meetings. Participation in the research will require an additional commitment to an interview.

Discomfort and appropriate facilities.

Women may find pregnancy physically uncomfortable, e.g., to sit for an hour.

They may also require facilities for an infant.

They may not be comfortable walking any distance within NHS sites to an interview room.

Distress It is possible that participants recall difficult memories associated with their experience e.g., childbirth pain either during or after the interview.

Adverse events may occur, and the participants require urgent perinatal clinical attention.

The participants in this population may have suffered from intimate partner violence (IPV) and trauma and the interview may prompt recall.

Risk management plan.

The researcher will monitor the participant throughout all contact and inform the site Duty Manager, Keyworker or GP of any sign of distress emerges.

The researcher will ensure that the clinical care team e.g., GP, and Keyworker of each participant is informed, post consent by the participant, and is aware of the research participation and given the opportunity to highlight any risks unique to the participant they foresee.

The Clinical Care team will be informed of the date and time of the interview so that they are aware of the activity of the participants in the event that context is required for any adverse event.

The Duty Manager will be informed of the date and time of the participant's interview in the event that any adverse events occur, care and risk plan can be enacted.

Interview times will be set to cause minimal inconvenience, with the option to coincide with other routine care appointments at substance abuse clinics or peri/post-natal appointments.

Rooms will be comfortable and afford childcare facilities if required.

The researcher will monitor the participant for any signs of physical discomfort, or distress and offer the participant the right to withdraw at any time or choose to postpone an interview. In the event of any adverse effects or feelings of discomfort, the researcher will make contact with the Duty Manager.

The researcher will allow time for any difficult memories to be empathetically supported, with the option for referral to therapeutic support.

The researcher will call each participant within 24 hours of the interview to ensure participants are well and not experiencing any sense of being unwell. If the event of any sense of unwellness, the researcher will contact the Duty Manager.

Any disclosure of self-harm or safeguarding issue will be reported as risk to the CI and Academic Supervisor, Duty Manager and Clinical Care team.

Any safeguarding issues concerning existing children or dependents of the participant will be raised with the Duty Manager and Clinical care team (See Section 9)

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

This study requires ethical review and approval by Research Ethics Committee (REC). A favourable opinion will be sought from a REC as well as for the study materials prior to the study starting.

Amendments requiring review by the REC will not be implemented until approved by the REC and the study sites can support implementation of the amendment.

Governance

The researcher will maintain ordered documents throughout the study and undertake a series of communications with the REC which are clear and transparent. The researcher will retain all correspondence with the REC and notify the REC at the end of the study. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which favourable opinion was given to the study. If the study ends prematurely, the researcher will notify the REC with an explanation for the early termination of the study. The researcher will submit a final report with the results, including any publications/abstracts, to the REC, within one year of the end of the study.

Regulatory Review & Compliance

The researcher and CI will ensure that approvals from the participating Trusts and recruitment sites are in place and comply with measures set out in the protocol. The researcher will work with the R&D team to ensure approval of amendments and any required amendment is implemented as approved.

Amendments

The researcher, CI and sponsor will assess whether an amendment is substantial or non-substantial and submit valid notices of amendment to the REC. The researcher will also ensure that all amendments are discussed with and communicated to the NHS R&D team.

Process

The process for determining whether an amendment is substantial or non-substantial will be determined by the researcher in discussion with the Sponsor (City University) and Academic Supervisor, and the NHS R&D team. The researcher will notify the REC and NHS R&D departments of any substantial amendment in writing. These might include a change in the procedure for participants or study materials. The amendment will set out what is required and the reasons, as well as any impact assessment on the study site. The protocol would be amended to absorb the amendment and document versions will be clearly indicated and tracked. The amendments will be competed on IRAStemplates.

8.3 Peer review

The study has been submitted to the following process of review by the Study sponsor (City University).

The key stages were:

A presentation of the objectives and methodology of the study (March 2022) to teaching staff and trainee cohort.

A 3000-word literature review (April 2022) which reviewed existing research in the field, identified a gap in UK research.

Research Proposal (July 2022) covering Methods, including the Background to the topic, Case for the Study and Method and Ethical issues + supporting appendices (e.g., Participant information sheet; Topic Guide) The above research preparation work was assessed by university teaching staff in the School of Health Sciences. Further feedback was provided other members of staff, and the work was moderated, and marks checked by a second member of staff.

Two reviews with Academic Supervisor (October-November 2022).

Submission of Methods chapter to City (February 2023) for review by School of Psychological Health Sciences, City

The study has been discussed and a summary of the research has been submitted to the following teams within the participating Trusts during April-October 2022.

NHS R&D Department, NHS Trust Camden & Islington (NHS C&I); this department also acts as the R&D team for NHS Barnet, Enfield & Haringey (NHS BEH)

Noclor, Research Manager

Clinical leads at substance abuse services, NHS BEH Barnet, Enfield & Haringey and NHS C&I.

8.4 Patient & Public Involvement

The study design includes working with either a Women's' recovery group or 2 women in the development of the Interview Topic Guide, the analysis of themes and results, and the dissemination of findings. Prior to recruitment of the study's participants, the researcher will recruit 2 women who are 18+ months post birth. The women will have prior experience of OUD and may still be receiving opioid replacement therapy (ORT). These women will be invited to participate in the research through information provided in the participating Trusts.

The PPI role will have 3 core contributions to the research.

a) To review and contribute towards the interview topic guide

b) To review and comment on the findings and data generated from the interviews.

c) To contribute towards dissemination of the results.

8.5 Protocol compliance

Protocol compliance will be monitored in routine meetings with the Academic supervisor; the researcher will identify any deviations, and log these, so that they can be monitored for occurrence and classified. The level of breach and risk impact will be assessed and recorded. A table of deviations and breaches will be maintained.

8.6 Data protection and patient confidentiality

The Sponsor (City) and researcher will ensure that the study complies with the provisions of the Data Protection Act 1998.

Confidentiality

The researcher will undertake clear measures to ensure that there is no breach of confidentiality in their use of identifiable personal data in the process of identifying potential participants.

The researcher will solely use personal data such as name and contact details to make contact about the research study, as necessary.

The minimum set of personal information will be used in the process of identifying potential participants.

The researcher will not store any personal information on any personal device at any time. An NHS Trust laptop is being provided for the purposes of recording and transferring data to the secure sponsor site.

The researcher will not use or transfer any personal information off NHS sites during the process of identifying participants.

The key step to inform participants of the potential use of their personal records is set out in the Patient Information Sheet (PIS) which will be provided early in the recruitment process.

The PIS will also explain that if the participant wishes to receive the results of the study, contact details will also be kept for this purpose.

The only person who will have access to identifiable information will be the researcher.

The identifiable personal data of any potential participant who does not wish to participate, or who becomes ineligible will not be retained.

Interview recordings and transcripts and journals will be de-identified, and labelled with a Study ID.

All participants will be assigned a study ID, and this will be kept in a separate file which cannot be linked to any personal data.

Transfer & storage, access and duration of storage to sponsor.

Research materials will be transferred electronically to secure University storage facilities, and password protected. Consent forms will be held at a University secure site. The academic supervisor will have access to the data (recordings and transcripts) on a University OneDrive site. If any personal identifying data is used during the interview, this will be deleted by the researcher. No data e.g., a direct quotation would be assignable to a respondent.

Personal data will be transferred, processed and stored electronically on secure University site specifically organised for this purpose.

Personal data will be kept for a period of up to 3 years. This is to allow contact with participants who may wish to receive the results after the study end.

The results will be kept in a secure University system called OneDrive.

The Supervisor will have access to the results (transcripts and results) via the secure University site.

Results and recordings are kept for 10 years by the University.

If any indication of violence, abuse, self-inflicted harm, harm to others, criminal activity, are revealed the researcher would be obliged to report this to a relevant NHS Duty Manager, or Supervisor

Data custodian

City, University of London is the sponsor and the data controller of this study based in the United Kingdom. This means that City as Sponsor is responsible for looking after personal data and using it properly. The legal basis under which this data will be processed is City's public task. To safeguard the participant's data, the study will use the minimum personal-identifiable information possible and comply with the measures above.

City provides transparent information as to how it handles data at https://www.city.ac.uk/about/governance/legal. The Information Commissioner's Office (IOC) https://ico.org.uk/.

8.7 Indemnity

The indemnity policy of the sponsor will apply to the study to meet the potential legal liability of the study such as harm to the participants arising from the management or design of the research.

8.8 Access to the final study dataset

Access to the final data set is limited solely to the researcher (PI) and CI. The Academic researcher has access to the data and results, without access to personal data. If a formal request is made for access to the full data set by investigators, this should be made to the CI and Academic Supervisor.

9. SAFEGUARDING PROTOCOL

All study procedures will follow the Trusts' Adult Safeguarding and Domestic Abuse protocol and is to be read in conjunction with the Trusts' Adult Safeguarding and Domestic Abuse Policy (v1 2.3.2023) and 'It's not OK protocol' (v1 2.3.2023).

9.1 Domestic abuse

The study involves contact and interactions with women who may be at risk of domestic abuse. Domestic abuse is defined as 'Any incident or pattern of incidents of controlling, coercive or threatening behaviour, violence or abuse between those aged 16 or over, who are or have been intimate partners or family members regardless of gender or sexuality. This can encompass but is not limited to the following types of abuse, psychological, physical, sexual, financial, emotional. (The Home Office, March 2013).

9.2 **Adult Safeguarding**

The study will comply with the Statutory Guidance issued under the Care Act2 , (October 2014) that states that adult safeguarding 'means protecting an adult's right to live in safety, free from abuse and neglect' (Section 14.7). The study recognises that this means that freedom from abuse and neglect is a key aspect of a person's well-being, and that adults may have care and support needs and unable to protect themselves from either the risk of, or the experience of abuse or neglect.

9.3 Safeguarding

The study will comply with the Trusts Safeguarding Protocols. The researcher will monitor all study procedures and interactions with the participant, in particular but not limited to the interview and journal for signs of physical abuse, domestic violence, sexual abuse, psychological abuse, financial or material abuse, modern slavery, discriminatory abuse, organisational abuse, neglect and acts of omission, self-neglect, whether that abuse and neglect appears to be caused deliberately or unintentionally.

The researcher recognises the legal obligation to stop abuse or neglect wherever possible, to prevent harm and reduce the risk of abuse or neglect to adults with care and support needs and safeguard adults in a way that supports them in making choices and having control about how they want to live.

9.4 **Pregnant Women with OUD or Mothers with OUD**

The researcher recognises that the study is recruiting a vulnerable population and that use of opioids and substances may relate to coping mechanisms in order to cope with, or 'block out', what is happening to them, and that the women may be victims of domestic abuse forced into drug or alcohol misuse by their abuser in order to intensify control. They may be drawn into sex working or other high-risk activity to pay for access to drugs or alcohol. The participants may have children and wider family who are implicated and impacted by abuse. The researcher recognises therefore that Adult Safeguarding is a primary concern to this study. The study acknowledges that the participants' use of opioids which are pain killers may make acknowledgment of risk and abuse difficult for them to recognise accurately, and therefore safeguarding is of primary importance throughout study procedures.

Ethnicity

The researcher recognises that women of black, Asian and minority ethnic origin (BAME) may be particularly vulnerable in the study population. The researcher recognises that there is under-reporting of domestic abuse by people from (BAME) communities in the general population, and there may be additional barriers to women with OUD bringing attention to their abuse or reporting it. Particular attention therefore will be paid to how women may manifest signs of abuse.

9.5 Management of Safeguarding – Participant, Children, Dependents and Family Members

The study recognises that abuse may impact the wider family. The researcher will monitor all interactions with the participants and take action to report any signs of abuse suspected, observed or voiced relating to themselves or other family members. This includes the participants' children, dependents, grandparents (other adults or family members living or not living with them).

The study recognises that where participants are subject to abuse, children living with or exposed to abuse, abuse are harmed, even if not physically harmed.

9.6 Procedure

In the event that the researcher observes and/or receives information indicating signs of abuse as described above, the researcher will report the incident in writing including information on the participants children, dependent and wider family to:

The Academic Supervisor and Chief Investigator

The Duty Manager of the Service

The participants' Keyworker

Substance Abuse Psychology Leads

The researcher recognises that the study and researcher may not be equipped to undertake full assessment of risk but that it is duty bound to report risk. **9.7 Risk to Researcher(s).**

The researcher acknowledges that it is working with a vulnerable population and will follow the Trusts' protocol for reporting abuse and harm from patients and / or Service Users. This is submitted as part of the study documents.

In the event of any incident of abusive behaviour, the researcher

will follow all NHS operational procedures when working on site.

will report the episode to the Duty Manager

Research Protocol References

Advisory Council on the Misuse of Drugs, 2024; ACMD advice on 2-benzyl benzimidazole and piperidine benzimidazolone opioids (accessible version) - GOV.UK (www.gov.uk) (accessed 23.03.2024)

Agar, M. (1996). The professional stranger: An informal introduction to ethnography. 2nd edition, Academic Press: San Diego, United States of America.

American Psychiatric Association. (2013). Diagnostic and Statistical Manual of Mental Disorders (5th ed.). Arlington, VA: American Psychiatric Publishing.

Alenezi, A., Yahyouche, A., & Paudyal, V. (2021). Current status of opioid epidemic in the United Kingdom and strategies for treatment optimisation in chronic pain. *International Journal of Clinical Pharmacy*, *43*(2), 318–322. https://doi.org/10.1007/s11096-020-01205-y

Andersson, C., Wincup, E., Best, D., & Irving, J. (2020). Gender and recovery pathways in the UK. *Drugs: Education, Prevention and Policy*, *28*(5), 454–464. https://doi.org/10.1080/09687637.2020.1852180

Back, S. E., Lawson, K. M., Singleton, L. M., & Brady, K. T. (2011). Characteristics and correlates of men and women with prescription opioid dependence. Addictive behaviors, 36(8), 829–834. https://doi.org/10.1016/j.addbeh.2011.03.013

Bhaskar, R., & Hartwig, M. (2010). The formation of critical realism: A personal perspective. Routledge

Bhaskar, R. (1975). Forms of realism. *Philosophica*, 15.

Boardman, J. P., Mactier, H., & Devlin, L. A. (2022). Opioids and the developing brain: Time to rethink perinatal care for infants of opioid-dependent mothers. *Archives of Disease in Childhood: Fetal and Neonatal Edition*, *107*(1), F98–F104. https://doi.org/10.1136/archdischild-2020-320102

Brady, K. T., & Lydiard, J. B. (2021). Women and Addiction. In *Textbook of Addiction Treatment* (pp. 1395–1405). Springer International Publishing. https://doi.org/10.1007/978-3-030-36391-8_98

BPS's. (2018). Code of Ethics and Conduct. *The British Psychological Society*, *July*, 100–102. www.bps.org.uk.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Braun, V., & Clarke, V. (2016). (Mis)conceptualising themes, thematic analysis, and other problems with Fugard and Potts' (2015) sample-size tool for thematic analysis. In *International Journal of Social Research Methodology* (Vol. 19, Issue 6, pp. 739–743). Routledge. https://doi.org/10.1080/13645579.2016.1195588

Braun, V., & Clarke, V. (2019). Reflecting on reflexive thematic analysis. *Qualitative Research in Sport, Exercise and Health*, *11*(4), 589–597. https://doi.org/10.1080/2159676X.2019.1628806

Braun, V., & Clarke, V. (2021). Can I use TA? Should I use TA? Should I not use TA? Comparing reflexive thematic analysis and other pattern-based qualitative analytic approaches. *Counselling and*

Brinkman,S., & Kvale,S. (2017). Ethics in Psychological Qualitative Research. In Willig, C., & Rogers, W. S. (Eds.). (2017). *The SAGE handbook of qualitative research in psychology*. Sage. Psychotherapy Research, 21(1), 37–47. https://doi.org/10.1002/capr.12360

Britannica (n.d); https://www.britannica.com/summary/positivism

British Psychological Society. Division of Clinical Psychology, Johnstone, L., Boyle, M., & British Psychological Society. (n.d.). *The Power threat meaning framework : overview*.

Burnham, J. (2018). Developments in Social GRRRAAACCEEESSS: visible–invisible and voiced–unvoiced 1. In *Culture and reflexivity in systemic psychotherapy* (pp. 139-160). Routledge.

Burr, V. (2015). Social constructionism. Routledge.

Cane, J., O'Connor, D., & Michie, S. (2012). Validation of the theoretical domains framework for use in behaviour change and implementation research. Implementation Science,7(1), 1–17.https://doi.org/10.1186/1748-5908-7-37

Canfield, M., Norton, S., Downs, J., & Gilchrist, G. (2021). Parental status and characteristics of women in substance use treatment services: Analysis of electronic patient records. *Journal of Substance Abuse Treatment*, *127*. https://doi.org/10.1016/j.jsat.2021.108365

CareAct, 2014 ; https://www.legislation.gov.uk/ukpga/2014/23/contents

Carminati, L. (2018). Generalizability in Qualitative Research: A Tale of Two Traditions. In *Qualitative Health Research* (Vol. 28, Issue 13, pp. 2094–2101). SAGE Publications Inc. https://doi.org/10.1177/1049732318788379

Chandler, A., Whittaker, A., Cunningham-Burley, S., Elliott, L., Midgley, P., & Cooper, S. (2020). Diagnosing uncertainty, producing neonatal abstinence syndrome. *Sociology of Health and Illness*, *42*(S1), 35–50. https://doi.org/10.1111/1467-9566.13000

Charmaz, K. (2000). Grounded theory: Objectivist and constructivist methods. In N. Denzin & Y. Lincoln (Eds.), *Handbook of qualitative research* (2nd ed., pp. 509-535). London: SAGE.

Charmaz, K. (2003). Grounded theory: Objectivist and constructivist methods. In N. K. Denzin & Y. S. Lincoln (Eds.), Strategies of qualitative inquiry (2nd ed., pp. 249-291). London: SAGE.

Cho, S. H., Torres-Llenza, V., Budnik, K., & Norris, L. (2016). The integral role of psychoeducation in clinical care. Psychiatric Annals, 46(5), 286-292.

ChildrenAct, 1989. Available at https://www.legislation.gov.uk/ukpga/1989/41/resources

Clarke, V., & Braun, V. (2021). Thematic analysis: a practical guide. *Thematic Analysis*, 1–100.

Clarke, V., & Braun, V. (2013). Successful qualitative research: A practical guide for beginners.

Cho, S. H., Torres-Llenza, V., Budnik, K., & Norris, L. (2016). The integral role of psychoeducation in clinical care. *Psychiatric Annals*, 46(5), 286-292.

Cromby, J. (2022). Meaning in the Power Threat Meaning Framework. *Journal of Constructivist Psychology*, *35*(1), 41–53. https://doi.org/10.1080/10720537.2020.1773355

Cudjoe, E. (2023). Making Sense of Husserlian Phenomenological Philosophy in Empirical Research. *International Journal of Qualitative Methods*, *22*. https://doi.org/10.1177/16094069231171099

Department of Health, 2017; https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management

Dilthey, W. (2018). Wilhelm Dilthey: Selected works: hermeneutics and the study of history.

Drugwise, 2024:https://www.drugwise.org.uk/synethic+opiods. (Accessed 23.03.24)

Dydyk, A. M., Jain, N. K., & Gupta, M. (2024). Opioid Use Disorder. In StatPearls. StatPearls Publishing.

Elliott, R., Fischer, C. T., & Rennie, D. L. (1999). Evolving guidelines for publication of qualitative research studies in psychology and related fields. *British Journal of Clinical Psychology*, *38*(3), 215–229. https://doi.org/10.1348/014466599162782

European Monitoring Centre for Drugs and Drug Addiction (2022); European Drug Report 2022: Trends and Developments; ; https://www.emcdda.europa.eu/publications/edr/trends-developments/2022_en; accessed 10.03.2024

Finlay, L., & Gough, Brendan. (2003). *Reflexivity : a practical guide for researchers in health and social sciences*. Blackwell Science.

Finlay, L. (2002). Negotiating the swamp: the opportunity and challenge of reflexivity in research practice. Qualitative Research, 2(2), 209-230. https://doi.org/10.1177/146879410200200205

Frost, N. (2016). Practising research: Why you're always part of the research process even when you think you're not. Palgrave.

Gilchrist, G., Dennis, F., Radcliffe, P., Henderson, J., Howard, L. M., & Gadd, D. (2019). The interplay between substance use and intimate partner violence perpetration: A meta-ethnography. International Journal of Drug Policy, 65, 8–23. https://doi.org/10.1016/j.drugpo.2018.12.009

Gilmour, L., Honeybul, L., Lewis, S., Smith, E., Cheyne, H., Aladangady, N., Featherstone, B., Maxwell, M., Neale, J., & Radcliffe, P. (2024). Scoping review: mapping clinical guidelines and policy documents that address the needs of women who are dependent on drugs during the perinatal period. *BMC Pregnancy and Childbirth*, *24*(1). https://doi.org/10.1186/s12884-023-06172-6

Given, L. M. (2008). Lived experience. In The SAGE Encyclopedia of Qualitative Research Methods (pp. 490-490). SAGE Publications, Inc., https://doi.org/10.4135/9781412963909

Glaser, B., & Strauss, A. (1967). Grounded theory: The discovery of grounded theory. *Sociology the journal of the British sociological association*, *12*(1), 27-49.

Glaser, B., & Strauss, A. (2017). *Discovery of grounded theory: Strategies for qualitative research*. Routledge.

Gilchrist, G., Dennis, F., Radcliffe, P., Henderson, J., Howard, L. M., & Gadd, D. (2019). The interplay between substance use and intimate partner violence perpetration: A meta-ethnography. *International Journal of Drug Policy*, *65*, 8–23. https://doi.org/10.1016/j.drugpo.2018.12.009

Grossman, M., & Berkwitt, A. (2019). Neonatal abstinence syndrome. *Seminars in Perinatology*, *43*(3), 173–186. https://doi.org/10.1053/j.semperi.2019.01.007

Grzanka, P. R., Santos, C. E., & Moradi, B. (2017). Intersectionality research in counseling psychology. Journal of counseling psychology, 64(5), 453.

Guba, E. G., & Lincoln, Y. S. (1994). Competing paradigms in qualitative research. Handbook of qualitative research, 2(163-194), 105.

Guest, G., Namey, E., & Chen, M. (2020). A simple method to assess and report thematic saturation in qualitative research. *PLoS ONE*, *15*(5). https://doi.org/10.1371/journal.pone.0232076

Hammond, A. S., & Chisolm, M. S. (2022). *Co-occurring Mental Health Conditions in Pregnant Women with Opioid Use Disorders*. 27–34.

HCPC (2016) https://www.hcpc-uk.org/resources/guidance/guidance-on-conduct-and-ethics-for-students/

Hennink, M. M., Kaiser, B. N., & Marconi, V. C. (2017). Code Saturation Versus Meaning Saturation: How Many Interviews Are Enough? In *Qualitative Health Research* (Vol. 27, Issue 4, pp. 591–608). SAGE Publications Inc. https://doi.org/10.1177/1049732316665344

Henwood, K. L., & Pidgeon, N. F. (1992). Qualitative research and psychological theorizing. *British journal of psychology*, *83*(1), 97-111.

Herr, K. and Anderson, G. L. (2014). The action research dissertation: A guide for students and faculty. 2nd edition, Sage: California, United States of America.

Hunt, J. (2020). Two decades of UK research on kinship care: an overview. *Family Rights Group: London, UK*.

King, N., & Hugh-Jones, S. (2018). The interview in qualitative research. *ng qualitative research in psychology: a practical guide. Sage, London*, 121-144.

Lang, I., King, A., Jenkins, G., Boddy, K., Khan, Z., & Liabo, K. (2022). How common is patient and public involvement (PPI)? Cross-sectional analysis of frequency of PPI reporting in health research papers and associations with methods, funding sources and other factors. *BMJ Open*, *12*(5). https://doi.org/10.1136/bmjopen-2022-063356

Leiner, C., Cody, T., Mullins, N., Ramage, M., & Ostrach, B. M. M. (2021). "The elephant in the room;" a qualitative study of perinatal fears in opioid use disorder treatment in Southern Appalachia. *BMC Pregnancy and Childbirth*, *21*(1), 1–13. https://doi.org/10.1186/s12884-021-03596-w

Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic inquiry*. sage.

Link, B. G., & Phelan, J. C. (2001). *CONCEPTUALIZING STIGMA*.

Link, B. G., & Phelan, J. C. (2006). Stigma and its public health implications. *Lancet*, *367*(9509), 528–529. https://doi.org/10.1016/S0140-6736(06)68184-1

Lorman, W. J. (2015). Substance use disorders. In *Psychiatric Nursing Made Incredibly Easy!: Second Edition*.

Lyons, E., & Coyle, A. (Eds.). (2021). *Analysing qualitative data in psychology*. Sage.

Madill, A., & Gough, B. (2008). Qualitative Research and Its Place in Psychological Science. *Psychological Methods*, *13*(3), 254–271. https://doi.org/10.1037/a0013220

Madill, A., Jordan, A., & Shirley, C. (2000). Objectivity and reliability in qualitative analysis: Realist, contextualist and radical constructionist epistemologies. *British Journal of Psychology*, *91*(1), 1–20. https://doi.org/10.1348/000712600161646

Malterud, K. (2016). Theory and interpretation in qualitative studies from general practice: Why and how?. *Scandinavian journal of public health*, 44(2), 120-129. https://doi.org/10.1177/1403494815621181

Meyer JP, Isaacs K, El-Shahawy O, Burlew AK, Wechsberg W. Research on women with substance use disorders: Reviewing progress and developing a research and implementation roadmap. Drug Alcohol Depend. 2019 Apr 1;197:158-163. doi: 10.1016/j.drugalcdep.2019.01.017. Epub 2019 Feb 21. PMID: 30826625; PMCID: PMC6440852.

Michie, S., Van Stralen, M. M., & West, R. (2011). The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implementation Science,6(1), 42.https://doi.org/10.1186/1748-5908-6-42

Miller, P. (Peter G., Strang, John., & Miller, P. M. (Peter M. (2010). *Addiction research methods*. Addiction Press/Blackwell Pub.

Abreu Minero, V., Best, D., Brown, L., Patton, D., & Vanderplasschen, W. (2022). Differences in addiction and recovery gains according to gender - gender barriers and specific differences in overall strengths growth. *Substance abuse treatment, prevention, and policy*, *17*(1), 21. https://doi.org/10.1186/s13011-022-00444-8

Misuse of Drugs Act 1971. http://www.legislation.gov.uk/ukpga/1971/38/contents; accessed 2.4.2022

Moran-Santa Maria, M.M., & Brady, K.T. (2015). Women and Addiction. In: el-Guebaly, N., Carrà, G., Galanter, M. (eds) Textbook of Addiction Treatment: International Perspectives. Springer, Milano. https://doi.org/10.1007/978-88-470-5322-9_96

Morrison, P. K., Yourish, E., Chang, J. C., Krans, E., & Pallatino-Trevelline, C. (2023). Barriers to Care for Pregnant and Post-Partum Women Experiencing Co-Occurring Intimate Partner Violence and Opioid Use Disorder. *Journal of Family Violence*, *38*(8), 1625–1637. https://doi.org/10.1007/s10896-022-00466-7

Neale, J., Werthern, H., Alhusein, N., Chater, A., Scott, J., & Family, H. (2021). Contraceptive choice and power amongst women receiving opioid replacement therapy: qualitative study. *Drugs: Education, Prevention and Policy*, *0*(0), 1–12. https://doi.org/10.1080/09687637.2021.1954599

National Institute on Drug Abuse, 2024; https://nida.nih.gov/publications/research-reports/substance-use-in-women/importance-including-women-in-research

National Institute for Health and Clinical Excellence. (2010) *Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors* (NICE guideline NG110). https://www.nice.org.uk/guidance/CG110/chapter/1 -Guidance#pregnant-women-who-misuse-substances-alcohol-andor-drugs

National Institute for Health and Clinical Excellence, 2022; https://cks.nice.org.uk/topics/opioid-dependence. (Accessed 16.03.2024).

National Institute for Health and Clinical Excellence, 2022; https://cks.nice.org.uk/topics/opioid-dependence/management/managing-special-circumstances. (Accessed 16.03.2024).

National Institute for Health and Clinical Excellence, 2007; https://www.nice.org.uk/guidance/cg52

National Institute for Health and Clinical Excellence, 2017; https://bnfc.nice.org.uk/treatment-summaries/substance-dependence

National Institute for Health and Clinical Excellence, 2014; https://www.nice.org.uk/guidance/cg192 2014

National Institute for Health Research. https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392; (accessed Dec 2022).

Neale, J., Werthern, H., Alhusein, N., Chater, A., Scott, J., & Family, H. (2021). Contraceptive choice and power amongst women receiving opioid replacement therapy: qualitative study. *Drugs: Education, Prevention and Policy*, *0*(0), 1–12. https://doi.org/10.1080/09687637.2021.1954599

Noclor: www.noclor.nhs.uk. (Accessed 01.10.2022)

Nowakowski, E., Dayananda, S., Morgan, M., Jarvis, O., Altamirano, V., LaSorda, K. R., ... & Lim, G. (2023). Obstetric pain management for pregnant women with opioid use disorder: A qualitative and quantitative comparison of patient and provider perspectives (QUEST study). *Addiction*, *118*(6), 1093-1104.

Nyblade, L., Stockton, M. A., Giger, K., Bond, V., Ekstrand, M. L., Lean, R. M., ... & Wouters, E. (2019). Stigma in health facilities: why it matters and how we can change it. BMC medicine, 17, 1-15.

Oates, J., Carpenter, D., Fisher, M., Goodson, S., Hannah, B., Kwiatowski, R., Prutton, K., Reeves, D., & Wainwright, T. (2021). BPS Code of Human Research Ethics. In *Uniwersytet śląski*. https://discovery.dundee.ac.uk/en/publications/bps-code-of-human-research-ethics

Office of National Statistics, 2022; https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsrelatedtodrugpoisoninginenglandandwales/registrations

Ogden, S. N., Dichter, M. E., & Bazzi, A. R. (2022). Intimate partner violence as a predictor of substance use outcomes among women: A systematic review. Addictive behaviors, 127, 107214. https://doi.org/10.1016/j.addbeh.2021.107214

O'Rourke-Suchoff, D., Sobel, L., Holland, E., Perkins, R., Saia, K., & Bell, S. (2020). The labor and birth experience of women with opioid use disorder: A qualitative study. *Women and Birth*, *33*(6), 592–597. https://doi.org/10.1016/j.wombi.2020.01.006

Osbeck, L. M., & Antczak, S. L. (2021). Generalizability and Qualitative Research: A New Look at an Ongoing Controversy. *Qualitative Psychology*, *8*(1), 62–68.

Phillips, H., Warshaw, C., Kaewken, O. (2020). Literature review: Intimate partner violence, substance use coercion, and the need for integrated service models. National Center on Domestic Violence, Trauma, and Mental Health

Prochaska, J. O., Norcross, J. C., & DiClemente, C. C. (2013). Applying the stages of change. Psychotherapy in Australia, 19(2), 10–15. https://search.informit.org/doi/10.3316/informit.254435778545597

Proulx, D., & Fantasia, H. C. (2021). The Lived Experience of Postpartum Women Attending Outpatient Substance Treatment for Opioid or Heroin Use. *Journal of Midwifery and Women's Health*, *66*(2), 211–217. https://doi.org/10.1111/JMWH.13165

Public Health England. (2019) United Kingdom drug situation focal point annual report. https://www.gov.uk/government/publications/united-kingdom-drug-situation-focal-point-annual-report/uk-drug-situation-2019-summary

Potter, J., & Wetherell, M. (1987). *Discourse and social psychology: beyond attitudes and behaviour*. Sage. https://go.exlibris.link/zfZSKgcn

Radcliffe P., et al., (2024) https://www.kcl.ac.uk/research/the-stepping-stones-study (Accessed 09.06.2024)

Radcliffe, P. (2011). Motherhood, pregnancy, and the negotiation of identity: The moral career of drug treatment. Social Science and Medicine, 72(6), 984–991. https://doi.org/10.1016/j.socscimed.2011.01.017

Roberts J.M. (2014) Critical realism, dialectics, and qualitative research methods. *Journal for the Theory of Social Behaviour*, 44(1), 1–23.

Robertson, J. E., & Norris, N. F. J. (2001). Generalization: The linchpin of evidence-based practice? Educational Action Research, 9, 303–310.

Roald, T., Koppe, S., Jensen, T. B., Hansen, J. M., & Levin, K. (2021). Why Do We Always Generalize in Qualitative Research? *Qualitative Psychology*, *8*(1), 69–81. https://doi.org/10.1037/qup0000138

Sanders, A. N., Vance, D. E., Dudding, K. M., Shorten, A., & Rice, M. (2022). Maternal-infant bonding for the opioid exposed dyad: A rodgers' evolutionary concept analysis. Nursing Forum, 57(1), 165–170. https://doi.org/10.1111/nuf.12663

Savin-Baden, M., & Howell-Major, C. (2013). Qualitative research: The essential guide to theory and practice. Routledge.

Scrambler, G. (2009), Health-related stigma. Sociology of Health & Illness, 31: 441-455. https://doi.org/10.1111/j.1467-9566.2009.01161.x

Scrambler, G., & Scrambler, S. (2015). Theorizing health inequalities: The untapped potential of dialectical critical realism. *Social Theory and Health*, *13*(3–4), 340–354. https://doi.org/10.1057/sth.2015.14

Scatliffe, N., Casavant, S., Vittner, D., & Cong, X. (2019). Oxytocin and early parent-infant interactions: A systematic review. International Journal of Nursing Sciences, 6(4), 445–453. https://doi.org/10.1016/j.ijnss.2019.09.009

Stigma and mental illness – Graham Scrambler

Scrambler, G. (2012) https://www.grahamscambler.com/stigma-and-mental-illness/2012 (Accessed 29.07.2024)

Scottish Government, 2018; https://www.gov.scot/binaries/content/documents/govscot/publications/research-and-analysis/2018/06/ drug-related-deaths-women-increasing-scotland/documents/00537476-pdf/00537476-pdf/govscot%3Adocument/00537476.pdf

Schiff, D. M., Work, E. C., Mufti, S., Partridge, S., MacMillan, K. D. L., Gray, J. R., Hoeppner, B. B., Kelly, J. F., Greenfield, S. F., Jones, H. E., Wilens, T. E., Ter plan, M., & Bernstein, J. (2022). "You have to take this medication, but then you get punished for taking it:" lack of agency, choice, and fear of medications to treat opioid use disorder across the perinatal period. *Journal of Substance Abuse Treatment*, 108765. https://doi.org/10.1016/j.jsat.2022.108765

Schaub, E., & Højholt, C. (2019). *Introduction: Subjectivity and Knowledge – The Formation of Situated Generalization in Psychological Research* (pp. 1–19). https://doi.org/10.1007/978-3-030-29977-4_1

Simpson, K. A., & Butethal, R. N. (2021). Qualitative Approaches to the Study of Substance and Behavioural Addictions. In *The Cambridge Handbook of Substance and Behavioural Addictions* (pp. 106–118). Cambridge University Press. https://doi.org/10.1017/9781108632591.013

Slaney, K. L., & Tafreshi, D. (2021). Scientific Generalization in Psychological Inquiry: A Concept in Need of Clarification. *Qualitative Psychology*, *8*(1), 82–94. https://doi.org/10.1037/qup0000186

Smith, J. A. (1996). Beyond the divide between cognition and discourse: Using interpretative phenomenological analysis in health psychology. Psychology and health, 11(2), 261-271.

Smith, J. A. (2017). Interpretative phenomenological analysis: Getting at lived experience. The journal of positive psychology, 12(3), 303-304.

Smith, J. A. (2011). Evaluating the contribution of interpretative phenomenological analysis. Health psychology review, 5(1), 9-27.

Stangl, A. L., Earnshaw, V. A., Logie, C. H., van Brakel, W., Simbayi, L. C., Barré, I., & Dovidio, J. F. (2019). The Health Stigma and Discrimination Framework: A global, crosscutting framework to inform research, intervention development, and policy on health-related stigmas. *BMC Medicine*, *17*(1), 18–23. https://doi.org/10.1186/s12916-019-1271-3

Staudt, M. (2018). Best practices for enhancing substance abuse treatment retention by pregnant women.

Stets, J. E., & Serpe, R. T. (2013). *Identity Theory BT - Handbook of Social Psychology* (J. DeLamater & A. Ward (eds.); pp. 31–60). Springer Netherlands. https://doi.org/10.1007/978-94-007-6772-0_2

Best Practices in Mental Health: An International Journal, 14(2), 48–63.

The importance of family connection was identified in the first PPI group meeting leading me to pay attention to it in the interviews.

Sullivan, C., & Forrester, M. A. (Eds.). (2019). *Doing qualitative research in psychology: a practical guide* (2nd ed.). SAGE .

Terplan, M., Kennedy-Hendricks, A., & Chisolm, M. S. (2015). Prenatal substance use: Exploring assumptions of maternal unfitness. Substance Abuse: Research and Treatment, 9, 1–4. https://doi.org/10.4137/SART.S23328

Terry, G., & Braun, V. (2013). "We have friends, for example, and he will not get a vasectomy": Imagining the self in relation to others when talking about sterilization. *Health Psychology*, *32*(1), 100–109. https://doi.org/10.1037/a0029081

Terry, G., Hayfield, N., Clarke, V., & Braun, V. (2017). Thematic Analysis. In *The SAGE Handbook of Qualitative Research in Psychology* (pp. 17–36). SAGE Publications Ltd. https://doi.org/10.4135/9781526405555.n2

Thoburn, J. (2023). Child welfare and child protection services in England. *The Oxford handbook of child protection systems*, 135-155.

Thomson, S., Khalil, A., Hafford, S., & Waterstone, M. (2021). Opioid misuse in pregnancy. *The Obstetrician & Gynaecologist*, 1–8. https://doi.org/10.1111/tog.12779

Thornicroft, G., Sunkel, C., Milenova, M., & Commission Implementation Partnership (2024). How to stop stigma: implementing The Lancet Commission on ending stigma and discrimination in mental health. *The lancet. Psychiatry*, *11*(2), 88–89. https://doi.org/10.1016/S2215-0366(23)00374-7

Trainor, L. R., & Bundon, A. (2021). Developing the craft: reflexive accounts of doing reflexive thematic analysis. *Qualitative Research in Sport, Exercise and Health*, *13*(5), 705–726. https://doi.org/10.1080/2159676X.2020.1840423

UK Government, 2020; https://www.gov.uk/government/statistics/substance-misuse-treatment-for-adults-statistics-2019-to-2020/adult-substance-misuse-treatment-statistics-2019-to-2020-report. (Accessed 15.03.2024)

UK Government, 2021; https://www.gov.uk/government/publications/from-harm-to-hope-a-10-year-drugs-plan-to-cut-crime-and-save-lives/from-harm-to-hope-a-10-year-drugs-plan-to-cut-crime-and-save-lives. (Accessed 22.03.24)

UK Government, 2006; https://webarchive.nationalarchives.gov.uk/ukgwa/20170807150623/http://www.nta.nhs.uk/uploads/nta_modelsofcare_update_2006_moc3.pdf (accessed 22.03.2024)

United Nations Office on Drugs and Crime. (n.d.). World drug report 2015.

Yardley, L., 2008 .Demonstrating validity in qualitative psychology. Eds. J.A. Smith. *Qualitative psychology: A Practical guide to research methods* (2nd ed.,). London: SAGE

Yardley, L. (2000). Dilemmas in qualitative health research. Psychology and health, 15(2), 215-228.

Walsh, R. T., Teo, T., & Baydala, A. (2014). A critical history and philosophy of psychology: Diversity of context, thought, and practice. Cambridge University Press. https://doi.org/10.1017/CBO9781139046831

Warshaw, C. & Tinnon, E. (2018). Coercion Related to Mental Health and Substance Use in the Context of Intimate Partner Violence: A Toolkit for Screening, Assessment, and Brief Counseling in Primary Care and Behavioral Health Settings. Chicago, IL: National Center on Domestic Violence, Trauma, and Mental Health. Retrieved from: http://www.nationalcenterdvtraumamh. org/wp-content/uploads/2018/03/NCDVTMH_MHSUCoercionToolkit2018.pdf

Wetherell, M., Taylor, S., & Yates, S. J. (Eds.). (2001). Discourse theory and practice: A reader. Sage.

Whittaker, A., Martin, F., Olsen, A., & Wincup, E. (2020). Governing Parental Drug Use in the UK: What's Hidden in "Hidden Harm?." Contemporary Drug Problems, 47(3), 170-187. https://doi.org/10.1177/0091450920941267

Wiggins, S. (2017). Discursive psychology. SAGE Publications Ltd., https://doi.org/10.4135/9781473983335

Wilkinson, S., & Kitzinger, C. (Eds.). (1996). Representing the other: A feminism & psychology reader. Sage.

Williams, L., Rycroft-Malone, J., & Burton, C. R. (2017). Bringing critical realism to nursing practice: Roy Bhaskar's contribution . In *Nursing philosophy* (Vol. 18, Issue 2, p. n/a-n/a). Wiley Subscription Services, Inc . https://doi.org/10.1111/nup.12130

Willig, C. (2013). I*ntroducing Qualitative Research in Psychology*. (Fourth Edition). McGraw-Hill Education (UK).

Willig, C. (2019a). Ontological and epistemological reflexivity: A core skill for therapists. *Counselling and Psychotherapy Research*, *19*(3), 186–194. https://doi.org/10.1002/capr.12204

Willig, C. (2019b). What Can Qualitative Psychology Contribute to Psychological Knowledge? *Psychological Methods*, *24*, 796–804. https://doi.org/10.1037/met0000218

Willig, C., & Borcsa, M. (2021). Conclusion: Qualitative research in mental health: Reflections on research questions, methods and knowledge. In *Qualitative Research Methods in Mental Health: Innovative and Collaborative Approaches* (pp. 251–261). Springer International Publishing. https://doi.org/10.1007/978-3-030-65331-6_11

Willig, C., & Rogers, W. S. (2017). The SAGE Handbook of Qualitative Research in Psychology. In *The SAGE Handbook of Qualitative Research in Psychology*. SAGE Publications Ltd. https://doi.org/10.4135/9781526405555

Zaborowski, H. (2011). Heidegger's hermeneutics: Towards a new practice of understanding. In *Interpreting Heidegger: Critical Essays* (pp. 15–41). Cambridge University Press. https://doi.org/10.1017/CBO9780511974465.003

11. Appendices

List of Appendices

11.1 Appendix 1- Study materials required with participating Trusts' logo.

	Study procedure & materials
1	Study poster
2	Participation Information Sheet
3	Letter to GP/Clinical team
4	Consent
5	Appendix 4 - Summary of Risk, Adverse Events And Risk Management Plan

11.2 Appendix 2 – Schedule of Procedures impacting the participant.

Study procedure & materials	**Identification of ptn**	**Recruitment**	**Interview**	**Call 24 hours post interview**	**Journal/diary**
Study poster	X				
Participation Information Sheet		X			
Letter to GP/Clinical team		X			
Consent			X		
Interview: Participant demographic data			X		
Interview: Topic guide			X		
Debrief			X	X	
Journal/diary			X		X

11.3

High level study timetable with key workstreams and stages.

Table 1: High-level research timetable Oct

Stage of research	2022 Q2	Q3	Q4	2023 Q1	Q2	Q3	Q4	2024 Q1	Q2	Q3	Q4	2025 Q1	Q2	Q3
Research Proposal sponsored by City														
Submission NHS Ethics														
NHS amendments														
Approval by NHS REC														
Study set up with R&D and Trusts														
Fieldwork; recruitment and calls with PPI														
Recruitment of participants														
Interviews & data collection														
Data transfer to sponsor														
Data analysis & drafting results														
REC Progress report														
Submission to City														
Dissemination														
REC Report														

11. 4 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

11.5

Appendix 4 - Summary of Risk, Adverse Events And Risk Management Plan

Risk or adverse event	Risk or adverse event	Risk management plan
Convenience and ease to participate	The participants are likely to have a busy schedule of perinatal/post-natal maternity care meetings. Participation in the research will require an additional commitment to an interview.	Interview times will be set to cause minimal inconvenience, with the option to coincide with other routine care appointments at substance abuse clinics or peri/post-natal appointments.
Physical discomfort	Women may find pregnancy physically uncomfortable, e.g., to sit for an hour. They may also require facilities for an infant.	Rooms will be comfortable and afford childcare facilities if required.
Access and physical discomfort	They may not be comfortable walking any distance within NHS sites to an interview room.	Interview rooms will be sourced and arranged with the participating Trusts to have easily accessible rooms.

Recall of difficult memories associated with pregnancy	It is possible that participants recall difficult memories associated with their experience e.g., childbirth pain either during or after the interview.	The researcher will allow time for any difficult memories to be empathetically supported, with the option for referral to therapeutic support given.
Adverse events	Adverse events may occur, and the participants require urgent perinatal clinical attention.	(a) The researcher will monitor the participant throughout all contact and inform the site Duty Manager, Keyworker or GP of any sign of distress emerges. (b) The researcher will ensure that the clinical care team e.g., GP, and Keyworker of each participant is informed and aware of the research participation and given the opportunity to highlight any risks unique to the participant they foresee. **c)** The Duty Manager will be informed of the date and time of the participant's interview in the event that any adverse events occur, care and risk plan can be enacted.
Recall e.g., of Intimate Partners Violence (IPV)	The participants in this population may have suffered from intimate partner violence (IPV) and trauma and the interview may prompt recall.	The researcher will monitor the participant throughout all contact and inform the site Duty Manager, Keyworker or GP of any sign of distress emerges.
Self-harm and risk	Disclosures of self-harm or risk during the interview	Any disclosure of self-harm or risk will be reported as risk to the Duty Manager and Clinical Care team.
Safeguarding	Safeguarding issues disclosed during interview	Any safeguarding issues concerning existing children or dependents of the participant will be raises with the Duty Manager and Clinical care team.
Post interview wellness		The researcher will call each participant within 24 hours of the interview to ensure participants are well and not experiencing any sense of being unwell. If the event of any sense of unwellness, the researcher will contact the Duty Manager.

9.1.4 Appendix D: HRA & HCRW Research Approval

Professor Carla Willig
City University,
Department of Psychology, Rhind Building,
St John Street, London
EC1R 0JD

Email: approvals@hra.nhs.uk

27 April 2023

Dear Professor Willig

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**"My Healthcare Journey Through Pregnancy and Substance Use". An Investigation of the Lived Experience of the Healthcare Journeys of Women with Opioid Use Disorder Who Become Pregnant.**
IRAS project ID:	**322110**
REC reference:	**23/NW/0042**
Sponsor	**City University**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form,protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towardsthe end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland andScotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set, and the study wide governance report(including this letter) have been sent to the coordinating centre of each participating nation.

The relevant national coordinating function/s will contact you as appropriate.

ease see IRAS Help for information on working with NHS/HSC organisations in NorthernIreland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work withyour non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "After Ethical Review – guidance for sponsors and investigators", issued with your REC favourable opinion, gives detailed guidance on reportingexpectations for studies, including:

Registration of research

Notifying amendments

Notifying the end of the study

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

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact detailsare below.

Your IRAS project ID is **322110**. Please quote this on all correspondence.Yours sincerely,

Theodora Chortara Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Professor Carla Willig*

9.1.5 Appendix E: Chief Investigator and Principal Investigator roles

From: Elkington, Susan [redacted]
Sent: 22 February 2023 08:40
To: Willig, Carla [redacted]
Subject: IRAS 322100 Pregnancy and OUD

Hi Carla,

Many thanks for your advice and help on Friday. I felt a weight lift from my shoulders!

Thank you for agreeing to be CI on this project. I fully appreciate that you cannot take on extra work as CI and I will ensure that I continue to carry the work out.

Amended (slightly) topic guide.
As per our discussion, I am attaching a minor redraft of the Topic guide and a response on the form (3). (I am still working on this document and have provided a response at point 3 which is marked green)

I have found it quite difficult to develop more questions - without making it sound like a drilling for information. Would you be able to have look at the redrafted Topic guide with any comments?

Progress on queries
I have made some progress on quite a few important queries. The substance abuse lead in Camden and Islington, Dominic O'Ryan was very helpful today and solved a few open queries very pragmatically (e.g. confirming that I will be part of the Clinical Care team//giving me a Trust laptop). He is about to commission a contract for me and wanted me to hook everyone up - so he has some information for the HR team.

Research project collaborators email
Therefore, I am about to send out an email to hook the collaborators up as per Dominic's request; I have cc'd you but do not think you need to get pulled into the intra Trust discussion.

City insurance
Am still waiting for City insurance to confirm coverage for pregnant women with OUD.

Many thanks again!

Susan

Susan Elkington (MBPs)
Trainee Counselling Psychologist
(MA; MSc)

9.1.6 Appendix F: Noclor Approvals For NHS Participating Trusts

From: NOCLOR, Contact (CENTRAL AND NORTH WEST LONDON NHS FOUNDATION TRUST)
[redacted]
Sent: 27 June 2023 14:05
To: ELKINGTON, Susan (BARNET, ENFIELD AND HARINGEY MENTAL HEALTH NHS TRUST)
[redacted]
Subject: IRAS 322110 - C&I - Confirmation of Capacity and Capability

Dear Susan Elkington,
Study Title: My Healthcare Journey Through Pregnancy and Substance Use
IRAS Ref: 322110
Initial HRA Approval: 27 April 2023
Protocol Version: 04/03/2023 Protocol: V2
Amendments: NSA01 (Changing name of PI on IRAS form)
Attached: Fully Executed OID
We are pleased to confirm capacity and capability at **Camden & Islington NHS Foundation Trust** for the above referenced study. Please find attached the fully executed OID.
The study end date stated for site is 03/06/2024 we will close the study record one month after this date if we have not received communication from yourself or the sponsor regarding study extension beyond this date.
Please notify R&D of any amendments, research-related incidents or changes to the study end date by emailing contact.noclor@nhs.net.

Kind regards,
Robert, on behalf of Alexi

From: NOCLOR, Contact (CENTRAL AND NORTH WEST LONDON NHS FOUNDATION TRUST) <contact.noclor@nhs.net>
Sent: 27 June 2023 14:04
To: ELKINGTON, Susan (BARNET, ENFIELD AND HARINGEY MENTAL HEALTH NHS TRUST) [redacted]
Subject: IRAS 322110- BEH - Confirmation of Capacity and Capability DRAFT

Dear Susan Elkington,
Study Title: My Healthcare Journey Through Pregnancy and Substance Use
IRAS Ref: 322110
Initial HRA Approval: 27 April 2023
Protocol Version: 04/03/2023 Protocol: V2
Amendments: NSA01 (Changing name of PI on IRAS form)
Attached: Fully Executed OID
We are pleased to confirm capacity and capability at **Barnet Enfield & Haringey NHS Mental Health Trust** for the above referenced study. Please find attached the fully executed OID.
The study end date stated for site is 03/06/2024 we will close the study record one month after this date if we have not received communication from yourself or the sponsor regarding study extension beyond this date.
Please notify R&D of any amendments, research-related incidents or changes to the study end date by emailing contact.noclor@nhs.net.

Kind regards,
Robert, on behalf of Alexi

9.1.7 Appendix G: Organisation Informational Documents – Signed With Noclor

Study Information

1.* IRAS Project ID	322110
2.* Full Title of the Study	''My Healthcare Journey Through Pregnancy and Substance Use''. An Investigation of the Lived Experience of the Healthcare Journeys of Women with Opioid Use Disorder Who Become Pregnant.
3.* Legal Name(s) of Sponsor/Co-Sponsors/Joint-Sponsors	City University

4. Contact details of person acting on behalf of Sponsor for questions relating to study set up. Please enter details of the person who is the Sponsor's main point of contact for all correspondence on setting up the study at this NHS / HSC organisation. This contact may be the Sponsor, a Study Manager, Clinical Research Scientist or Study Coordinator. Where a Contract Research Organisation (CRO) or Clinical Trials Unit (CTU) has been delegated to handle set up on behalf of the Sponsor, the contact at the CRO or CTU should be named here.

Name	Susan Elkington
Telephone Number	07785 706837
Email Address	[redacted]

5.* Are all participating NHS / HSC organisations undertaking the same protocol activities?

Yes

If 'No' give details of the activities taking place at NHS / HSC organisations that you will use this outline Organisation Information Document with. Additional outline Organisation Information Documents may be required for NHS / HSC organisations undertaking different activities.

If no, give details

Participating NHS / HSC Organisation Information

6. Name of Participating NHS / HSC Organisation. If this Organisation Information Document is being used as an Agreement the name must be entered prior to agreement

Camden and Islington NHS Foundation Trust

7. Location/s*:* Please provide detail below where it is planned to undertake the research only at specified locations with the participating NHS / HSC organisation (i.e. hospital(s), GP Practice(s) and/or Research Unit(s)). It is not intended that the level of detail provided here captures individual departments within the participating NHS / HSC organisation.

Location (enter text below)	**Activity** (enter text below)
Substance Misuse Services	1. Attendance Clinical Team Meetings (CTMs) 2. Recruitment of participants 3. Onsite meeting (interview) with participants for data collection

8*. What is the role of the person responsible for research activities at the participating NHS / HSC organisation?

- Principal Investigators are expected to be in place at participating NHS / HSC organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single centre studies where the Chief Investigator will also be the Principal Investigator.
- Where this is not the case, local collaborators are expected to be in place where central study staff will be present at the participating organisation to undertake research procedures (the role of the Local Collaborator is to facilitate the presence of Sponsor / CRO research staff).
- Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at the participating NHS / HSC organisation, select Chief Investigator.

Principal Investigator

9. Contact details of person responsible for research activities at this participating NHS / HSC organisation as indicated in question 8 (if known). If known, please enter the details of the person you have spoken to about their role in this study at this participating NHS / HSC organisation. If unknown, please leave blank and that person can be identified and listed here during the setup of the study.

Name	Susan Elkington
Post / Job Title	Trainee Counselling Psychologist
Name of Employing Organisation	NHS Barnet, Enfield and Haringey (Substance Abuse Services)
Email Address	[redacted]

Telephone number	[redacted]

Timescales

10. Predicted Start and End Dates of the Study at this Participating NHS / HSC Organisation

The Sponsor or authorised delegate should propose a date on which it intends to start and complete research activity at this participating NHS / HSC organisation. Alternatively, this may be left blank when the Local Information Pack is shared, for agreement during study set up at the Participating NHS / HSC Organisation.

Predicted Start Date (activities at this organisation)	01/06/2023
Predicted End Date (activities at this organisation)	03/06/2024

For many types of study, the following dates are not applicable, and this may be stated in answer. Where they are applicable, they should be provided by the Sponsor or authorised delegate before sharing the Local Information Pack, as indicative targets for agreement, or they may be negotiated between Sponsor or authorised delegate and participating NHS / HSC organisation after sharing the pack**.**

Predicted Site Initiation Visit Date	02/05/2023
Predicted Start Date for participant recruitment	01/06/2023
Predicted End Date for participants recruitment (i.e. when the study moves into "follow up" activities.)	01/03/2024
Predicted End Date for all study activities (i.e. "last patient visit" completed and study is ready to be archived.)	01/06/2025

Participant Numbers

11. How many research participants are expected at this participating NHS / HSC organisation?

For studies not directly involving human participants, please indicate the number of samples or data-sets to be obtained.

Please state if number of participants is per month, per year, overall, etc.

4

Study set up and delivery arrangements at Participating NHS / HSC Organisations

12*. The following are needed at the participating NHS / HSC organisation to deliver the study: e.g. specific equipment, patient/participant groups, service support, nursing time, etc. Please detail any specific requirements for participating NHS / HSC organisations to deliver this study, including by clarifying any requirements on participating NHS / HSC organisations relating to monitoring / self-monitoring, e.g. requirements for staff signature and delegation logs to be returned to the Sponsor and/or any particular access requirements that the Sponsor may have that it wishes to bring to the attention of the participating NHS / HSC organisation, likelihood of staff not employed at the participating NHS / HSC organisation coming on site, etc.

1. Identification of potential participants by clinical team; potential participants to contact PI if interested in participating further.
2. On site marketing space/support for research poster and flyers for participant recruitment
3. Room to hold interviews (room needs to be appropriate for study population – ie pregnant women; sound proofed to ensure the meeting can be recorded)
4. Risk management and safeguarding plan – (Duty Manager to be made aware of interviews date/time in event of adverse events)
5. Identification of potential research team PPI members (N=2) (if required)

13*. The following training will be provided by the Sponsor or authorised delegate for local research team members. Where only specific team members (e.g. the Principal Investigator) will receive this training, this should be specified

Briefing of study will be carried out by PI (student researcher) within clinical teams, so that they are aware and may support process of recruitment.

Clinical teams not required to carry out research tasks beyond assist in identifying potential participants which are referred to the PI (student researcher).

Clinical teams to be made aware of Risk Management plan (pre/during and post interview)

14*. The Sponsor expects that local research team members will have the following skills and where they do not have those skills that they will undertake the relevant training before undertaking the relevant study activities.
It would not be usual for the Sponsor to expect study specific training additional to that which it will provide. This section does however allow Sponsors to state, for example, that when they expect training in Good Clinical Practice for appropriate team members where the study is a Clinical Trial of an Investigational Medicinal Product, they will accept UK nationally recognised GCP training, training recognised on the Transcelerate mutual recognition scheme, etc.

Not required

15*. The following funding/resources/equipment, etc. is to be provided to this participating NHS / HSC organisation. The Sponsor should answer this question whether this Organisation Information Document is to be used as the Agreement with the participating NHS / HSC organisation or not. Where the document is intended as the Agreement, further detail should be provided in Appendix 2.
The sponsor is providing to the study -funding for vouchers for the participants, -secure storage for study materials and participant details -secure recording device and software for data analysis -No equipment or resources are being provided directly to the participating NHS Trusts by the Sponsor

16^ The Participating NHS / HSC Organisation confirms (by use of the drop-down box) that the Principal Investigator, where one is required, is aware of and has agreed to discharge their responsibilities in line with the UK Policy Framework for Research and Social Care..	Confirmed
17^ The Participating NHS / HSC Organisation has considered and mitigated any conflict/s of interest declared by the principal investigator.	Not applicable
If yes, please detail conflict of interest	

Sponsor Authorisation

18* Authorised on behalf of Sponsor by:	
Name	Professor Sebastian Gaigg
Job Title	Professor of Psychology and Head of Department
Organisation Name	City University
Date	20 April 2023

Appendices

Appendix 1: General Provisions
Appendix 2: Finance Provisions
Appendix 3: Material Transfer Provisions
Appendix 4: Data Processing Agreement
Appendix 5: Data Sharing Agreement
Appendix 6: Intellectual Property Rights The sponsor or authorised delegate should answer the question at the top of Appendix 1 and, if it intends that this Organisation Information Document will be incorporated into an exchange of correspondence to form the Agreement ("Agreement") between itself and the participating NHS / HSC organisation, the questions that appear at the top of each subsequent appendix.

Appendix 1: General Provisions

***Does the Sponsor intend that this Organisation Information Document forms the Agreement between itself and the participating NHS / HSC Organisation, or has a separate site agreement been provided?**	Organisation Information Document

1. OBLIGATIONS OF THE PARTIES

1.1. The Parties agree to comply with all relevant laws, regulations and codes of practice applicable to this Agreement including to the performance of the study. The Parties agree to comply with the World Medical Association Declaration of Helsinki, titled "Ethical Principles for Medical Research Involving Human Subjects" (where applicable) and the UK Policy Framework for Health and Social Care Research. The Parties shall conduct the study in accordance with:

1.1.1. the Protocol, including appropriately made amendments thereto (which is/are hereby incorporated into this Agreement by reference);

1.1.2. the terms of all relevant permissions and approvals. These may include but are not limited to the terms and conditions of the favourable opinion given by the relevant NHS Research Ethics Committee, where applicable.

1.2. The Parties shall carry out their respective responsibilities in accordance with this Agreement.

1.3. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participants and study personnel.

1.4. The Sponsor shall, on the giving of reasonable prior written notice to the Participating NHS / HSC Organisation, have the right to audit the Participating.
NHS / HSC Organisation's compliance with this Agreement. The Sponsor may appoint an auditor to carry out such an audit. Such right to audit shall include access, during normal working hours to the Participating NHS / HSC Organisation's premises and to all relevant documents and other information relating to the study.

1.5. The Participating NHS / HSC Organisation shall.

1.5.1. promptly notify the Sponsor should any responsible body conduct or give notice of intent to conduct any inspection at the Participating NHS / HSC Organisation in relation to the study.

1.5.2. allow the Sponsor to support the preparations for such inspection; and

1.5.3. following the inspection, provide the Sponsor with the results of the inspection relevant to the study. The Sponsor will be responsible for sharing such results with the funder if required.

1.6. In accordance with participant consent, the Participating NHS / HSC Organisation shall permit the Sponsor's appointed representatives and any appropriately appointed monitor access to all relevant data for monitoring and source data verification. The Parties agree that such access will be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the study, reasonable access to relevant members of staff at the Participating NHS / HSC Organisation and the right to examine any procedures or records relating to the study, subject at all times to clause 6 of this appendix.

The Sponsor will alert the Participating NHS / HSC Organisation promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the study.

2. LIABILITIES AND INDEMNITY

2.1. Nothing in this clause 2 shall operate so as to restrict or exclude the liability of a Party in relation to statutory or regulatory liability (including but not limited to breach of the data protection legislation), death or personal injury caused by the negligence or wilful misconduct of that Party or its agent(s), fraud or fraudulent misrepresentation or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.

2.2. Where a Party is a non-NHS/HSC organisation, or an NHS/HSC organisation that is not a member of an NHS indemnity scheme, then that Party shall maintain all proper insurance or equivalent indemnity arrangements to cover liabilities arising from its participation in the study, in respect of any claims brought by or on behalf of a participant. Where the Party is an NHS/HSC organisation and is a member of an NHS indemnity scheme, it shall maintain its membership therein or otherwise ensure it has appropriate cover against claims arising as a result of clinical negligence by the Party and/or its agents brought by or on behalf of the participants. Each Party shall provide to the other such evidence of their insurance or equivalent indemnity cover maintained pursuant to clause 2.2 as the other Party shall from time to time reasonably request, such evidence might comprise confirmation that an NHS/HSC organisation is a member of one of the NHS indemnity schemes.

2.3. Subject to clauses 2.4, 2.5, 2.6, 2.7 and 2.8, the Sponsor shall indemnify the Participating NHS / HSC Organisation and its agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands ("Claims") to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Sponsor, and/or contracted third party, in its performance of this Agreement or in connection with the study.

2.4. Subject to clauses 2.3, 2.5, 2.6 and 2.8, the Participating NHS / HSC Organisation shall indemnify the Sponsor/each of the co-Sponsors/each of the joint-Sponsors and its/their respective agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Participating NHS / HSC Organisation, or its agents, in its performance of this Agreement or in connection with the study.

2.5. An indemnity under clauses 2.3 or 2.4 shall only apply if the indemnified Party:

2.5.1. informs the Party providing the indemnity in writing as soon as reasonably practicable following receipt of notice of the claim or proceedings.

2.5.2. upon the indemnifying Party's request and at the indemnifying Party's cost gives the indemnifying Party full control of the claim or proceedings and provides all reasonable assistance; and

2.5.3. makes no admission in respect of such claim or proceedings other than with the prior written consent of the indemnifying Party.

2.6. Any indemnity under clauses 2.3 or 2.4 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from the negligent acts or omissions or wilful misconduct or breach of statutory duty of the indemnified Party.

2.7. The indemnity under clause 2.3 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from:

2.7.1. Participating NHS / HSC Organisation carrying out a treatment or procedure that would be routinely undertaken at or for that Participating NHS / HSC Organisation as part of National Health Service treatment; or

2.7.2. Participating NHS / HSC Organisation preparing, manufacturing or assembling any equipment which is not done in accordance.

2.7.2.1. with the protocol; or

2.7.2.2. with written instructions of the manufacturer; or

2.7.2.3. (where such instructions differ from the instructions of the manufacturer) other written instructions of the Sponsor.

2.8. No Party shall be liable to another in contract, tort/delict, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts, or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement.

2.9. If a Party incurs any loss or damage (including costs and expenses) ("Loss") arising or resulting from this Agreement and:

2.9.1. All Parties are NHS bodies as defined in Section 9(4) of the National Health Service Act 2006 or Section 17 of the National Health Service (Scotland) Act 1978 or Section 7 (4) of the NHS (Wales) Act 2006 or Articles 16 and 26 of the Health and Personal Social Services (Northern Ireland) Order 1972, which established the Boards and Central Services Agency respectively and Article 10 of the Health and Personal Social Services (Northern Ireland)
Order 1991: which established Trusts in Northern Ireland as appropriate; or

2.9.2. One or more Party is an NHS body, and the other Party (ies) is a NHS Foundation Trust; or

2.9.3. All Parties are NHS Foundation Trusts; Then clauses 2.10,
2.11 and 2.12 shall apply.

2.10. If all Parties are NHS bodies / NHS Foundation Trusts in England, Wales or Northern Ireland and are indemnified by the same indemnity scheme (being one of the NHS Resolution's clinical negligence schemes or the Welsh Risk Pool or the Clinical Negligence Fund in Northern Ireland) and the Party incurring any loss can recover such loss under one of the indemnity schemes, then such Party shall rely on the cover provided by the indemnity scheme and not seek to recover the Loss from the other Party (ies). Where the other Party (ies) caused or contributed to the Loss, it undertakes to notify the relevant indemnity scheme(s) to take this into account in determining the future levies of all Parties in respect of the indemnity schemes.

2.11. If:

2.11.1. The Parties are members of the same indemnity scheme in England, Wales or Northern Ireland and the Party incurring the Loss is not indemnified for that Loss by its indemnity schemes; or

2.11.2. All Parties are NHS bodies in Scotland; or

2.11.3. The Parties are NHS bodies/Foundation Trusts established in different jurisdictions within the United Kingdom.

Then the Parties shall apportion such Loss between themselves according to their respective responsibility for such Loss.

2.12. If one or more Parties are NHS Foundation Trusts and the Party incurring the Loss is not responsible for all or part of the Loss and is not indemnified in respect of the Loss by one of the indemnity schemes, then the Party incurring the Loss shall be entitled to recover the Loss from the other Party (ies) pursuant to the provisions of this Agreement.

2.13. Subject to clause 2.1 and 2.7 the liability of the Participating NHS / HSC Organisation to the Sponsor and the liability of the Sponsor to the Participating NHS / HSC Organisation arising out of or in connection with any breach of this Agreement or any act or omission of either Party in connection with the performance of the study should be the greater of the amount of fees payable by the Sponsor to the Participating NHS / HSC Organisation under this Agreement or

one hundred thousand (£100,000 GBP) pounds. For the avoidance of doubt, this cap applies also but not exclusively to the indemnities offered under clauses 2.3 and 2.4.

2.14. Notwithstanding clause 2.13, in the case of equipment loaned by or on behalf of the Sponsor to the Participating NHS / HSC Organisation for the purposes of the study, the Participating NHS / HSC Organisation's liability for damage to or loss of that equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the replacement value of the equipment.

3. PUBLICITY

3.1. Neither Party shall use the name, logo or registered image of the other Party or the employees of such other Party in any publicity, advertising or press release without the prior written approval of an authorised representative of that Party.

3.2. The content and timing of any publicity, advertising or press release shall be agreed by all Parties, such agreement not to be unreasonably withheld.

4. PUBLICATION

4.1. In accordance with all relevant laws, regulations and codes of practice, it is agreed that the Sponsor has an obligation to and shall publish the results of the full study and that the Participating NHS / HSC Organisation shall not publish any study data, including through presentation or submission of an abstract, without the prior permission in writing from the Sponsor (which shall not be unreasonably withheld or delayed).

5. FREEDOM OF INFORMATION

5.1. Parties to this Agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another Party shall notify and consult that Party, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.

5.2. The Parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the Party responding to the request.

5.3. Where the Party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other Party in writing, giving at least four (4) working days' notice of its intended disclosure.

6. CONFIDENTIALITY

6.1. Subject to clause 5 above, the Participating NHS / HSC Organisation agrees to treat the results, excluding any clinical data of the study, as confidential information of the Sponsor and the Sponsor agrees to treat personal data and confidential patient information as confidential information.

6.2. The receiving Party agrees:

6.2.1. To take all reasonable steps to protect the confidentiality of the confidential information and to prevent it from being disclosed otherwise than in accordance with this Agreement.

6.2.2. To ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the Study are made aware of, and abide by, the requirement of this clause 6.2.

6.2.3. To use confidential information solely in connection with the operation of the Agreement and not otherwise, except in the case where the confidential information is personal data and/or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the data protection legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.

6.2.4. Not to disclose confidential information in whole or in part to any person without the disclosing Party's prior written consent or, where the confidential information is personal data and/or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the data protection legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.

6.3. The provision of clause 6.2 shall not apply to the whole or any part of the confidential information that is:

6.3.1. lawfully obtained by the receiving Party free of any duty of confidentiality.

6.3.2. already in the possession of the receiving Party and which the receiving Party can show from written records was already in its possession (other than as a result of a breach of clause 6.2.1 or 6.2.2).

6.3.3. in the public domain (other than as a result of a breach of clause 6.2.1 or 6.2.2).

6.3.4. independently discovered by employees of the receiving Party without access to or use of confidential information.

6.3.5. necessarily disclosed by the receiving Party pursuant to a statutory obligation.

6.3.6. disclosed with prior written consent of the disclosing Party.

6.3.7. necessarily disclosed by the receiving Party by virtue of its status as a public authority in terms of the FOIA or the FOI(S)A.

6.3.8. published in accordance with the provisions of clause 4.

6.4. The restrictions contained in clause 6.2 shall remain in force without limit in time in respect of personal data and any other information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

Appendix 2: Finance Provisions

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
*Are there funds / resources / equipment, etc. being provided to this participating NHS / HSC organisation by the Sponsor? If no, this appendix should be left blank. If yes, this finance appendix forms part of the Agreement between the participating NHS / HSC organisation and the Sponsor.	No

A. Financial Arrangements

The overall, study-wide recruitment for this study requires a maximum figure of 12. Participants. Once this target has been reached, the Sponsor will notify the Participating. NHS / HSC Organisation. No additional per participant payments will be made by the Sponsor to the Participating NHS / HSC Organisation for participants consented after such notification becomes effective.

	*Area of Cost	*Payment (£ Sterling)
1*		
2*		

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment of the agreed costs on presentation of a VAT invoice in which the VAT is stated as a separate item. Such invoices should quote the Participating NHS / HSC Organisation's VAT registration number. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

Schedule of payments and details of payment arrangements N/A

B. Supplies Arrangements : N/A

Appendix 3: Material Transfer Provisions

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
*Does this study involve the transfer of human biological material from this participating NHS / HSC organisation to the Sponsor or its agents? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	No

Material, as used in this appendix, means any clinical biological sample or portion thereof, derived from participants, including any information related to such Material, supplied by the Participating NHS / HSC Organisation to the Sponsor/Joint Sponsors/either of the CoSponsors or [its] / [their] nominee.

1. In accordance with the protocol, the Participating NHS / HSC Organisation shall send Material to the Sponsor/joint Sponsors/a co-Sponsor or, in accordance with provision 7 below, to a third party nominated by the Sponsor/joint Sponsor s/either of the co-Sponsors.

2. The Participating NHS / HSC Organisation warrants that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)) and as required by the protocol.

3. Subject to provision 2 above, the Materials are supplied without any warranty, expressed or implied, including as to their properties, merchantable quality, fitness for any particular purpose, or that the Materials are free of extraneous or biologically active contaminants which may be present in the Materials.

4. The Sponsor/joint Sponsors/one of the co-Sponsors shall ensure, or procure through an agreement with the Sponsor's/joint Sponsors'/co-Sponsor's nominee as stated in provision 1 above that:

4.1.the Material is used in accordance with the protocol, the consent of the participant, and the ethics approval for the study.

4.2.the Material is handled and stored in accordance with applicable law.

4.3.the Material shall not be redistributed or released to any person other than in accordance with the protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the participant's consent.

5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.

6. The Participating NHS / HSC Organisation and the Sponsor/joint Sponsors/a co-Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this appendix.

7. To the extent permitted by law the Participating NHS / HSC Organisation and its staff shall not be liable for any consequences of the supply to or the use by the Sponsor/joint Sponsors/co-Sponsor of the Material or of the supply to or the use by any third party to whom the Sponsor/joint Sponsors/co-Sponsor subsequently provides the Material or the Sponsor's/joint Sponsors'/co-Sponsor's nominee as stated in provision 1 above, save to the extent that any liability which arises is a result of the negligence of the Participating NHS / HSC Organisation.

8. The Sponsor/joint Sponsors/co-Sponsor undertake(s) that, in the event that Material is provided to a third party in accordance with provision 2 above, [it] / [they] shall require that such third party shall undertake to handle any Material related to the study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in this appendix.

9. Any surplus Material that is not returned to the Participating NHS / HSC Organisation or retained for future research (in line with participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)).

*These provisions do not remove the need for the Sponsor to clearly lay out in their protocol (and to potential participants in the participant information) at a minimum the following information for all Material taken: 1) The nature of the Materials, 2) The reason that the Material is being taken, 3) where the Material is to be sent and, 4) what will happen to any remaining Material once it has been processed/analysed, etc. for the purposes of this study (e.g. return, retention or destruction). Detailed guidance on what information should be included in a protocol may be found on the HRA website: www.hra.nhs.uk.

Appendix 4: Data Processing Agreement

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
*Does **t**his study involve any processing of personal data by this participating NHS / HSC organisation on behalf of the Sponsor. If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation. For the avoidance of doubt, when used, these provisions are intended to form a legally binding contractual obligation for the purposes of compliance with the GDPR, specifically GDPR Article 28 (3).	Yes

1. For the purposes of the data protection legislation, the Sponsor is the controller, and the Participating NHS / HSC Organisation is the Sponsor's processor in relation to all processing of personal data that is processed for the purpose of this study and for any future research use under the controllership of the Sponsor, that would not have taken place but for this Agreement regardless of where that processing takes place.
2. The Parties acknowledge that whereas the Sponsor is the controller in accordance with Clause 1 of this appendix, the Participating NHS / HSC Organisation is the controller of the personal data collected for the purpose of providing clinical care to the participants. This personal data may be the same personal data, collected transparently and processed for research and for care purposes under the separate controllerships of the Sponsor and Participating NHS / HSC Organisation.
3. Where the Participating NHS / HSC Organisation is the Sponsor's processor and thus where the processing is undertaken by the Participating NHS / HSC Organisation for the purposes of the study, Clauses 5.a. to 5.j below will apply. For the avoidance of doubt, such Clauses do not apply where the Participating NHS / HSC Organisation is processing the participant personal data as a controller.
4. The Participating NHS / HSC Organisation agrees only to process personal data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the study and to ensure the Sponsor's compliance with the data protection legislation.
5. The Participating NHS / HSC Organisation agrees to comply with the obligations applicable to processors described by Article 28 GDPR including, but not limited to, the following:

    a. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the controller by Article 28(1).

    b. to not engage another processor without the prior written authorisation of the Sponsor (Article 28(2)).

    c. to process the personal data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Participating NHS / HSC Organisation shall notify the Sponsor before processing, or as soon as possible after processing if legislation requires that the processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a)).

    d. to ensure that personnel authorised to process personal data are under confidentiality obligations (Article 28(3b)).

    e. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c)).

    f. to respect the conditions described in Article 28(2) and (4) for engaging another processor (Article 28(3d)).

    g. to, taking into account the nature of the processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising data subjects' rights (Article 28(3e)).

h. to assist the controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the processing and the information available to the Participating NHS / HSC Organisation (Article 28(3f)).

i. to, at the choice of the Sponsor, destroy or return all personal data to the Sponsor at the expiry or early termination of the Agreement, unless storage is legally required (Article 28(3g)) or where that personal data is held by the Participating NHS / HSC Organisation as controller for the purpose of clinical care or other legal purposes; and

j. to maintain a record of processing activities as required by Article 30(2) GDPR.

6. The Participating NHS / HSC Organisation shall ensure that:

a. its agents do not process personal data except in accordance with this. Agreement (and in particular the protocol).

b. it takes all reasonable steps to ensure the reliability and integrity of any of its agents who have access to the personal data and ensure they:

i. are aware and comply with the Participating NHS / HSC Organisation 's duties under this clause.

ii. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and

iii. are informed of the confidential nature of the personal data and understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.

7. The Participating NHS / HSC Organisation agrees to:

a. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Participating NHS / HSC Organisation's compliance with the obligations described by this Appendix, data protection legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the participating site and/or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and

b. obtain prior agreement of the Sponsor to store or process personal data outside the European Economic Area.

8. Where the Participating NHS / HSC Organisation stores or otherwise processes personal data outside of the European Economic Area as the Sponsor's processor, it warrants that it does so in compliance with the Data Protection Legislation.

Appendix 5: Data Sharing Agreement

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS/HSC organisation, please select an option below.	
*Does this study involve the transfer of personal data from this participating NHS / HSC organisation to the Sponsor or its agents, or transfer of confidential information between the Parties? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	Yes

1. Personal data shall not be disclosed to the Sponsor by the participating NHS / HSC organisation, save where this is required directly or indirectly to satisfy the requirements of the protocol, or for the purpose of monitoring or

reporting adverse events, or in relation to a claim or proceeding brought by a participant in connection with the study.

2. The Sponsor agrees to use personal data solely in connection with the operation of the Agreement, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular,
   2.1. Not to disclose personal data to any person except in accordance with applicable legal requirements and codes of practice.
3. The Sponsor agrees to comply with the obligations placed on a controller by the data protection legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to processing of personal data (Article 5 GDPR)
4. The Sponsor agrees to ensure persons processing personal data under this Agreement are equipped to do so respectfully and safely. In particular:
   4.1. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the participating NHS / HSC organisation) processing personal data understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.
   4.2. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating NHS / HSC Organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
5. The Sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular,
   5.1. To ensure that personal data are only accessible to persons who need it for the purposes of the study and to remove access as soon as reasonably possible once it is no longer needed.
   5.2. To ensure all access to personal data on IT systems processed for study purposes can be attributed to individuals.
   5.3. To identify, review and improve processes which have caused breaches or near misses, or which force persons processing personal data to use workarounds which compromise data security.
   5.4. To adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice.
   5.5. To take action immediately following a data breach or near miss.
6. The Sponsor agrees to ensure personal data are processed using secure and up to date technology. In particular,
   6.1. To ensure no unsupported operating systems, software or internet browsers are used to support the processing of personal data for the purposes of the study.
   6.2. To put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as Cyber Essentials.
   6.3. To ensure IT suppliers are held accountable via contracts for protecting personal data they Process and for meetings all relevant information governance requirements.

Appendix 6: Intellectual Property Rights

Where this Organisation Information Document is to be used as the Agreement between Participating NHS / HSC organisation, please select an option below.	
*Does this study require the protection of background intellectual property rights, or is there potential for the generation of new intellectual property? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	Yes

1. All background intellectual property rights (including licences) and know-how and their improvements used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not knowingly infringe any third party's rights.
2. All intellectual property rights and know how in the Protocol, and in the study data, excluding clinical procedures developed or used by the Participating NHS / HSC Organisation independently of the Study, shall belong to the Sponsor. The Participating NHS / HSC Organisation hereby assigns all such intellectual property rights, and undertakes to disclose all such know how, to the Sponsor.
3. Subject to clauses 1 and 2, all intellectual property rights deriving or arising from the Material, or any derivations of the Material provided to the Sponsor by the Participating NHS / HSC Organisation shall belong to the Sponsor.
4. At any time within the duration of the Study, the Participating NHS / HSC Organisation shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest the intellectual property rights in the Sponsor. To give effect to this clause 4, the Participating NHS / HSC Organisation shall ensure that its agents involved in the Study assign such intellectual property rights falling within clauses 2 and 3 and disclose such know how to the Participating NHS / HSC Organisation.
5. Subject to this Clause 5 and Clause 6, nothing in this Appendix shall be construed so as to prevent or hinder the Participating NHS / HSC Organisation from using its own know how or clinical data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor, or their funder. This clause 5 does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results. Any study data not so published remains the confidential information of the Sponsor, or their funder.
6. The Participating NHS / HSC Organisation may, with the prior written permission of the Sponsor (such permission not to be unreasonably withheld), use study data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor or their funder. This clause 6 does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the Study.

Authorisation When Using This Organisation Information Document as An Agreement

(when used as an Agreement, the Participating NHS Organisation is a "Party" to the Agreement and the Sponsor is a "Party" to the Agreement – collectively the "Parties").

Authorisation on behalf of Participating NHS / HSC Organisation It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the Sponsor and participating NHS / HSC organisation. Instead, Sponsors are expected to accept confirmation by email from an individual empowered by the Participating NHS / HSC Organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).	
^ Authorised on behalf of Participating NHS / HSC Organisation by:	
Name	Lynis Lewis
Job Title	R&D Services Director
Organisation Name	Camden and Islington NHS Foundation Trust
Date	27 June 2023

9.1.8 Appendix H: Insurance provided by Sponsor, City University

[redacted]

IRAS ID 322110 LETTER TO CONFIRM MM INSURANCE [redacted]-CIY UNIVERSITY 2022-2023 [29913] 09.03.2023 v1

1st August 2022

TO WHOM IT MAY CONCERN

We, the undersigned Insurance Brokers, hereby certify that the following described insurance:

VERIFICATION OF INSURANCE

Unique Market Reference:	[redacted]
Type:	Medical Malpractice Insurance
Insured:	City University London
Period:	From: 1st August 2022 To: 31st July 2023 Both days inclusive at Local Standard Time.
Interest:	This Policy will indemnify/Cover the Insured for Medical Malpractice and as more fully described within the Policy Wording
Limit of Indemnity:	GBP [redacted] any one Claim and GBP [redacted] in the aggregate Legal Costs in addition
Excess:	[redacted]
Underwriter:	1[redacted] [redacted] [redacted] [redacted]

This document is for information only and does not make the person or organisation to whom it is issued an additional Insured, nor does it modify in any manner the Contract of Insurance between the Insured and the Insurers. Any amendment, change or extension to such Contract can only be affected by specific endorsement attached thereto.

Should the above mentioned Contract of Insurance be cancelled, assigned or changed during the above policy period in such manners as to affect this document, no obligation to inform the holder of this document is accepted by the undersigned or by the Insurers. The information provided is correct at the date of signature.

[redacted]

Authorised [redacted]
[redacted]

[redacted]

[redacted]

IRAS ID 322110 LETTER TO CONFIRM INSURANCE 09.03.2023 v 1

TO WHOM IT MAY CONCERN

21/10/2022

Dear Sirs

We are the Risk and Insurance Managers for the client below and have pleasure in confirming details of their insurance arrangements as follows:-

Insured Details:

Name(s)	**City University of London**
Postal Address	**Northampton Square, London, EC1V 0HB**
Our Ref	**5068871**

Professional Indemnity

Insurer	:	[redacted]
Policy No.	:	B1262FI1910921
Expiry Date	:	01 August 2022 to 31 July 2023, both days inclusive
Limit of Indemnity	:	[redacted]
Jurisdiction		

Professional Indemnity

Insurer	:	[redacted]
Policy No.	:	FI1911021
Period of Cover	:	[redacted]
Limit of Indemnity	:	
Jurisdiction	:	

Cover is subject to the full terms, conditions and exclusions of the policy.

This document is issued to you as a matter of information only and the issuance of this document does not: -

9.1.9 Appendix I: Clarification Of Insurance Cover For Pregnant Women

IRAS ID 322110 INSURANCE EMAIL CONFIRMATION RE NO EXCLUSIONS 09.03.2023 v 1

From: [redacted]
Sent: 09 March 2023 09:32
To: [redacted]
Cc: [redacted]
Subject: RE: D.Psych Doctoral Research: Insurance for research within the NHS

Morning Susan

Apologies for delay

The NHS Ethics Committee has given a provisional approval subject to reverting with a few queries; one of these is:

Please confirm that there are no applicable exclusions that would affect the insurance cover available for study participants (Pregnant at 24 weeks to 24 months post birth with a diagnosis of OUD).

I can confirm that there are no specific pregnancy exclusions that will be applied to this study that would affect insurance cover for available study participants

[redacted]
Financial and Professional Risks

[redacted]

9.1.10 Appendix J: Redacted Data Extract – Clinical Care Records (RIO)

FIRST_NAME	LAST_NAME	DOB	SEX	TRIAGED	DRUG1	KEYWORKER
			Female		Heroin Illicit	
			Female		Heroin Illicit	
			Female		Heroin Illicit	
			Female		Heroin Illicit	
			Female		Heroin Illicit	
			Female		Heroin Illicit	
			Female		Heroin Illicit	

9.1.11 Appendix K: Redacted Data Extract – Clinical Care records (ILLY-CAREPATH)

Surname	Initial Inward Referral Agency	NDTMS Drug Group (Four)	Pregnant	Parental Status	Parental Responsibility	of children living with	Age Of Client	Gender	Ethnic Origin	Injection Status	Primary Problem Substance	Secondary Problem Substance	Tertiary Problem Substance	NDTMS Consent
	Self	Opiate	No	Not Set	No	0		Female	Other White	Never injected	Heroin illicit	Cocaine Freebase	Buprenorphine	Yes
	Self	Opiate	No	Not Set	No	0		Female	Other White	Never injected	Heroin illicit	Buprenorphine	Methadone uns	Yes
	Outreach	Opiate	No	Not Set	No	0		Female	White and Black A	Currently injecting	Heroin illicit	Cocaine Freebase	Cannabis Unspe	No
	Self	Opiate	No	Not Set	No	0		Female	Other Black	Never injected	Heroin illicit	Cocaine Unspecified		Yes
	Self	Opiate	No	Client decline	Not Set	0		Female	White British	Currently injecting	Heroin illicit	Cocaine Freebase	Methadone uns	Yes
	Self	Opiate	No	None of the c	Yes	0		Female	Caribbean	Never injected	Cocaine Freebase (c	Heroin illicit	No Third Drug	Yes
	Self	Opiate	No	Not Set	No	0		Female	Other Asian	Never injected	Opium	No Second Drug	No Third Drug	Yes
	Self	Opiate	No	Not Set	No	0		Female	African	Never injected	Heroin illicit	Cocaine Freebase	Benzodiazepine	Yes
	Self	Opiate	No	Not a parent	Not Set	0		Female	Other White	Previously injected (b	Heroin illicit	Cocaine Freebase	No Third Drug	Yes
	Self	Opiate	No	Not Set	No	0		Female	Other Mixed	Never injected	Heroin illicit	Cocaine Freebase	No Third Drug	Yes

9.1.12 Appendix L : Participant Consent Form

Barnet, Enfield and Haringey NHS Mental Health NHS Trust

A University Teaching Trust

Camden and Islington NHS Foundation Trust

"My Healthcare Journey Through Pregnancy and Substance Use".
Participant Consent Form

(IRAS ID 322110 PARTICIPANT CONSENT FORM CLEAN v 5 20/12/2023)

Name of Chief Investigator:
Professor Carla Willig
Student and Principal Investigator:
Susan Elkington

IRAS ID: 322110
REC reference number:
Reviewing Committee: North West - Greater Manchester West REC

		Please tick or initial box
1	I confirm that I have read and understood the participant information dated [18.12.2023 Version 8] for the above study. I have had the opportunity to consider the information and ask questions which have been answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw without giving a reason without my medical care or legal rights being affected, or being penalised, or disadvantaged.	
3.	I understand that I will be able to withdraw my data up to the time of transcription.	
4.	I agree to maintain the confidentiality of my interview.	
5.	I agree to City recording and processing this information about me. I understand that this information will be used only for the purpose(s) explained in the participant information and my consent is conditional on City complying with its duties and obligations under the General Data Protection Regulation (GDPR).	
6.	I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from City University (the sponsor) 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 these notes and data.	
7	I understand that my General Practitioner (GP) and Clinical Care Team will be informed of my participation in the study, following my acceptance and signature of the Consent Form.	
8.	I understand that confidentiality might be broken in the event that there is any indication of violence or abuse (to me), self-inflicted harm, harm to others or acts of criminal activity.	
9.	I agree to take part in the above study.	
10.	This clause is optional; please only tick if you agree to the following statement: I would like to be informed of the results of this study once it has been completed and understand that my contact details will be retained for this purpose.	

1

Name of Participant	Signature	Date

Name of Researcher	Signature	Date

When completed, 1 copy for participant; 1 copy for researcher file.

2

9.1.13 Appendix M: Letter to Potential Participant

Barnet, Enfield and Haringey NHS Mental Health NHS Trust

A University Teaching Trust

Camden and Islington NHS Foundation Trust

(IRAS ID 322110 LETTER TO INTERESTED POTENTIAL PTNS REDLINED 18/12/2023 v7 Amendment.doc)

Date:

Dear

Invitation to support research.

I am a student and Trainee Counselling Psychologist, and we are writing to you to invite you to take part in a research study which is being carried out in your NHS Trust XXX.

What is the purpose of the study?
We would like to understand the experiences of healthcare of women who have taken illicit opioids (such as heroin), who are currently taking methadone and who are pregnant, or who have had a baby in the last 8 years. This means that you may be pregnant or have a child of eight years old. The child may be living with you, or in care,. You may have also recovered from substance use and ceased to take any form of opioid replacement therapy (e.g. methadone, subutex or buprenorphine).

We are studying this to understand how it feels to become pregnant and receive and engage in such an important range of healthcare. We want to discover if we are meeting the complex needs of women with opioid use disorder (OUD) and to learn if and how we might be able to improve it.

Why have I received this letter?
We believe you may fulfil the requirements of the study.

These requirements include:

- You have taken substances (e.g. illicit heroin), you have started to take opioid replacement therapy (e.g. methadone, Subutex, buprenorphine) and you are at least 24 weeks pregnant or up to eight months post birth. (24 weeks is approximately 5 months pregnant).
- Or, you have taken substances (e.g. heroin), and you have successfully recovered and ceased to take opioid replacement therapy (e.g. methadone, subutex, buprenorphine) and you have had a baby in the last eight years
- We are aiming to recruit 12 women.
- You do not have another serious health condition.
- Your English is sufficient to participate in the study.
    - We will only be able to include you as a participant if you meet these requirements.

If you decide not to take part, it will have no effect on the treatment you receive throughout your pregnancy and after the birth of your baby.

- **You are not obliged to take part and you can just throw this letter and the Participation Information Sheet away if you are not interested.**
- **If you are interested, please read the attached Participation Information Sheet. You can ask questions about the study without any obligation of taking part.**
- You should contact me via the following telephone numbers or email: Telephone number: [redacted]
  Email: [redacted]

If you do decide to take part, we will arrange a time for the interview, and you will be asked to sign a consent form. We would like you to keep a notebook for 3 weeks following the interview of any further thoughts you may have.

I look forward to hearing from you,

Kind regards,

Susan Elkington

Trainee Counselling Psychologist, The Grove, Substance Abuse Service, Barnet, Enfield and Haringey, NHS Mental Health Trust.
[redacted]

Trainee Counselling Psychologist, Camden and Islington Substance Misuse Services
Camden and Islington NHS Foundation Trust.
[redacted]

CC:
Professor Carla Willig,
Chief Investigator and Academic Supervisor
E: [redacted]

9.1.14 Appendix N: Participation Information Sheet

PARTICIPANT INFORMATION SHEET

(IRAS ID 322110 PTN INFORMATION SHEET Clean v 8 04/11/2023.)

''My Healthcare Journey Through Pregnancy and Substance Use''

Name of Principal Investigator.

My name is Susan Elkington, and I am a student, a Trainee Counselling Psychologist interested in investigating the lived experience of women) who become pregnant, have children and who also manage their substance abuse (e.g. illicit opioids). The children may be in your care and living with you, or they may not be living with you or in your care. You may also have successfully recovered from substance use during your pregnancy and this period.

Invitation to support research.

We would like to invite you to take part in this research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you.

- Please take time to read the following information carefully and discuss it with others if you wish.

- Please ask me if there is anything that is not clear or if you would like more information. You will be given a copy of this information sheet to keep.

What is the purpose of the study?

This study is investigating the experiences of women who have taken illicit opioids such as heroin, who are currently taking methadone and who are pregnant, or who have had a baby in the last 48 months.

- The study aims to understand the experience of women who use or who have used drugs (e.g. illicit opioids) and the experience of their healthcare journey which supports them through pregnancy, birth and the following ten years.
- We want to investigate through research using interviews if we are meeting the complex needs of women e.g. with opioid use disorder (OUD) during and after pregnancy,
- We want to learn if and how we might be able to improve the healthcare we offer during this important time.

Why have I been invited to take part?

You have been invited to consider this information as we believe you may fulfil the requirements of the study.

These requirements include:

- You have taken substances (e.g. heroin) and you have successfully completed opioid replacement therapy (e.g. methadone) and you are between 24 weeks pregnant, and up to 8 years post birth.
- You have taken substances (e.g. heroin) and you have started to take opioid replacement therapy (e.g. methadone) and you are between 24 weeks pregnant, and up to 8 years post birth. (24 weeks is approximately 5 months pregnant).
-
- You can participate if your child is or is not living with you, or your child is subject to care proceedings.
- We are aiming to recruit 12 women.
- You do not have another serious health condition.
- You are proficient in English to meet the demands of the study.

We will only be able to include you as a participant if you meet these requirements.

Please rest assured that if you decide not to take part, it will have no effect on the treatment you receive throughout your pregnancy and after the birth of your baby.

Do I have to take part?

- No. Participation is entirely voluntary, and you may withdraw at any stage. If you decide to take part, you can avoid answering questions which you feel are too personal or intrusive.
- If you decide to withdraw at any stage, this will not affect any future treatment, and you will not be penalized if you choose to withdraw.
- **Consent form**: If you do decide to take part, you will be asked to sign a consent form.
- If you decide to take part, you are still free to withdraw at any time and without giving a reason.
- You will be asked to maintain the content of your interview confidential. This is to ensure that all participants engage without worrying about whether content of their interview risks being made public outside of the study.
- In a study of this kind, the data produced by the study is anonymized. Once the data has been anonymized or published you will not be able to withdraw your data.
- If you wish to withdraw your data after the interview, you need to contact the researcher within 2 weeks following the date of the interview.

If you consent to participate, we will write to your GP and clinical care team to let them know, after you have signed your consent form; this is to ensure that your clinical care team

is aware of your decision to participate. Everything you say in the interview is confidential and the clinical care team and GP will have no access to the recording.

What will happen if I take part?

If you decide to take part, your participation will follow the following process.

Introduction to the Study

- At this meeting, we will discuss the Participation Information Sheet to see if you have any questions about it.
- It will be in an NHS venue, by telephone, or online and designed to be convenient for you.
- There will only be two people present at this meeting, you and the researcher.

Interview – face to face meeting.

There will be four stages to this in person meeting which will last 60 minutes and be conducted face to face at an agreed time and place.

- Firstly, you will need to sign a consent form.
- Secondly, we will take some information about you (e.g. date of birth, substance use history, medical history and pregnancy).
- Thirdly, we will start the interview which will be recorded. This is a series of questions to guide our discussions about your pregnancy, your experience of healthcare, what has helped you and what has not.
- **We are also offering women the opportunity to attend a focus group which may include 2 -4 women. This will follow the same process, and you will also need to sign a consent form.**

Finally, there will be time to debrief and for you to ask the researcher any questions. **Follow up call.**

- The researcher will call you to check you are ok the following day and you will have a number to call in case you feel you want to talk about anything which has come up during the meeting.

Journal-3 weeks.

- You will be invited to make notes about anything else you think about in the following 3 weeks.

- This will need to be returned to me at the end of this period and I will contact you to arrange this.

What type of questions will I be asked at the Interview?

- These are some example questions:
    - Please describe your experiences and feelings when you found out you were pregnant.
    - How do you feel about managing and taking methadone whilst pregnant?

What are your experiences of the meetings and interactions and meetings with healthcare teams you are having? e.g. how to care for a baby, feeding, changing, caring for a toddler.

What other information will you ask?

- We will also ask you some detail about yourself e.g., age, name of your GP and Care team.
- We will also ask for some information about your history of substance use, and family history.

How do I get to the meetings, and will you pay travel expenses?

- We plan to meet at an NHS venue.
- We will pay reasonable travel expenses if you occur costs to come to the interview; you will need to demonstrate your costs of travel (e.g. cost of return bus fares). Reasonable costs are up to £8 for the return journey.

What else will happen at the interview?

To ensure your wellbeing throughout the interview, the research will monitor you to check for any signs of discomfort. If you were to be sure of signs of distress or became unwell, the researcher will contact the site Duty Manager. **When will it be finished and who is organizing it?**

- We are aiming to interview 12 participants, and our research will be completed in September 2024.
- The research is being completed at City University in partnership with two NHS Trusts.

What are the possible disadvantages and risks of taking part?

- The possible disadvantages for you include the possibility that the interview may make you remember things which you find difficult to talk or think about.
- You may also be quite busy with your pregnancy healthcare appointments and may not wish to travel to our meetings.

What are the possible benefits of taking part?

- Participating in this study will give you the chance to talk about your experience of the healthcare you are receiving during your pregnancy journey and how it feels.
- You would also be playing a significant role in contributing to our understanding of women who use heroin or other illicit opioids and how we can help and support them during pregnancy, childbirth and the first two years.

Expenses and Payments

- We are offering a voucher of £25 for the time you have taken to participate in this research. This will be in the form of a voucher you can send in a leading store.

We will also pay your expenses up to £8 for a return journey to attend the meetings, though you will need to demonstrate your costs of travel.

How is the project being funded?

- The project has received support and approval from the NHS and funding City University.

Conflicts of interests

- There is no conflict of interest.
- You should know that I have worked in an NHS Substance Abuse service and have experience of working with women who have taken substances and you have become pregnant. You should be aware that I am a researcher in this project and not acting as a therapist.

What should I do if I want to take part?

If you wish to take part:

- You should check to see that you fulfil the inclusion criteria.
- You should contact me to let me know that you wish to take part.
- After that, we will arrange our first Screening meeting.

Data privacy statement

- City, University of London is the sponsor and the data controller of this study based in the United Kingdom. This means that we are responsible for looking after your information and using it properly. The legal basis under which your data will be processed is City's public task.
- Your right to access, change or move your information are limited, as we need to manage your information in a specific way for the research to be reliable and accurate.
- To safeguard your rights, we will use the minimum personal-identifiable information possible.

For further information please see https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/public-task/).

- City will use your name and contact details to contact you about the research study, as necessary. If you wish to receive the results of the study, your contact details will also be kept for this purpose.
- The only people at City who will have access to your identifiable information will be the researcher. City will keep identifiable information about you from this study for ten years after the study has finished.
- You can find out more about how City handles data by visiting https://www.city.ac.uk/about/governance/legal. If you are concerned about how we have processed your personal data, you can contact the Information Commissioner's Office (IOC) https://ico.org.uk/.

Will my taking part in the study be kept confidential?

- Your data will be anonymized which means you will not be identifiable and matched to the information you have provided.
- You will be assigned a Study ID, and this will be used and attached to any audio recording. If you use any personal identifying data during the interview, this will be deleted by the researcher.
- Data will be kept in a secure University system called OneDrive. Recordings are usually kept for 10 years.
- If you reveal any indication of violence, abuse, self-inflicted harm, harm to others, criminal activity, the researcher would be obliged to report this to a relevant NHS Duty Manager, or Supervisor.
- We will seek to publish the research in line with Open Scholarship principles. Any data you have contributed will not be identifiable.

What will happen to the results?

We will aim to publish the results of our research in the future. Your anonymity will be maintained if we publish. If you wish to receive results from the study, we will need consent from you to keep contact details for you. The report may not be available to be shared until 2025, so we would need to keep your details until then at least.

- We will aim to publish in journals which cover substance abuse, counselling and psychology. Examples of these are *Drugs: Education, Prevention & Policy, British Journal of Health Psychology, Counselling and Psychotherapy Research.*

Who has reviewed the study?

- This study has been approved by City, University of London and the North London NHS Research Ethics Committee.

What if there is a problem?

- If you have any problems, concerns or questions about this study, you should ask to speak to a member of the research team whose details are below.
- You can also contact the Patient Advice and Liaison Service (PALS) on:
  Tel: 020 8887 3172
  North Middlesex University Hospital,
  Sterling Way
  London
  N18 1QX
  Or
  Tel: 020 3447 3042
  University College Hospital,
  1 Grafton Way
  London
  WC1E 6AS
- If you remain unhappy and wish to complain formally, you can do this through City's complaints procedure. To complain about the study, you need to phone 020 7040 3040. You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them of its reference number [IRAS 322110]
- You can also write to the Secretary at:

John Montgomery,

Research Integrity Manager
City, University of London, Northampton Square
London, EC1V 0HB
Email: [redacted]

Insurance

- City holds insurance policies which apply to this study. If you feel you have been harmed or injured by taking part in this study, you may be eligible to claim compensation. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for legal action.

Further information and contact details.

- The Chief Investigator and Supervisor for this Research project is.
  Professor Carla Willig. [redacted]
- The student researcher and Principal Investigator is:
  Susan Elkington [redacted]

Thank you for taking the time to read this information sheet.

9.1.15 Appendix O: Interview Demographic Questionnaire

Interview Questionnaire

(IRAS ID 322110 PTN DEMOGRAPHICS QUESTIONNAIRE 18.01.2023 v 2)

Participant Demographic, Personal History, and Clinical characteristics

1	**Socio-demographic-clinical**	
	Please tell me your date of birth	
	Please tell me your gender at birth	
	Are you registered at a substance abuse clinic?	
	Please tell me which one	
	Or Please tell me under whose care you are?	
	Please give me details of your GP, NHS number and name of your key worker.	
2	**Substance use history**	
	What is the age of your first use of substance(s)?	
	Please describe your substance use	
	-Please tell me what you used?	
	-Please tell me the frequency of use	
	-Please tell me how long you used for	
	-Please describe any current use	
	Please tell me how long you have been on methadone (ORT)	
	Please tell me your current methadone prescription	
3	**Family history**	
	Do you have other children or dependents living with you?	
	Or, not living with you?	
	Can you please tell me their ages?	
4	**Current Pregnancy**	
	Can you tell me how many months you are pregnant?	
	What is your expected due date?	
	Please tell me the name of the lead of your perinatal care lead	

9.1.16 Appendix P: Interview Topic Guide

CITY UNIVERSITY OF LONDON EST 1894

Barnet, Enfield and Haringey NHS Mental Health NHS Trust

A University Teaching Trust

NHS Camden and Islington NHS Foundation Trust

Interview Questionnaire Topic Guide
Peri-natal and Postnatal

(IRAS ID 322110 INTERVIEW TOPIC GUIDE REDLINED 04.03.2023 v 3)

	Pregnancy - Peri-natal topic and interview guide (>24 weeks pregnant)
1	Please describe your experiences and feelings when you found out you were pregnant.
2	How do you feel about managing and taking methadone whilst pregnant? Probe: How do you feel about the information you have received about your pregnancy e.g about methadone?
3	What are your experiences of the meetings and interactions and meetings with (perinatal) healthcare teams you are having? e.g., with a birth plan; with the stages of pregnancy.
4	What have you found helpful/not helpful in the care you are receiving? Can you think of things which could support you in your pregnancy which are not currently available or being talked about?
5	How do you feel about using substances? Has this changed for you since becoming pregnant? Do you think it will change in the future after the birth?
6	Can you describe your feelings about being a mother? Are there things you feel you would like advice on, or to know more about in the care of a baby?
7	Did you tell friends and family about your pregnancy. Probe: How did this feel?
8	Is there anything else you feel would be helpful for you at this stage or which you would like to add?
	Post birth topic and interview guide (post birth)
1	Please describe your experiences and feelings when you found out you were pregnant.
2	How do you feel about managing and taking methadone as a mother? Probe: How do you feel about the information you have received about your pregnancy eg about methadone?
3	What are your experiences of the meetings and interactions and meetings with healthcare teams you are having? e.g. how to care for a baby, feeding, changing, caring for a toddler. Probe: Is there anything you have found helpful/unhelpful.
4	What have you found helpful/not helpful in the care you are receiving? Can you think of things which could support and help you as a mother which are not currently available or being talked about?
5	How do you feel about using substances? Probe: Has this changed for you since having a baby?
6	Did you tell friends and family about being pregnant and giving birth and how did this feel?
7	How do you feel about the future?
8	Is there anything else you feel would be helpful for you at this stage or which you would like to add?

[redacted]

Project ID: 322110

9.1.17 Appendix Q: Risk Management Procedures

Summary of Risk, Adverse Events And Risk Management Plan

Risk or adverse event	**Risk or adverse event**	**Risk management plan**
Convenience and ease to participate	The participants are likely to have a busy schedule of perinatal/post-natal maternity care meetings. Participation in the research will require an additional commitment to an interview.	Interview times will be set to cause minimal inconvenience, with the option to coincide with other routine care appointments at substance abuse clinics or peri/post-natal appointments.
Physical discomfort	Women may find pregnancy physically uncomfortable, e.g., to sit for an hour. They may also require facilities for an infant.	Rooms will be comfortable and afford childcare facilities if required.
Access and physical discomfort	They may not be comfortable walking any distance within NHS sites to an interview room.	Interview rooms will be sourced and arranged with the participating Trusts to have easily accessible rooms.
Recall of difficult memories associated with pregnancy	It is possible that participants recall difficult memories associated with their experience e.g., childbirth pain either during or after the interview.	The researcher will allow time for any difficult memories to be empathetically supported, with the option for referral to therapeutic support given.
Adverse events	Adverse events may occur, and the participants require urgent perinatal clinical attention.	(c) The researcher will monitor the participant throughout all contact and inform the site Duty Manager, Keyworker or GP of any sign of distress emerges. (d) The researcher will ensure that the clinical care team e.g., GP, and Keyworker of each participant is informed and aware of the research participation and given the opportunity to highlight any risks unique to the participant they foresee. **d)** The Duty Manager will be informed of the date and time of the participant's interview in the event that any adverse events occur, care and risk plan can be enacted.
Recall e.g., of Intimate Partners Violence (IPV)	The participants in this population may have suffered from intimate partner violence (IPV) and trauma and the interview may prompt recall.	The researcher will monitor the participant throughout all contact and inform the site Duty Manager, Keyworker or GP of any sign of distress emerges.
Self-harm and risk	Disclosures of self-harm or risk during the interview	Any disclosure of self-harm or risk will be reported as risk to the Duty Manager and Clinical Care team.
Safeguarding	Safeguarding issues disclosed during interview	Any safeguarding issues concerning existing children or dependents of the participant will be raises with the Duty Manager and Clinical care team.
Post interview wellness		The researcher will call each participant within 24 hours of the interview to ensure participants are well and not experiencing any sense of being unwell. If the event of any sense of unwellness, the researcher will contact the Duty Manager.

9.1.18 Appendix R: Summary of Amendments

Summary of Amendments IRAS 322110
20/12/2023 v 7

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	EA-64596	22nd June 2023	Susan Elkington (PI)	Change of Principal Investigator at participating sites
2	EA-65237	30th June 2023	Susan Elkington (PI)	Amendment of inclusion criteria to include women who are 36 months post birth (to extend it from 24 months post birth).
3	EA-65748	16th July 2023	Susan Elkington (PI)	To update contact information for PI for participating Trusts on study documents To extend participant inclusion criteria to include women who are up to 48 months pregnant and update on study document
4	EA-69404	27th September 2023		To change name of supervisor at the Grove from Dr Athanasiadou to Dr Dent
5	EA-71298	4th November 2023		PPI - so that PPI contributions may come from Women's Recovery groups and communities, as well as individuals. The interview process of participants may be held in groups of 2+ participants if this is preferable to women who consent to participate Inclusion criteria are extended to mothers, 96 months post birth, i.e mothers with children up to 8 years old.
7	EA-73680	20th December 2023		Amendments to Inclusion criteria- so that women who are recently in recovery and have ceased to take illicit opioids and opioid substitute therapy may also participate.

9.1.19 Appendix S : Coding Analysis-Reflexive Notes On Each Participant

P1	P1 was my first interviewee, and I found her account very uplifting; it made me hopeful for this group of women. It was moving and we both became emotional. It was a wonderful first interview; the following interviews and stories have been less hopeful. Here was a woman aged 38 y/o who started using heroin aged 16, now a mother of a 3 year old, heroin free, working and with plans to attend college. She felt the interview was the first time she had really talked about everything; she felt she stepped back and could see how far she had come. I liked her wisdom, especially her focus on using problems to learn from. I have reflected a lot on her experience, and issues of intersectionality. She came to UK with very nothing – save for the support of an old boyfriend; she was returning to the Netherlands to get her methadone to start off, having no idea she could get it in the UK. She seems to have been lucky to have some good boyfriends and she seemed to have a good family behind her. She had very few negative words to say about her experience in the NHS, or critical observations. I have wondered whether the fact that she feels she would not get the same care or support in her country of origin made her more compliant, less complaining of services she found in the NHS. I also felt she is incredibly enterprising and resourceful. I felt her evolving relationship with methadone was very interesting and clear in the interview. She remains on methadone now and seemed to be defensive about this. (I felt myself agreeing with her on this, that it was like any other medication). I know and like her Keyworker (KW)and felt happy and grateful he is her KW. I wondered whether the fact that I like her is creating a blind spot in analysing her interview and whether I am failing to look at deeper meanings. I also wonder what she is not saying.
P2	P2 was a total contrast. I knew from her KW that she had something to get off her chest and that she had suffered traumatic experiences 'in the system' pre and post birth. I was shocked by her experience and found myself looking up reviews on Mother and Baby Rehab clinics in the city she attended. Her experience sounded awful.I felt like reporting it to the Guardian. It seemed worthy of an underground investigation. I have tried not to take it at face level. I took some of the extract to our TA group and this helped me think about her experience at a more latent level. At least 2 of the other trainees told me they did not like her. I have often found my topic to be difficult and less acceptable amongst the CP cohort. Even CP Trainees think ill of women who take heroin. I still found myself wondering how P2 had ended up on heroin and in the interview at all. She seemed to have a family with reasonable resources, who had taken her child in as guardians. She has limited/some access rights. I wondered whether there was more I could have asked her to better understand her background – but felt somewhat constrained by my NHS approved topic guide and how much she wanted to tell me about her treatment by social services and the midwife. It is also not the focus of the research. I have found myself wanting to support her therapeutically. She is the youngest and white. I wondered about her indignation and fury at her treatment compared to the other interviews. It was as if she was expecting she would be treated with respect, whereas some of the other participants seemed grateful for any treatment at all.
P3	P3 's interview was very moving. She had 4 children. A times, the flow of her narrative was chaotic, as to which child she was talking about…whether she was using heroin at the time of pregnancy and what was happening. I felt some of the chaotic nature of her life, as it tumbled out. She was 15 y/o when she was first pregnant, and working in Finsbury park as a prostitute. I felt naïve having to get her to clarify what she meant about – going back to Sevens Sisters…which was clearly understood as sex work. She went straight back to work, 3 days after having a caesarean.

	She has lost her youngest 2 to social care and feels cheated into asking for help…and her children being taken away. She lost her apartment and lived on the landing, and described being weed on. I have never come so close to someone talking about such suffering and destitution. There was also so much warmth and love running through her story. It is incredible how well connected she still is with her 4 daughters. I liked her a lot, and I believed she had instilled values in her daughters. I liked her interest and motivation to education younger women in schools.
P4	P4 had just had her baby and her maternity experiences were very recent. She described how she had given up both OST and heroin and crack during pregnancy – yet still feel very judged by midwives. She could describe quite clearly what it felt like to be ashamed of referring to heroin and crack use. I could nt help feel that she was the participant who had come through recovery, and was nursing s 6 week year old baby, and how was it the system made her feel like this. I couldn't help wondering more about her early beginnings and why she had ended up taking drugs at all. She seemed to have so many good resources around her. She is the only participant who followed up with more thoughts which she sent by text and then by email. She had I felt, good insight into what would help during pregnancy, and she could summarise it well. It was also possibly her confidence which helped her describe what she felt was lacking or what could help women like her
P5	I felt relief at this interview as I had been struggling so much to recruit. I found the interview so unusual as Janet seemed to display so much agency about how she wanted to live her life...including that she wanted to continue using heroin at the weekends, having taken care of her children by installing them with her mother as guardian. There were so many parts to her account which I felt needed to be talked about and were so unusual - including her struggle to bring her first child back from abroad where her partner had custody – because of suspected child abuse. She too referred to sexual abuse as a child and I again felt that we were not giving justice to her past. She reflected well on her past and gave many useful insights. In the following weeks her Keyworker asked me about her – as he had just taken her on, and felt he didn't get her. I replied that I could not talk about the interview…but that I felt that she had developed agency as to how she wanted to lead her life, but that this included continued use. It made me think about what agency meant; did it also allow for self-harm..? Was agency a term we used when we agreed with behaviour? She could describe how she knew that she did not meet other people's expectations. I felt curious and a bit conflicted about he,r as I felt that she was a good mother, in spite of the continued substance use.

9.1.20 Appendix T: Coding Analysis - Questions To Develop My Analytical Sensibility

Questions to develop my Analytical Sensibility during the familiarisation phase	
	What is my research question? Am I looking for data points at key stages of the journey? Why am I doing that? Look for data points on OST, therapy and recovery? How did they experience the complexity I refer to? Or am I just looking for it? Why might the women be making sense of things in this way (and not in another way?) Why are their experiences so different? What is the intersectional lens I need to look through? What assumptions do the women make in describing the world? What assumptions do the women make about their healthcare? Why might I be reacting to the data in this way? What is my theoretical framework? Am I analysing the data inductively or deductively? Am I coding semantic or deductively? Am I coding semantic or latent meaning or both? What is my research question? What are my assumptions about the topic? Am I expecting their accounts to be mainly full of stigma and judgement?

9.1.21 Appendix U: Transcript Extract of Draft Notes and Draft Development of Codes

TRANSCRIPT P4 DRAFT CODING NOTES

IRAS ID 322110
Confidential – Research Materials

		My Notes /Questions	Notes on larger data set items	Codes
R:	Ok, that's great. So, um, I'm going to talk about your experiences and feelings when you first found out you were pregnant. How did that feel?			
P4:	Yeah, **I was excited! It was a bit of a shock at first, but I was excited. I was very happy, I always wanted children. I'd always struggled with my periods and that, so I thought I wouldn't be able to have them, so I was very happy**.	Relates non-pregnancy to doubt over periods – rather than user identity?	Early positive reaction to pregnancy	**JOY AND SURPRISE on DISCOVERING PREGNANCY**
R:	Yeah. And when you say you always wanted children, did you always sort of want to be a Mum?	Closed question; don't use.		
P4:	Yeah.			
R:	Um. And so, when you discovered you were pregnant, um, um, and you were also at that point, you were also taking Buprenorphine…did you, how did you decide about how to manage those two things together, being pregnant, and also going to the clinic to get the Burprenorphine.			
P4:	Um, well like I say, **when my partner went to the clinic, they said, it makes sense for both of us to get, to go on the script,** and I said to them that I'm pregnant. So, we did discuss with the Doctor we'd be working on what was safest for the baby , we did discuss, um, **you know, that I'd be on it for 3 months, and have the last 3 months of the pregnancy clean. I actually stopped taking the**	Substance using partner – also supported at the clinic. Female Psychiatrist. Did this help??	Relationship to SMS for both important Helpful relationship with addiction psychiatrist	**RE-ENGAGEMENT WITH OST** **USE OF INFORMATION**

	Buprenorphine myself, and they kept saying against their advice, um, because, my heroin wasn't heavy, I was on 6 ml of Buprenorphine. Yeah, so, um it was sort of supervised, but my chemist let me take it and go, and I took the last 3 tablets out and just took them in the last couple of days. So, I was completely clean from withdrawals.	Interesting behaviour''against their advice..''	Decision to do it alone without SMS …	**AGENCY TO STICK TO HER PLAN**
R:	And how did it feel? Was it difficult to do that?			
P4:	Um, I mean it was a bit of discomfort in terms of like sneezing, but nothing like cold turkey. **But I done that, as I felt it was a better choice for me, and I always said to the clinic**, I still want to engage. It's not that, you know, I'm not engaging, it's just how I felt. I know for me, it just felt better that way.	She is not the heaviest user in the group… She withdrew home to stop OST ..and clinic did not like it….	Family support; was very important at this time.	**TREATMENT OPTIONS SUPPORT AGENCY**
R:	No, I can see you ve been brilliantly engaged. And I think that's what everyone has felt. It's just really interesting how you've managed that yourself. Did you feel at the time, that those early meetings, did you feel that you got enough information about being pregnant and Buprenorphine? Did you feel it was good information and helpful?		seems surprised that I might think she doesn't have family support…	
P4:	I mean, I guess, it was…discussed what substance use could do to the unborn baby, and it was discussed that Buprenorphine is safer than methadone and stuff…err. **But the different doctors advise you differently. The one doctor I spoke to, we, sort of made up a plan of using Buprenorphine and the last 3 months clean, and then another Doctor I spoke to wanted me to, she even wanted me to stay on the medicine even after birth, um, you know, so** …	Sounds unsure how to respond. That' odd. Why?	Is choice helpful or unhelpful at this stage? Options to choose. Information and options develop agency?	**TREATMENT OPTIONS ARE CONFUSING**
R:	So, was that a bit confusing, to get two different bits of advice and have two different clinicians explaining two different plans?			
P4:	Possibly, yeah, yeah.			
R:	And how did you decide which one? Because it sounded to me as if you were quite clear about what you wanted to do.			

P4:	**Well yeah, because the plan of having the last 3 months clean, sounded better to me, because that meant that the unborn baby is clean as well, and he's not born with withdrawing** like that. So yeah…	Linda used the information to make a choice. Sense of choice about how she wanted to engage feels important. Being treated as an equal..?		**AGENCY TO MAKE DECISIONS**
R:	Can I ask you, because it's interesting, because one of the things, just so you understand, one of the things that has come in the interviews is that relationship and understanding between the use of methadone or buprenorphine, or suboxone, and experiences of managing that whilst pregnant,um, because it changes in women's understanding, did you get one set of advice from the clinic, and one set of advice from a GP? What bit of services were there…I'm just curious to know where those bits of advice came from.	Is this a leading question?	Happy at the discovery of pregnancy	**(DEVELOPING) AGENCY FOR TWO**
P4:	Both of those pieces of advice came from the clinic. I got to see two different Doctors on two different occasions, I can't remember why, I couldn't tell you now why. Oh no…..**They probably got me to see another Doctor, as, in the beginning my tests were still coming back positive. I wasn't using heroin, but there was still a bit…so they were coming back positive, so I think they just sort of wanted to re-assess…**.like..yeah..	Odd that the clinic would be giving out different treatment plans?? Was she aware of the link between tests and treatment options; did anyone explain this? Explanation for seeing 2 different doctors	Being given choices is important Made a plan with the doctor Confusion of advice between different doctors.	**UNCLEAR TESTING REGIME**
R:	And it was positive for heroin use, heroin and crack?			
P4:	Yeah.			
R:	OK. Um, well it sounds as if you've done really well in that phase to manage both things. You know being pregnant and managing to manage down the heroin use, as well as the …so that's really great, well done. Because it is hard, it is a lot to think about.			
P4:	Yeah, yeah.			
R:	Can I ask you…so when you think about using substances and now being a mum, has it changed your views about substance use?			**DEVELOPMENT OF INSIGHT// CHANGE IN INTERNAL PROCESSES**
P4:	Yeah. **I was actually thinking about it the other night. I was thinking about the way I was and the way I am now.** Imagine me going off now and like getting, probably not the heroin, but like			

	even crack or something. ..like waiting 'til the evening when the baby is asleep and having a cheeky one. And I sort of I thought…about how the drug made me feel like anxious. **And I thought, I wouldn't really want to feel like that around the baby, if she starts crying…I would not be able to deal with her, and I thought, I would, not want to be around her.** <u>The things I've learnt being with the service about the particles</u>. I thought about how the drug used to make me feel, and I wouldn't want to feel anxious you know, while I am being a Mum and stuff….so.. Yeah, definitely. **Before I think it was a bit like…before I didn't have responsibility, so it was just, um, you do it to yourself you know…kind of… so it was something…self-inflicted.**	Reflecting on previous identity as user and now with a baby Self-harm recognition? Seems to recall well the information well… What are particles?	….	**AGENCY/RESPONSIBILITY FOR HER PLUS BABY** **DEVELOPMENT OF INSIGHT/REFLECTION**
R:	You mentioned something about the particles around the baby, what did you mean by that?			
P4:	Just like getting the gear out, it gets into their system, you know, it all gets passed on to them, you know, so…			
R:	Yeah. And did you get information about that? Was that..?		Shift towards understanding of self and baby	
P4:	Yeah, that was through social services…**because they said, you know, there might be some use, as you are still at early days whatever, and they just want you to be doing it safely…they just taught us about how to keep her locked away safely, and to wipe down the gear**, so, yeah, they gave us that information.			**INFORMATION IS RETAINED AND IS HELPFUL**
R:	Yeah. Yeah. And did you….um..sorry – were you going to say something?	Recalling how the crack impacts the baby….	Social services advice sounds as if they are seeking to understand and support	**NO JUDGEMENTAL ADVICE// ADVICE GIVEN (WITH NO JUDGEMENT**
P4:	No… **it's just that I haven't been using…but it's just that they were saying, we expect that there might be.**			
R:	So, they were just telling you how to use, if you were going to do it…how to do it safely…And do you feel, how do you feel about the feelings about being a mother…? It sounds as if you're really happy and you are really settling into it…	Positive recall of social services Linda has recalled and used info well, and doesn't feel /sound defensive about it….	Definite shift in thinking about impact on baby	

P4:	**Yeah, I really am, I'm really enjoying motherhood. To be honest, I'm actually quite surprised at myself**…as I thought I'd be a little bit more nervous, and you know frightened and not know what to do…**but I kind of feel I've really kind of like….I can't find the right words…..sailed into it, if you like.**	Contrasting feelings of self doubt and sailing into it….	Information about crack from social services	**EVOLVING MOTHERHOOD IDENTITY** **DISCOVERING OF SELF**
R:	Yeah.	Feels natural		
P4:	Its kind of happening naturally and I'm really enjoying it..			
R:	Yeah, that's great. You always sound really relaxed whenever Ive spoken to you since before Christmas. And did you tell friends and family about your pregnancy.		Adapting to motherhood and enjoying it	
P4:	Yeah. Yeah. **I told my Mum straightway I think when I found out I was pregnant. And she just, we discussed what I'm going do, and my Mum always spoke about children, and she's been waiting for children.** And I said yeah, I'm going to have it…..Whatever…decides, I'm doing it for me…	Family communication is important		**RELFECTION ON ADVICE** **SHARING NEWS WITH FAMILY IS IMPORTANT**
R:	And did you feel that they were supportive and helpful?			**FAMILY ROLES BEING FULFILLED**
P4:	Yeah, yeah	What does this mean – for me?		
R:	Um, was there anything, up to the point of being, during the period of being pregnant, and managing the Burprenorphine….was there anything you feel that would have helped you…looking back at it…was there anything you feel would have helped you more?		Involvement of family….	
P4:	I don't know, um, I just like, I just think, I don't know, um, I dunno, **it's really down to the individual person, how much they want it and how much effort they put in…it's about will-power//, I think it's down to individual person, and the tools given by the clinic**. The, the excuse is that that you re withdrawing, so you've been given a medication…and that's stopping you withdrawing, so you shouldn't be using, so I think it's down to individual…**it's down to individual, and if they are struggling and if they reach out…then the help is there.** Um..	Interesting reflections on self and will power, personal responsibility. It makes me wonder why not before.		**DEVELOPMENT OF RESPONSIBILITY** **REFLECTION ON PERSONAL RESPONSIBILITY**

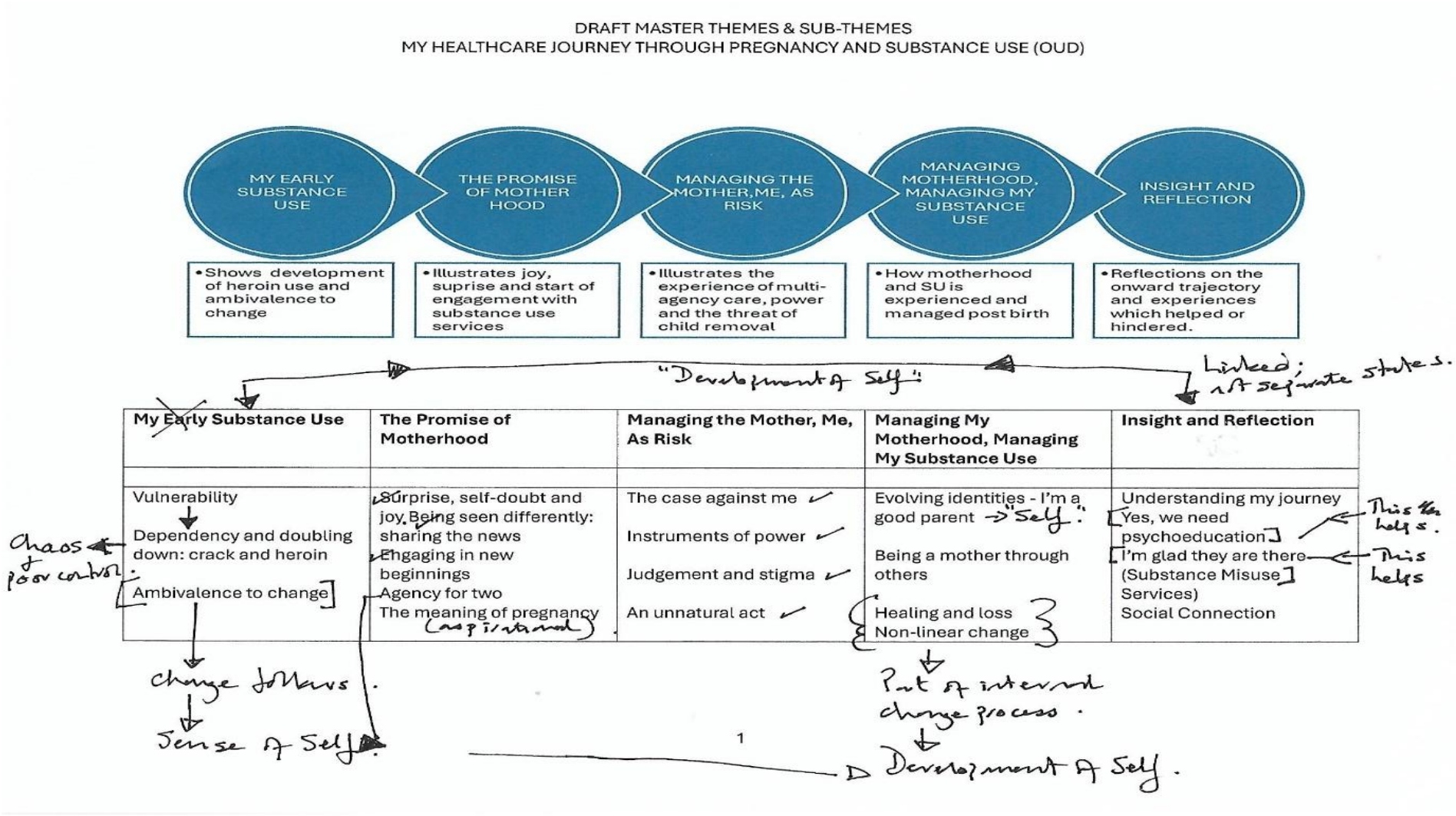
R:	And you mentioned tools by the clinic, were there tools which you found particularly helpful?			**RELATIONSHIP WITH SMS IS IMPORTANT/ PRESENCE OF SMS HELP IS IMPORTANT**
P4:	**I think just having the services in general, that you can go to, and that you can meet, or be given some sort of medication or some help, or able to see someone, that alone is helpful**. In other places, you might not get that…	Interesting comment about other places – likely her home country?	Difficulty of switching mid-wives; Embarrassing to explain all the time about the substance use.	
R:	Yeah.			
P4:	Its something to be grateful for.	Gratitude expression..		
R:	And in those actual meetings, and in all the interactions with, you know, the perinatal services or the clinic.. or social services, was there anything you found was not helpful…? Or you didn't understand, or you found not helpful….		Emotional about being accused/impact on baby…?	**REFLECTION ON PERSONAL RESPONSIBILITY**
P4:	Maybe things like seeing different mid-wives all the time…; um, I've had a couple when Ive gone in…and social services are involved and the midwife does a toxicology test, as well, when you go in, and I was having to go in and see different mid-wives all the time, and having to tell them…ok, can I have a toxicology test? And they are like ..**Why.? Then you have to explain yourself and, say you know, at the beginning there was substance use,** and like one midwife, and I think I was like 8 months pregnant then, um, and when they measured the baby and I had the scans and everything, and they ve actually said the baby is in the 90th percentile, that he's a quite big baby. **But every time I ve had a couple of appointments with her, and every time she felt the baby, she said the baby is small, the baby is small, and that my blood pressure is high and stuff…and I think I just used to get nervous now about seeing her.** When I see her, my blood pressure would go up. **And she'd send me to the hospital, and I went to the hospital a couple of times, to get it checked, and when I'm at the hospital, they'd say…your blood pressure is absolutely fine since you ve been here.** //So then she sent me for an extra scan to	Why wouldn't they know some of her case history??	Testing seen as a punishment…	**SENSE OF FELT SHAME (FROM PRIOR USE)** **TESTS CREATED ANXIETY** **TESTS EXPERIENCED AS JUDGEMENT**

	check the baby…and how he is growing and everything…and they said **the baby is fine, the baby is big, is growing. So, I just felt like you know...there might be a bit of judgement you know, just because Ive told her…there was a bit of use, especially maybe the type of drug, as they know what I'm taking. As when you hear it aloud, crack and heroin …sounds very dark,** and you know bad, you know, which it is, **and in black and white on paper, when it is written down I can imagine how it looks from the outside…so you know.** And in hospital, um, once the baby was born, she had slight jerky movements…**you know when like the muscles sort of jerk but the muscles aren't developed properly and one of the midwives was like….it could be because she's withdrawing; that made me emotional**, and I said it can't be, it can't be…I haven't been taking anything, and deep down in my heart I know I haven't been taking anything. But and yeah, just the whole process of testing the baby as well…they kept putting cotton wool in his um, nappy, and he kept missing the nappy and not going, **they kept coming in to test him and there just hands on him constantly. And, in the end they put a bag over him, so he can just wee in the bag. And I just thought…why not just do that in the first place?** You collected that and it was easy… and you collected it all in one go , and there was no need for all the faffing about…and coming to wake the baby up all the time, do you know what I mean?	Shame attached especially to heroin and crack…. Writing it down makes it worse… Is this NAS? Interesting that she thinks they did not do it correctly…	Sense of interference with the baby…. Gap in time between advice of what would happen and being in hospital.. Had been curious about what would happen….	**TESTS EXPERIENCED AS JUDGEMENT** **INTERNALISED SHAME** **EXPEREINCE OF GUILT – NAS?** **NAS TESTING - INTERFERENCE WITH MY BABY**
R:	Yeah. Did they explain to you why they were doing that?			
P4:	Yeah, at the hospital not so much, but I was so aware that that all that was going to happen; we'd discussed all that with the social services in the meetings and the midwives that have said, once the baby was born, this is what we are going to do…but that was quite before I gave birth, sometime before I gave birth. **So, I was aware that all that was going to happen. But in the hospital, the**			

	midwives did not (explain) not so much. I hadn't really thought about it until you asked that question. But only because I think I was aware; I knew that all that was going to happen. I was actually asking…you know, because they made me aware. **Also, in the meetings, I was asking…are you going….at the hospital are you guys going to keep me? Are you going to want to monitor the baby**. //XX **as in the meetings with the social services, there was so much of the damage I could have done to the baby whilst using….so you know like it might be born disabled**, or it might be born with you know this or that, they ll have to do these tests. **I had so much fear in me about that being true…um, I was constantly asking questions, are you going to test the baby are you going to do this or that**…?	Why would midwives not explain?	Fear from the information given…..	**TIMING OF INFORMATION IS IMPORANT** **DEVELOPMENT OF RESONSIBILITY FOR BABY OUTCOMES** **FEAR/AWARENESS OF NAS IMPACT ON FOETUS**
R:	It must have been really hard, even if you knew that was what they were going to do…to give birth, then see all of that going on, see all those processes going on, it must have been hard			**EMOTION REGULATION IMPORTANT**
P4:	It was in a way, **but I always tried to keep my spirits up and in a way, um, in the beginning // when I got the first social worker, we really didn't gel, there was something about her, we really didn't gel, //I just felt like she wasn't listening, when she came to the house, she wasn't taking any notes**. One time I spoke to her and told her about my partner, that we're in a relationship but we don't live together and stuff , but she just assumed that she asked all those questions, were we living together..der der der.. I need to see your bathroom, can I see your flat, and she has seen Ive got a bath, and she knows we re not living together. In the next meeting, she just said…oh,you guys are living together.Oh, XX you haven't got a bathroom, you're going to XX for a shower, you guys are living together…and I thought…you ve just seen everything. **I felt like she was just not listening.** And then luckily, she went on leave for a month. So, then XX, my		Mood low? First social worker…did not gel. Senior social worker much better….. Inconsistencies in meetings…. Sensitivity to possibly being	**IMPORTANCE OF CONNECTION WITH THE PROFESSIONALS.** **LACK OF TRUST IN PROCESS** **PROCESSES ARE IMPORTANT / POWERFUL TOOLS**

current social worker, came in; she s a senior social worker , and then said, **I'm going to take notes, I hope you don't mind. And I was like please do – the last one didn't!// And we had all these inconsistencies when it came to the meetings, you know…so I said, please do, I'd prefer it if you do**! She said she would like to keep the case on, and I was like, I said I'd prefer it if she kept the case on…since then, I felt a lot better…because ..**one things I felt was that the process with my other social worker, was that all the processes felt like a punishment**. **Every time I had a meeting with her, I felt more anxious…more fearful, rather than feeling that they are there to help with XX. //With the new social worker, like she said to me, we don't want you to feel like it is punitive, like it's a punishment. So I said, thank you for saying that**. //**Because I was having nightmares and everything, I was dreaming about the social worker..I was dreaming about them in the hospital and coming to take the baby** or what the other midwife has said, or what the notes are. Because, I just felt like, there was no um consistency…and some of them felt just l like really cold.		judged incorrectly….? Processes with social worker were like a punishment….. Where as the new social worker said – its not a punishment….	**PROCESSES ARE IMPORTANT / POWERFUL TOOLS** **PROCESSES ARE ANXIETY PROVOKING** **PROCESS AS TOOL OF JUDGeMENT** **UNDERSTANDING ME AND MY JOURNEY** **PROCESSES PROVOKE TRAUMA RESPONSE (EG NIGHTMARES)**

9.1.22 Appendix T: Development of Themes



VIII. Section C: Publishable Paper. The Healthcare Journey of Women with Opioid Use Disorder

9.1.23 Introduction to Section C

This section includes the publishable paper based on the Doctoral research (section A). The paper is intended for publication in the journal, *Qualitative Health Research,* (QHR, SAGE). It is selected for its multidisciplinary scope and focus on qualitative research methods. The guideline for authors is set out in Appendix A.

9.1.24 Publishable Paper Title Page

Author Name: Susan Elkington

Affiliation: Department of Psychology,
Professional Doctorate in Counselling Psychology (DPsych)
City, University of London
Department of Psychology
School of Health and Psychological Sciences

Author contact information: [redacted]

Contribution list: Susan Elkington: Writing – original draft; conceptualization; Principal Investigator; design, methodology, data collection and analysis. Thesis academic supervision and review: Professor Carla Willig.

Acknowledgements: The author wish to thank all the participants who shared their views and experiences in interviews, to the NHS substance Misuse Clinics in the participating Trusts, to Dr Dent and Dr O'Ryan for their support in the field, to Professor Willig for Thesis Supervision.

Ethical Statement: *''My Healthcare Journey Through Pregnancy and Substance Use''. An Investigation of the Lived Experience of the Healthcare Journeys of Women with Opioid Use Disorder Who Become Pregnant''* received NHS Ethics Approval from the North-West Greater Manchester West Rec

REC reference:23/NW/0042 IRAS (Project ID: 322110)
All participants provided written informed consent prior to enrolment in the study.

Funding Statement: The author(s) received no financial support for the research, authorship, and/or publication of this article.

Conflict of Interest Statement: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

ORCID: Susan Elkington https://orcid.org/0000-0002-9770-0550

9.1.25 Main Manuscript Abstract

This qualitative study investigated the lived experience of women who have used illicit opioids such as heroin who become pregnant, and their complex journey of peri-natal and post-natal healthcare. The study used Reflexive Thematic Analysis (RTA) to identify findings from the women's lived experiences to inform current practice and services aimed at supporting women with opioid use disorder (OUD) who become pregnant and have children. The study received NHS Ethics approval in April 2023. The cross-sectional study design was based on interviews with a single cohort of women between 24 weeks pregnant and eight years post birth. Each participant (N=5) was engaged in opioid substitute therapy (OST), at the time of the interview, or had recently ceased OST and was interviewed once. Semi-structured interviews were conducted with five women and were transcribed verbatim by the author. Data were analysed using Reflexive Thematic Analysis (RTA). The findings suggest that pregnancy and the promise of motherhood represent a pathway of potential change and recovery for the women, yet the women's feelings of stigma and experiences of being objectified as a risk in multi-agency health care serve to undermine the women's nascent recovery and sense of self. Clinical implications include repositioning in multi-agency health care, providing the women with more information about multi-agency healthcare, a greater role for NHS Substance Misuse Services to which the women displayed high levels of attachment, stigma training incorporating motivational interviewing, and the use of mid-wives trained in substance misuse.

Key words: Pregnancy; Pregnant; Motherhood; Opioid Use Disorder; Illicit Opioids; Peri & Post Natal.

9.1.26 Introduction

This qualitative research focusses on women who are diagnosed with opioid use disorder (OUD) and who are amongst the most marginalised people in UK today. OUD is a diagnostic term used to describe a chronic condition in which individuals using opioids become dependent (APA, 2013). The physiological and psychological dependence associated with opioid tolerance requires increased quantities to attain the desired effect. The dependence results in a range of difficult symptoms including withdrawal symptoms if the opioids are withdrawn or reduced (APA, 2013; Dydyk et al., 2024).

Women are relative newcomers to substance use research and the development of treatment models and women using substances continues to be under reported (Meyer et al., 2019). The National Institute on Drug Abuse (NIDA) started reporting gender in 1995, with prior research focussed on men or animals and recommends a move including more women in research (NIDA, 2024). The UN reports that one in three people with a substance use disorder (SUD) is female, yet only one in five of people in treatment is a woman (UN, 2015). The roles of sex (hormones, anatomy, physiology, genetics) and gender (identity, social normal, relations, power) are understood to play very different roles on how substance use evolves, the social context and the impact on the life trajectory (NIDA, 2024). The term telescoping is often used to describe the more severe impacts of substance use on women. Biological factors include how women metabolise substances due to larger deposits of fat than men, the hormonal cycle, pregnancy and menopause (Peters et al., 2019).

Women who use illicit opioids are understood to start using heroin at a younger age than men, be influenced by opioid using partners, advance more rapidly to dependency, experience more cravings and suffer more medical, psychiatric and adverse consequences than men (Back et al., 2011; Brady & Lydiard, 2021). Issues of intimate partner violence (IPV), past and present histories of trauma, including sexual abuse, other aggravating health conditions and complex social needs are associated with more than 50% of women diagnosed with OUD (Moran-Santa & Brady, 2015).

Women who use class A drugs such as heroin run the risk of being considered to have deviated from societal norms (Terplan et al., 2015), and many have difficult histories of mental, physical illness, physical violence and sexual abuse (Gilchrist et al., 2019; Hammond & Chisolm, 2022). They may be considered to have broken UK law where heroin is categorized as a Class A drug under the UK Misuse of Drugs Act (1971). Experiences of

judgement and stigma are one of the most widely reported findings in qualitative studies with pregnant women and mothers using substances in UK, (Chandler at al., 2013) and the US (Bakos-Block et al., 2024), especially women using illicit opioids. These experiences stem from the pregnant mothers being defined and managed as the risk to the foetus (Stengel, 2014) and viewed as having deviated from accepted norms of motherhood (Radcliff, 2011).

UK has the highest rate of opioid use compared to EU countries. In Scotland, the percentage increase in the number of drug related deaths (DRD)s was greater for women (169%) than for men (60%) between 2012-2016 (Scottish Gov., 2018). The trend indicates that even though substance use disorders are more prevalent in men, this difference is narrowing over time. Data indicates that 4.2% of opiate users presenting to substance abuse clinics are pregnant, and 58% of females receiving substance abuse treatment are parents or lived with children (Public Health England, [PHE] 2019). Opioid and/or crack cocaine is associated with younger mothers, housing problems, trauma and domestic violence (Canfield et al., 2021).

The Department of Health (DoH, 2017) and the National Institute for Clinical Excellence (NICE, 2010) provide clinical guidelines for the treatment of pregnant mothers diagnosed with OUD. This includes the assessment and treatment of the opioid disorder, initiation of opioid substitution therapy (OST), specialised maternity care, the monitoring for neonatal abstinence syndrome (NAS), as well as psychosocial and onward social support. The disciplines of psychiatry, pharmacology, substance abuse, midwifery, obstetrics & gynaecology contribute to the guidelines defining these journeys resulting in a model of multi-agency clinical treatment for pregnant women with an OUD (Thomson et al., 2021). A UK wide scoping review (Gilmour et al., 2024), which mapped 111 clinical guidelines for women who use substances, including illicit, and prescribed opioids, identified significant gaps in UK's current guidelines, especially concerning the provision of care for women whose babies are removed, a lack of patient or public involvement in the creation of guidelines, and in some cases, a lack of evidence underpinning the guidelines, including inconsistencies on testing protocols during pregnancy and the observations of newborns for NAS.

Women using illicit heroin are under researched in the UK and represent an important research field. The experience of stigma and the fear of legal action can make it difficult to reach drug using populations in research, making it complex to understand whether well intentioned healthcare guidelines are working.

Background to the Study

This qualitative study focuses intentionally on women who have used illicit heroin, rather than on other illicit substances widely used in the UK such as cocaine, ketamine, benzodiazepines. The participants are diagnosed with OUD and are registered NHS service users in a UK healthcare process which seeks to care for both the mother and infant. The combination of pregnancy and OUD make the experience of pregnancy and the promise of motherhood extremely challenging to manage or attain for the women. Societal norms place substance use as a deviance and motherhood as an ideal, and the women face the challenge of managing both. The study investigates the lived experience of women with OUD, to understand the complex journey of peri-natal and post-natal healthcare in order to contribute towards clinicians' understanding of the treatment model and to promote better outcomes for mother and infant.

9.1.27 Methodology

9.1.27.1 Research Design

The study design was cross sectional and sought to investigate the lived experience of twelve women, diagnosed with OUD who are between >24 weeks pregnant and eight years post birth. The ontological and epistemological approach taken was critical realism and phenomenological. Critical realism is widely used in healthcare research for its overt recognition of complex healthcare models, health inequalities and interventions and what is working in specific contexts (Scambler & Scambler, 2015; Williams et al., 2017). Reflective Thematic Analysis (RTA) (Braun & Clarke, 2022) was adopted as the analytical method to identify patterns and differences in the lived experience.

Ethical Considerations

There is physiological and ethical complexity in recruiting pregnant women with OUD who are vulnerable and simultaneously navigating pregnancy, motherhood and substance use. Major considerations were the safety of the foetus, the psychological and physical wellbeing of the woman pre- and post-birth and the rights to anonymity in perpetuity, of the unborn foetus, the future child, and any existing children. Safety, anonymity and data management procedures were embedded and carefully managed (Appendix B&C). There are ethical issues where there is an imbalance of power between the researcher and participant. Steps were taken to embed procedures in research on a population of women who are impacted by the intersections of gender, economic status, substance misuse, ethnicity and idealised models of motherhood. I ensured my role as a Counselling Psychology Trainee was clear, and that participation would not change treatment for them.

The study received Ethical approval from NHS REC reference: 23/NW/0042 IRAS (Project ID: 322110)

9.1.28 Research Procedures and Materials

Setting

The study recruited five women (N=5) from NHS Substance Misuse Services (SMS) in two adjoining north London NHS Trusts who fulfilled the inclusion criteria (Table 1).

Table 1 : Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Female and/or capable of pregnancy	Comorbid with a serious mental health condition e.g., bipolar disorder or Psychosis
Age 18+ years old	
Pregnant at ≥24 weeks to 8 years post birth	
Diagnosis of OUD[1] (illicit)	Other forms of sole substance abuse e.g., alcohol
Initiated OST[2] or recently completed OST	Not initiated on OST
Sufficient understanding of English in order to be able to engage in the study	Lack of child custody not an exclusion criterion
Custody of children is not an inclusion criterion (i.e., mothers may have babies in care or be subject to care proceedings)	

Participants, Sampling and Recruitment

Purposeful sampling was adopted as a means to identify and recruit cases which were representative of the healthcare journey i.e. across a time frame, which captured heterogeneity amongst the women, and allowed the consideration of theory, difference and similarities to be studied. Three methods of recruitment were used to identify participants: via a poster placed in reception areas (Appendix D); the use of clinical records; discussions with the clinical team.

Data collection and procedure

Five women were interviewed for durations ranging from twenty-six minutes to fifty-six minutes, with a mean duration of thirty eight minutes and were held on NHS sites. The first questionnaire aimed to identify demographic data including age of first drug use and the second stage was designed to explore the lived experience of the health care journey through substance use, pregnancy and motherhood using a topic guide. The women were asked to keep a short journal in the following 3 weeks to capture any other thoughts they had following the interview. The women received a £25 voucher for participation.

The Participants

Five women (N=5) were interviewed, aged 27 years to 45 years old. All women had given birth, and the age of children ranged from 6 weeks to 8 years old. Two women had more than one child, with the older children ranging from 13 years old to 27 years old. All women had started using heroin between the ages of 15 to 21 years old. Four of the women gave birth within the Trusts where recruitment had taken place, and one of them had her baby in another region of England and moved to London during the year following birth. All participants have been assigned pseudonyms, all locations de-identified and any locations including the clinics given a generic number in the analysis (Table 3).

Consent

All women signed two Consent forms at the start of the interview and retained one copy for themselves.

Table 2: Participant Descriptive Data

Participant	P1	P2	P3	P4	P5
Pseudonym	Megan	Elizabeth	Gail	Linda	Janet
Ethnicity	White European	White British	Ethnic British	White European	Black British
Age	38	27	45	30	43
Age of first substance use	16	18	15	16	17
Age of first heroin use	16	21	15	20	17
Opioid Substitution Therapy	Methadone	Subutex, Buvidal	Methadone	Methadone, Buprenorphine	Methadone
No of children	1	1	4	1	2
Age of child/youngest child	36 months	24 months	8 years old	6 weeks	8 years old
Parental responsibility / Access/Arrangements	Yes	No. Has access rights. Kinship arrangements	No. Has access through Contact centre. Foster care	Yes	No. Has access rights. Kinship arrangements
Attended Tier 4 Service : Mother and Baby Unit or Rehab	No	Yes; Mother and Baby Unit	Yes; rehab	No	Yes; Mother and Baby Unit

9.1.28.1 Data analysis

Data was analysed thematically following Braun and Clarke's (2022) guidelines for six phases of familiarisation, coding, generating initial themes, reviewing themes, defining and naming themes and writing results. The audio was transcribed verbatim, and familiarisation was undertaken through listening to the audio and repeated readings of the transcripts. An analytical framework was used to look at both semantic and latent meanings to develop my own analytical sensibility (Braun & Clarke, 2013). Analysis aimed to explore patterns in the data including both common and atypical views, using a primarily inductive approach, with some deductive elements to answer specific research questions (such as the experience of stigma).

9.1.28.2 Data Management

The collection of identifiable data was kept to a minimum, with interview materials assigned a study ID, unrelated to personal information (Appendix B). Data management was carefully considered on site, within NHS premises, and in a second stage, in relation to the University who acted as Data Custodian for the study.

9.1.28.3 Patient and Public Involvement (PPI)

I attended a women's recovery group to contribute to the development of the interview topic guide. The rich and lively discussion about their own experiences of addiction, recovery and motherhood helped inform the topic guide and validated findings.

9.1.28.4 Quality and Generalisability

The ontological-epistemological design framework of the study aimed to provide a coherent methodology to support the research question to produce insights and findings which are useful in a clinical setting. A key measure of quality is whether the study helps facilitate the phenomenon of interest and 'productive action' (Madill, 2000 et al., p.13). I allowed four to six weeks per recording and found it helpful to immerse myself on consecutive days. I adopted some methodological features to support transferability. I have set out to investigate unique and individual lived experience and identify patterns which may relate or differ to the cohort as a whole.

9.1.29 Positionality and Reflexivity

. My understanding of the importance of boundaries developed through the research process. I feel deeply compassionate for the women in my study, all of whom started using

heroin as teenagers. I reflected on the power imbalance between myself, and my participants and I tried never to lose sight of the implications of this for a vulnerable and under researched population, with whom I share very little in terms of lived experience, education, economics and privilege. I thought about the implications of my dual role as researcher and clinician, and the importance of keeping boundaries between these two roles. I reflected on our differences and what contributed towards the power imbalance between my participants and myself. I am not a member of this group, and I am technically an outsider researcher. The intersubjectivity between the participants and myself felt as if it was at the centre of my reflexivity, and I have also reflected on my Social Graaces (Burhnam, 2018; Finlay, 2002) including the age difference which may confer an authority or a maternal role on to me.

9.1.30 Methodological Challenges

These related to recruitment. No women responded to the poster directly and it was difficult to achieve standout on clinic notice boards. I made amendments to the inclusion criteria to allow for women with older children, up to eight years old post birth whereas the original design included women up to 24 months post birth. Only one participant returned any secondary data.

10 Qualitative Findings.

10.1.1 Introduction to Themes and Sub-themes

The analysis generated four main themes which are presented as an overview in Figure 2. Each main theme has sub-themes which are presented in Table 3, followed by a narrative account with illustrative samples of the data.

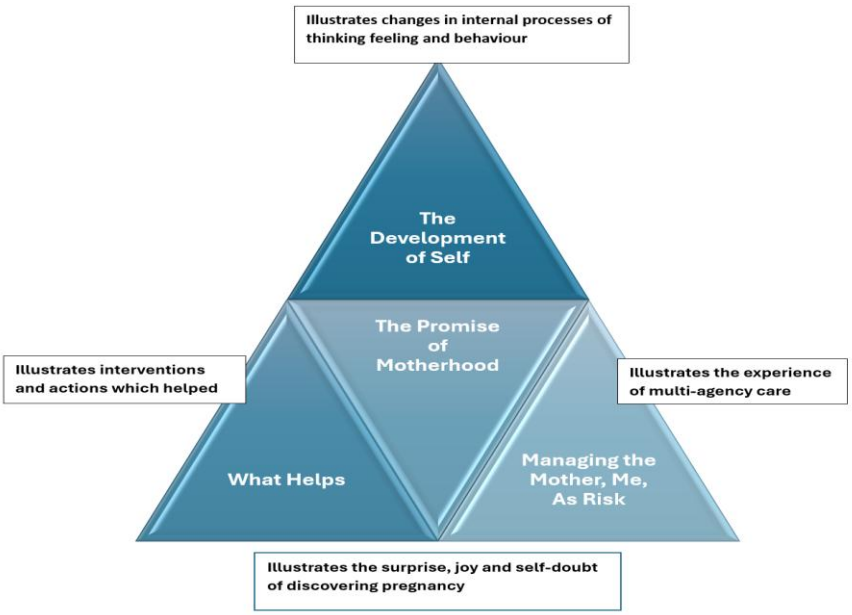


Figure 2: Overview of Main Themes

The analysis shows a journey of immense personal challenge, at the end of which two women have custody of their children, two have kinship arrangements where the women's parents have legal guardianship, and one woman has her youngest two children in foster care. The women described many aspects of their healthcare experiences from pregnancy to motherhood as challenging.

The first theme, ***The Promise of Motherhood***, seeks to illustrate early experiences of surprise and joy on discovering pregnancy and the sense of being viewed differently by others. ***Managing the Mother, ME, as Risk*** illustrates the difficult experiences of the women in multi-agency healthcare through pregnancy and the programme of tests and monitoring, resulting in feelings of fear and shame. The third theme, ***What Helps*** illustrates the varied ways the women felt supported, or not helped by structures, processes and interactions. The fourth theme ***The Development of Self*** shows the women starting to think

about themselves differently and moving from one of self -harm to one of motivation to re-engage in OST, to change substance use patterns on behalf of the baby and themselves. Table 3 illustrates each main theme with its sub-themes

Table 3: Themes and Sub-Themes

	Themes	Sub-Themes
1	**The Promise of Motherhood**	• Joy and self-doubt • Being seen differently: sharing the news • Engaging in new beginnings • Meanings of pregnancy
2	**Managing the Mother, Me, as Risk**	• Instruments of power • The case against me • Judgement and stigma • An unnatural act: child removal
3	**What Helps**	• Understanding my journey • Yes, to information • I'm glad they are there: Substance Misuse Services • Loss & Healing
4	**The Development of Self**	• Ambivalence to engagement • Agency for two • Non-linear recovery paths • Evolving identities

10.1.2 Theme 1: The Promise of Motherhood

All women expressed positive emotions on discovering they were pregnant, describing their pregnancies as unexpected and unplanned, with at least two women expressing doubt that they could get pregnant.

10.1.2.1 Joy and Self-Doubt

Gail had four children and had started using heroin at the age of fifteen. She describes her feelings on discovery of being pregnant with her third child at the age of 34 years old. She was in a relationship and had described the pregnancy as something which both herself and her partner wanted.

''I was so happy. The first time I found out I was pregnant…I went straight to the hospital… I just wanted them to confirm (it) with me. And… they took me for a scan. And they done the pregnancy shot, and they said, yeah, yeah, you' re pregnant.''[Gail]

Megan had started using heroin when she was sixteen years old. Megan's disbelief in her own fertility was marked by self-doubt in her potential role as a mother. The lack of self-belief was related directly to the way she was living. Megan found it difficult to imagine a life very different from the one she was living, or that she could ever become a mother, even though she had a concept of a 'good mom'.

''I was in love with the children, but because of my world…I never think I'm gonna be a good mom…I was needing…you know the heroin... I never done something bad to someone else. I was doing something bad to myself like.'' [Megan]

10.1.2.2 Being Seen Differently: Sharing the News

All women described how they shared the discovery of pregnancy with close family members, especially mothers and sisters. Communicating pregnancy news with family members illustrates not only the importance of bonding with family members but how pregnancy and the arrival of a baby allows family members to fulfil future and expected roles as grandmothers, uncles or aunts. The women's accounts suggested that the positive interactions contributed to how the women started to view themselves.

Linda's account of sharing the news with her mother suggests she was fulfilling a normative role as daughter, and that she is meeting an expectation to have children. This bonding between Linda and mother is likely to have contributed to Linda's commitment to move forward with the pregnancy and to step into a new role.

''I told my Mum straightway I think when I found out I was pregnant. And …we discussed what I'm going do, and my Mum always spoke about children, and she's been waiting for children. And I said yeah, I'm going to have it…'' [Linda]

Identity theory suggests that interactions with others would help confirm or deny the development of a new identity (Stets & Serpe, 2013). These early positive affirmations with family members and experiences of being seen differently may have helped both women think about themselves differently, with a nascent identity as a mother. They may have also helped them forego their long-held attachment to being a substance user.

10.1.2.3 Engaging In New Beginnings

The theme of ***Engaging in New Beginnings*** aims to provide context of the women's journeys. All the women described embedded use over long periods ranging from six to twenty five years. The women described rapid progression to heroin use, the use of crack and heroin together, experiences of dependency, and experiences of spiralling out of control. The women were all aged between fifteen to twenty one years old when the heroin use started; they showed a lack of awareness over the risks, and development of their dependency.

Elizabeth described the speed at which she felt she was dependent on heroin, and the need to combine crack and heroin.

''It just completely spiralled out of control….you just completely lose track of time, you lose who you are, you lose everything. You just think about that drug. And then the crack cocaine and heroin goes hand in hand.. most people can't take the crack without taking the heroin…the heroin addiction started… straight, straight away, to be honest, about two days in from starting to take crack.'' [Elizabeth]

Heroin and crack have different effects on the brain's reward circuit, with contrasting effects of euphoria and relaxation versus intense stimulation to feeling distressed. The rapid use of both drugs by Elizabeth would likely serve to balance the contrasting effects of each drug. Elizabeth made contact with an NHS substance misuse service and described the support as helpful.

Prior to discovering pregnancy, Gail, Linda, Janet and Megan had been in contact with services, and all four of them intermittently combined OST with heroin and crack. Janet did not express any doubt or sense of hesitancy about renewing contact with the substance misuse service which she previously knew.

'' I don't think I was registered in a clinic at the time; then after I found out I was pregnant, I went to Clinic 2, to get on a script. They were helpful. I was with a lady called Sally; she was a really good Keyworker at the time. ..Once I got back on my script… I was actually trying.'' [Janet]

The readiness to reach out to SMS clinics at an early stage of pregnancy is notable in the women's journeys.

10.1.2.4 Meanings of Pregnancy

The meaning of pregnancy varied for the five women, and there is a pattern of difference in the motivations for the pregnancy and what motherhood might mean to each of them. In Elizabeth's account, she identified pregnancy as a reason not to be an addict, suggesting that the pregnancy was a means to end her addiction and shed this identity.

''I was in active addiction when I discovered I was pregnant… about two months in… I was happy because I saw it as a way out of my addiction. …Right! I have a reason now…not …to be a drug addict. This is my reason to give up drugs now.'' [Elizabeth].

Megan described a strong motivation to engage in training, enrolling herself in an online course, suggesting that pregnancy promoted thinking about the future, engagement in structure and an interest in personal development.

''The moment I find I'm pregnant, I signed myself as a student in a college, so …. in the time when I was pregnant… I was in college.'' [Megan]

In three cases, the meaning of pregnancy related to the relationship with the partner, two of who were substance users. The contribution of substance using or non-substance using romantic partners in their pregnancies and lives to positive outcomes for the women is mixed.

10.1.3 Theme 2: Managing the Mother, Me, As Risk

The Promise of Motherhood contrasts starkly with this theme. The women's initial early joy on becoming pregnant evolves into an experience of being managed as a risk to the developing foetus. Prior to pregnancy, all of the women were actively using heroin and crack, and their main NHS relationship was with their GP and the Substance Misuse Service. The women's pregnancy initiates a multi-agency health care model with different teams in the Trust, including perinatal services and social services.

10.1.3.1 Instruments of power

The multi-agency healthcare processes were largely experienced as negative and frightening by the women. These include inter-agency information sharing, meetings, reports, and tests. These facilitate the functioning of multi-agency protocols and procedures and are embedded within structures within the healthcare system and women's journey.

Agencies are obliged to make referrals where a child safeguarding case exists. Linda described how she learned about the involvement of other services and professionals. The

sharing of information between clinical teams, agencies and services was experienced as frightening by Linda and she withdrew from contact from services.

''The first time I knew of social services involvement was when my social worker called and introduced herself …she said that my midwife would've told me that she's passing the matter on to the social services. I explained to her that I wasn't aware, no one had told me anything. I also spoke to my key worker at Clinic 2 and… said to her that I feel the midwife was too quick to report me.. as getting clean is a process; my key worker said 'oh I've reported you too'…I'm not sure whether legally they were meant to tell me or not, but it was quite a shock and scary. It made me afraid to work with social services.'' [Linda]

Linda had discussed a plan for managing OST during pregnancy with the Addiction Psychiatrist in a constructive way. The reporting of the midwife stemmed from Linda continuing to show unclear tests, after she had ceased to use any substances which is not unusual. The discovery that a new agency had become involved, had her mobile number and had the right to contact her was experienced as scary. Linda's reaction was to withdraw from contact.

In Elizabeth's case, she described meetings with her social worker as not reflecting her understanding of what had happened in the meetings in follow up letters and reports

''She befriended me… pretended that she was my friend by asking certain questions and saying, *oh..I can help you with this, I can help you with that*. And then a week later, you'd get a report about our meeting. And it says a completely different thing to what actually happened in our meeting.''*[Elizabeth]*

Elizabeth felt the written communication did not reflect the friendly tone which existed at the meetings and this damaged her trust in the process. Elizabeth expressed the view that she would record all meetings if presented with the same situation.

The process of NAS testing was experienced as extremely difficult by several women, with the feeling of the baby being interfered with, or the tests being withheld from the mother who felt she was not to be trusted. Gail described her baby being taken away for tests, and felt the tests were being deliberately hidden from her.

''Furthermore, you took my daughter under the pretence that she had a cough, and I found this withdrawal sheet under her mattress.. with zero, zero, zero on it though…''

[Gail]

These processes of inter-agency referral and information sharing, reports, and tests were experienced as threating by the women. There were many more examples to illustrate this point.

10.1.3.2 The Case Against Me.

The women all expressed feelings that they were expected to fail and were not trusted. Elizabeth experienced it as a case being mounted against her as an unfit mother, which would result in child removal.

''As soon as I met my social worker, she wasn't there to help me at all. She was there to build a case… straight away. She weren't there to help me. All she was doing was building the case straight away…the social worker would just say to me up front, blank, 'I'm taking your baby, we know you're not going to be able to do it, your baby's getting taken. So, you might as well just give up now'. You know what I mean?'' [Elizabeth].

Janet described her engagement with multi-agency care as being under attack. She also felt that what she was saying was not being represented accurately, and that she was being set up to fail. Failure would result in child removal.

''And they were trying to make me do all these different things, that were like difficult, whilst trying to be on a script, going to my appointments at hospital, being pregnant for the first time, not expecting to be pregnant, not being in a stable relationship, it was just a lot. They were trying to get me to engage with all these different agencies. I just felt like I was being attacked. And they were going to take away my child, my first child, without giving me a chance…whatever I was telling them, it was kind of like getting changed. I felt like they were waiting for me to fail basically… I still feel like that.'' [Janet]

She felt the multiple interactions with different social workers were assigned meanings in unfamiliar contexts and were not being reported accurately.

10.1.3.3 Judgement and stigma

All the women gave examples of feeling stigmatised by being pregnant and a mother, with a diagnosis of OUD. The experiences of stigma varied, as to whether it stemmed directly from an interaction with a healthcare worker, or whether it stemmed from an internalised sense of shame. Elizabeth was angry throughout her description of her time in a MBU, where she described feeling very ill and being 'forced off' OST within three weeks

following birth. She felt both the social worker and midwife told her directly that she was being written off by them, would not get 'clean' or retain custody of her child.

''Where the social worker would just say to me up front, blank, 'I'm taking your baby, we know you're not going to be able to do it, your baby's getting taken. So, you might as well just give up now'. You know what I mean?'' [Elizabeth][2]

[2][The interaction between Elizabeth, the midwife and social worker did not take place in the participating Trusts of this study and Elizabeth's place in the MBU was not commissioned by them].

The women were required to attend routine appointments with perinatal services during pregnancy. Linda described difficulties in meetings with perinatal services where she would routinely meet a new midwife and would need to explain her particular circumstances, unique to her. In Linda's case she managed to come off all illicit drugs as well as buprenorphine under the guidance of the Addiction Psychiatrist during the pregnancy. She was required to ask mid-wives for toxicology tests and explain her personal history of substance use.

''…Can I have a toxicology test? Then you have to explain yourself and, say… at the beginning there was substance use. Like one midwife... when I saw her, my blood pressure would go up... So, then she sent me for an extra scan to check the baby…and they said the baby is fine … I just felt like ...there might be a bit of judgement … just because I've told her…there was a bit of use, especially maybe the type of drug.''[Linda]

Linda displayed an internalised sense of shame, not only because of substance use, but because of the heroin and crack use at the start of pregnancy.

Janet internalised societal judgements and a sense of disappointment and futility, as to how she has ended up as the person she also judges negatively.

''Well, I didn't want to be using drugs…nobody wants to be a drug user and having a baby, and I always, I remember, I used to be judging people who were like pregnant and using drugs…I never thought I'd end up being that person.''[Janet]

Stigma theory in healthcare settings is defined by Scambler (2009) as a social process whereby a person with a health condition or problem experiences rejection, blame or

devaluation, or some form of discriminatory and adverse judgement or behaviour. There were many examples in the accounts.

10.1.3.4 An unnatural act

Four women described the experience or threat of child removal. Three of the five women described having had their babies removed, with two women using parents as legal guardians and one having her two youngest children placed in foster care, a year after birth. Elizabeth compares the feelings to what a wild animal might feel like, when a baby is removed. The women did not seem to understand the conditions under which it might happen. Janet appeared to have little understanding that she would not leave hospital with her baby. She described returning home without the baby, and family and friends asking her where the baby was

"At the time, I didn't think they were just going to be able to just take my daughter away like that. ..after they took my daughter away, they told me to express some milk... I had all the baby stuff. I went home to my house, I had all the cot and everything there, so that was really traumatic.'' [Janet].

The post-birth period and child removal is particularly difficult and associated with relapse. Janet went on to describe how she relapsed , struggling to cope with the loss of her child, and the start of unfamiliar court proceedings.

10.1.4 Theme 3: What Helps

All the women gave examples of what they felt would have helped them and these relate to different stages of their journeys and interactions with different departments.

10.1.4.1 Understanding my journey

Janet had a positive experience of spending time in a mother and baby unit (MBU) with her second baby. The absence of threat from baby removal was highly valued, and she felt as if she was better known and understood by social services and supported appropriately. Not all experiences with MBU and Tier 4^2 rehabilitation centres were positive.

Linda provided contrasting examples of her experiences of switching between mid-wives, resulting in a lack of consistency and different reactions to her substance use history. Linda valued the recognition and encouragement given to her by some mid-wives who had

experience of substance use. Linda had to explain to each midwife her substance use history, with the risk of judgement.

''It would make sense, to have one midwife in general assigned to your case…or at least if they update each other on your case… I just felt there was no consistency…and some of them felt … really cold..A couple of midwives.. said, 'you should be really proud of yourself, not a lot of women manage to get through this'. I just think as it makes sense to have some kind of team, or a midwife assigned to you who can see your progress, that you haven't got to explain yourself constantly and be judged. And that they are skilled in that area, and they understand the substance use, the struggles and the journey.'' [Linda]

Linda points to the struggles and the journey that she has taken and wants that to be recognised by mid-wives. She calls for mid-wives to recognise the progress being made, and be '***skilled in that area***', as if it requires training.

10.1.4.2 Yes to Information

There was a variation in what information the women received on the impact of heroin use on the developing foetus. In Elizabeth's case, she described learning about a syndrome called Alcohol Foetal Syndrome (AFS) in the mother and baby unit she spent time in, in another Trust. It is curious that Elizabeth refers to AFS which is specific to babies exposed to alcohol.

..''In the rehab, I've actually learned of something called AFS -alcohol, foetal syndrome - where your baby can actually have deformities from taking drugs and drinking alcohol. But no, no one told me anything like that! There was no information around that at all''. [Elizabeth]

This contrasts with Linda who provides an interesting description about information provided by social services about the use of crack with an infant present.

''…The things I've learnt being with the service about the particles…Just like getting the gear out, it gets into their system… it all gets passed on to them…that [information] was through social services…because they said… there might be some use, as you are still at early days. They just want you to be doing it safely…they just taught us about how to keep her locked away safely, and to wipe down the gear..''[Linda]

Linda's account suggests she found the information useful and that it was given in a non-judgemental way.

10.1.4.3 I'm Glad They Are There: NHS Substance Misuse Services

There were consistent expressions of gratefulness for the presence of NHS SMS services. This related to periods pre-pregnancy, during pregnancy and post pregnancy, suggesting that the relationship the women had with the NHS substance misuse services lasted many years and was valued. Linda expressed gratitude for the presence of substance misuse services, for being able to see someone or get medication, making comparisons with other places.

''I think just having the services in general, that you can go to, and that you can meet, or be given some sort of medication or some help, or able to see someone, that alone is helpful.In other places, you might not get that… It's something to be grateful for.''[Linda]

Elizabeth's description suggested she valued the relationship with the staff at the NHS substance misuse service she contacted, on discovering pregnancy and felt cared for.

''They were just more supportive …and more like… caring. And they were there for you more, especially being pregnant, they just helped you more like and… told you like, things will be okay''. [Elizabeth]

The women used first names of their keyworker in the NHS Substance Misuse Services suggesting there was a close and trusting relationship. There is a singular lack of references to first names in all accounts with any service outside of the substance misuse services. The relationship with the substance misuse services seemed to form a key part of the fabric of the women's lives.

10.1.4.4 Loss and Healing

For the women who had their children removed, there was an acute sense of loss, with an unclear legal process to face. These are acute moments of risk and relapse for mothers. Janet acknowledged that her recourse to comfort herself was to start using again.

''Obviously for me, my coping mechanism was to use, even though they tell you not, because you are trying to get your baby back. But going home to that environment, and everyone is like, where is the baby? And stuff like that…all the neighbours, your family and that. I had no one to talk to." [Janet].

For Elizabeth she expressed a sense of loss of her former life, with the relationship with social services experienced as a trauma, and the intensity of change required in rehab. She referenced a sense of loss of her former life and a lack of therapeutic support.

''Maybe if I had some support with my mental health…or maybe in the rehab, if I had had some support for my mental …but I was just coming off the street from XXX as a full blown addict… I've left a whole life behind… the trauma I had been through with social services…I wasn't doing well as I was missing my old life.'' [Elizabeth].

Elizabeth's parents took legal custody of her child, and she acknowledged that she needed to heal and continued recovery from relapse in the post birth period.

10.1.5 Theme 4: The Development of Self

The interviews show changes in how the women think and talk about themselves, and in their descriptions of thoughts, feelings and behaviours.

10.1.5.1 From Ambivalence to Engagement

Prior to pregnancy, all the women showed high levels of ambivalence to engage fully in recovery and continued to use crack and heroin, along with methadone. The reasons for this lack of engagement were not fully investigated in the interviews yet the women revealed that their ambivalence to OST stemmed from a lack of belief that methadone would work as a substitution for heroin and that factors maintaining use had not changed.

"I was 27-28, I start with the methadone… I was thinking.. it cannot help me to run from the heroin; I know, it's very bad to use them together…but I was still enjoying it.''[Megan]

The ambivalence to weave heroin use, with intermittent methadone scripts pervaded four women's accounts, suggesting that the initial contact with NHS substance misuse services was an important first step, but neither were the women committed to abstinence, or understood the risk and implications of combining methadone and heroin.

'' I'd been on and off of it; it wasn't a thing where I didn't want to be on a script, it is just that I hadn't bothered.'' [Janet]

The ambivalence to fully engage in recovery suggests that underlying reasons to maintain substance use had not been addressed.

10.1.5.2 Agency for two

There is a marked change in the women's thinking early in pregnancy as they start to show interest in how OST and heroin might impact the baby. Megan described a motivation and interest in wanting to understand the impact of methadone on the foetus and set out to gain more information from clinic 1 where she was registered.

''I have only one question that I ask people who were more informed. What should I do? Do I need to stop it now? Or what? ..So, they say we just need to keep you on it until the end of the pregnancy…because …I may go through that … but the baby doesn't understand what's going on, …they say better keep, better keep the methadone.'' [Megan]

All women described how they started to think and act on behalf of two, themselves and the foetus. Janet described an important shift in thinking about the going out to buy street drugs whilst pregnant. Janet's description points to self-disapproval of scoring drugs with her pregnant 'belly'.

'' I felt more relaxed, always not having to go out and score. Or trying to get money whilst being pregnant…or me using the street drugs whilst being pregnant as well, like going to score with my belly and all that kind of stuff, and so it was easier when I was on the methadone''.[Janet]

These changes suggest that women develop a sense of agency early in pregnancy to gain knowledge about OST extends to how it is impacting their infant, as well as themselves.

10.1.5.3 Non-linear recovery paths

There are distinct variations in the women's recovery paths in the post birth years. Linda and Megan described abstinence from substance use, with Megan continuing on a low dose of methadone (15 ml) from her regular clinic. Linda had a 6 week old baby, was abstinent and not taking OST at the point of the interview. Gail and Elizabeth had relapsed in the first year post birth, and Janet described continued heroin use at weekends. Gail became homeless and lived on the street for several months, with her youngest two taken into foster care. Gail attended a rehab unit and was eventually rehoused by the same Council who had evicted her, two years earlier. Elizabeth reached abstinence in the post birth year and showed a sense of regret of not having managed it earlier, even a sense of futility of becoming clean.

Megan retained custody of her child and continued to receive a low dose of methadone. She described her continued use of OST as part of routine medication, similar to blood pressure medication. She was careful to explain that she was not ready to cease OST yet.

''It's the same like people who take medication for blood pressure…You wake up, you need to take your medication… I take my medication.. I know there will be a day where I have to stop it. I don't want to push it because I'm not ready.'' [Megan]

10.1.5.4 Evolving identities

The women described starting points of chronic heroin and crack use and an ambivalence to change, yet displayed changes in how they thought about themselves, and their identities and roles as mothers. Motherhood was enacted in different ways, which partly related to the legal status of custody of their children.

For Linda, she desired what she saw as normative identities, structures and goals such as 'being a mum', 'leading a normal life' and her child 'starting school'. Linda's vision of a future indicates a desire to move forward with 'how things are supposed to be'.

''I'm just generally looking forward to going back to work and just being a mum and like leading a normal life. Just how you are supposed to and how it should be. I'm looking forward to seeing xxx grow…and starting school and all those milestones.'' [Linda].

Gail expressed a desire to share her experience in schools as if recognising that her knowledge and experience might serve a wider societal purpose, which she wanted to contribute.

''I'd like to …get a little portfolio together of all my daughters' pictures…when she was born… and I'd like to go around to schools and talk to the children and girls about prostitution, about drugs and about what can happen to their baby if they take drugs when they're pregnant.''[Gail]

10.1.6 Discussion

This qualitative study suggests that pregnancy and motherhood represents for women with OUD a moment of potential transition in how they view themselves, leading to

change in entrenched substance use. The notion of change is important in substance use work. Tiny imperceptible steps towards thinking about change is involved in many approaches in substance misuse therapy (Prochaska et al., 2013). The women motivation to change is important. For the women, the current status of substance use is inconsistent with the promise or goal of motherhood in the future. The change is guided by the personal awareness and understanding that the present behaviour is not aligned with personal goals (Mitcheson & Grellier, 2011).. The change brought by pregnancy promises motherhood and enables the women to see a different version of themselves, as mothers. When this is reflected back by close friends and family it confirms and strengthens this nascent identity and readiness to change.

The women described interactions with their respective substance misuse clinics which suggested an enduring relationship characterised by a therapeutic alliance and trust in the NHS Substance Misuse Clinics. The therapeutic alliance can be described as the bond between client and therapist which evolves during the process of therapy (Horvath et al., 2011). The importance of this relationship at the heart of the lived experience suggests that substance misuse services are likely exhibiting non-judgmental behaviours and offering practical support.

Yet, the women find themselves objectified as risk in their own pregnancy, creating anxiety, fear and anger. The sub-theme *'Instruments of Power'* suggests the experience of multi-agency healthcare is poorly understood and threatening. The women lack information as to who, when and why an agency would become involved or contact them, particularly social services. All of the women gave examples of internalising shame and stigma, not just for substance use, but for being a mother, being pregnant and for using drugs, for '*being that person'*. Scambler (2012) suggests that felt stigma can be as damaging to people's lives as enacted stigma, in that it is conveyed non-verbally, is difficult to respond to and internalised, leading to diminished self-worth. Power dynamics play a key role in stigmatisation, leading amongst other experiences to a loss of status by the stigmatised person (Link and Phelan, 2001). For the women, much of their experience relates to power differences.

The role and impact of information and psychoeducation runs through the women's accounts e.g. what NAS is, how it might be tested. This suggests that the information is not

provided in a way that all the women could retain or use. Similarly, the role of social services and the family courts does not seem fully explained or understood by the women.

The women's accounts illustrate a variability in outcomes and recovery paths, with three women relapsing in the post birth years, two women assuming full parenting roles, and three with their babies in care or with grandparents acting as guardians. It is impossible to ignore the variation in the women's experience in the post birth years. Women with OUD are understood to be vulnerable to relapse in the post birth months and qualitative studies have identified factors which may contribute to the risk of relapse include a lack of social support, mother-infant attachment and mental health (Renbarger et al., 2020).

Strengths and Limitations

The lived experience has allowed the women to speak freely, albeit following a semi-structured topic guide. All the interviews were conducted in the same clinics familiar to the women and helped to put them at their ease during the interview process. The use of a cross-sectional design provided valuable insights of change over time. English was not the first language for all women, and the decision to use Reflexive Thematic Analysis has allowed patterns to be examined without the differences in use of language amongst the women to delimit findings. In this way, RTA has allowed me to accept the women's language as a window on to their world and identify patterns, differences, and insights.

My research focussed on women with OUD who were responsive to treatment and interventions, but did not include women with untreated OUD. A number of women did not attend interviews as planned. There are many eligible women registered within the clinics, but who were intermittently relapsing, and too unwell to participate. The findings are drawn from data from interviews with women with OUD who were engaging and electing to participate. It is possible that the lived experience of women who continued to struggle with illicit opioid use, may have revealed insights not captured in the interviews with the women included here.

10.1.7 Clinical Implications

The findings suggest that there is a potential opportunity for the multi-agency healthcare journey to be a pathway for enduring change. This may require a repositioning in a series of micro-processes of interactions between healthcare staff and women with OUD. The provision of tailored support is key, especially in the post birth phase where risk of

relapse is heightened, and during periods following rapid OST detox, or the social care and legal process. The provision of a booklet co-produced by the agencies and disciplines involved in the provision of care, with detailed and accessible information about the stages of the healthcare would assist in empowering the women.

The use of a specialist midwife team familiar with the woman's case history, and who had received training in substance misuse, especially the background and context of use (e.g. intimate partner violence, sex work). The NHS SMS could take a greater role in ensuring that other agencies are appropriately trained in substance use, as a form of interprofessional education (IPE). Addressing stigma, using motivational interviewing, is fundamental to delivering quality healthcare and achieving optimal outcomes (Bielenberg et al., 2021).

10.1.8 Suggestions for future research

Suggestions for future qualitative research include the lived experience of Keyworkers, midwife teams and social workers working with women with OUD to provide a fuller understanding of healthcare workers experiences of working with women with OUD, and psychological therapies for women who have had their babies removed, to identify the best approaches.

i

11 References

American Psychiatric Association. (2013). *Diagnostic and statistical manual for mental disorders* (DSM-5). American Psychiatric Association.

Back, S. E., Lawson, K. M., Singleton, L. M., & Brady, K. T. (2011). Characteristics and correlates of men and women with prescription opioid dependence. *Addictive behaviors*, 36(8), 829–834. https://doi.org/10.1016/j.addbeh.2011.03.013

Bakos-Block, C., Yatsco, A., Cohen, A. S., Vega, F., & Champagne-Langabeer, T. (2024). "My Addiction Doesn't Define Me"—Experiences of Stigma among Mothers with Opioid Use Disorder. *Pharmacoepidemiology*, 3(1), 57-68.

Bielenberg, J., Swisher, G., Lembke, A., & Haug, N. A. (2021). A systematic review of stigma interventions for providers who treat patients with substance use disorders. *Journal of Substance Abuse Treatment*, 131, 108486.

Brady, K. T., & Lydiard, J. B. (2021). Women and Addiction. In *Textbook of Addiction Treatment* (pp. 1395–1405). Springer International Publishing. https://doi.org/10.1007/978-3-030-36391-8_98

Braun, V., & Clarke, V. (2022). *Thematic Analysis: A Practical Guide.* SAGE Publications.

Braun, V., & Clarke, V. (2013). *Successful qualitative research: A practical guide for beginners.* London: SAGE

Burnham, J. (2018). Developments in Social GRRRAAACCEEESSS: visible–invisible and voiced–unvoiced 1. In *Culture and reflexivity in systemic psychotherapy* (pp. 139-160). Routledge.

Canfield, M., Norton, S., Downs, J., & Gilchrist, G. (2021). Parental status and characteristics of women in substance use treatment services: Analysis of electronic patient records. *Journal of Substance Abuse Treatment*, *127*. https://doi.org/10.1016/j.jsat.2021.108365

Braun, V., & Clarke, V., (2021). *Thematic analysis: A practical guide.* SAGE Publications

Department of Health, 2017; https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management; accessed 01.03.2024

Dydyk, A. M., Jain, N. K., & Gupta, M. (2024). *Opioid Use Disorder*. In StatPearls Publishing.

Finlay, L. (2002). Negotiating the swamp: the opportunity and challenge of reflexivity in research practice. *Qualitative Research*, 2(2), 209-230. ttps://doi.org/10.1177/146879410200200205

Gilchrist, G., Dennis, F., Radcliffe, P., Henderson, J., Howard, L. M., & Gadd, D. (2019). The interplay between substance use and intimate partner violence perpetration: A meta-

ethnography. *International Journal of Drug Policy*, *65*, 8–23. https://doi.org/10.1016/j.drugpo.2018.12.009

Gilmour, L., Honeybul, L., Lewis, S., Smith, E., Cheyne, H., Aladangady, N., Featherstone, B., Maxwell, M., Neale, J., & Radcliffe, P. (2024). Scoping review: mapping clinical guidelines and policy documents that address the needs of women who are dependent on drugs during the perinatal period. *BMC Pregnancy and Childbirth*, *24*(1). https://doi.org/10.1186/s12884-023-06172-6

Hammond, A. S., & Chisolm, M. S. (2022). *Co-occurring Mental Health Conditions in Pregnant Women with Opioid Use Disorders*. 27–34.

Horvath, A. O., Del Re, A. C., Flückiger, C., & Symonds, D. (2011). Alliance in individual psychotherapy. *Psychotherapy*, 48(1), 9.

Link, B. G., & Phelan, J. C. (2001a). Conceptualizing stigma. *Annual review of Sociology*, *27*(1), 363-385.

Madill, A., Jordan, A., & Shirley, C. (2000). Objectivity and reliability in qualitative analysis: Realist, contextualist and radical constructionist epistemologies. *British Journal of Psychology*, *91*(1), 1–20. https://doi.org/10.1348/000712600161646

Malterud, K., Siersma, V. D., & Guassora, A. D. (2016). Sample size in qualitative interview studies: guided by information power. Qualitative health research, 26(13), 1753-1760.

Meyer, J. P., Isaacs, K., El-Shahawy, O., Burlew, A. K., & Wechsberg, W. (2019). Research on women with substance use disorders: Reviewing progress and developing a research and implementation roadmap. *Drug and alcohol dependence*, 197, 158–163. https://doi.org/10.1016/j.drugalcdep.2019.01.017

Misuse of Drugs Act 1971. http://www.legislation.gov.uk/ukpga/1971/38/contents; Accessed 2.4.2022)

Mitcheson, L., & Grellier, B. (2011). Motivation and change. *Principles and Practice of Group Work in Addictions*, 17.

Moran-Santa Maria, M.M., & Brady, K.T. (2015). Women and Addiction. In: el-Guebaly, N., Carrà, G., Galanter, M. (eds) *Textbook of Addiction Treatment:* International Perspectives. Springer, Milano. https://doi.org/10.1007/978-88-470-5322-9_96

National Institute on Drug Abuse, 2024; https://nida.nih.gov/publications/research-reports/substance-use-in-women/importance-including-women-in-research; Accessed 01.02.2024)

National Institute for Health and Clinical Excellence. (2010) *Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors* (NICE guideline NG110). https://www.nice.org.uk/guidance/CG110/chapter/1 -

Guidance#pregnant-women-who-misuse-substances-alcohol-andor-drugs; (Accessed 01.09.2023)

Peters, W., Guille, C., & Mittal, L. (2019). Substance use disorders in women. *Neurology and Psychiatry of Women: A Guide to Gender-Based Issues in Evaluation, Diagnosis, and Treatment*, 103–113.

Prochaska, J. O., Norcross, J. C., & DiClemente, C. C. (2013). Applying the stages of change. *Psychotherapy in Australia*, 19(2), 10–15. https://search.informit.org/doi/10.3316/informit.254435778545597

Public Health England. (2019) United Kingdom drug situation focal point annual report. https://www.gov.uk/government/publications/united-kingdom-drug-situation-focal-point-annual-report/uk-drug-situation-2019-summary

Radcliffe, P. (2011). Motherhood, pregnancy, and the negotiation of identity: The moral career of drug treatment. *Social Science and Medicine*, 72(6), 984–991. https://doi.org/10.1016/j.socscimed.2011.01.017

Renbarger, K. M., Shieh, C., Moorman, M., Latham-Mintus, K., & Draucker, C. (2020). Health Care Encounters of Pregnant and Postpartum Women with Substance Use Disorders. *Western Journal of Nursing Research*, 42(8), 612–628. https://doi.org/10.1177/0193945919893372

Scambler, G. (2009), Health-related stigma. *Sociology of Health & Illness*, 31: 441-455. https://doi.org/10.1111/j.1467-9566.2009.01161.x

Scambler, G., & Scambler, S. (2015). Theorizing health inequalities: The untapped potential of dialectical critical realism. *Social Theory and Health*, *13*(3–4), 340–354. https://doi.org/10.1057/sth.2015.14

Scambler, G. (2012) https://www.grahamscambler.com/stigma-and-mental-illness/2012 (Accessed 29.07.2024)

Scottish Government, 2018; https://www.gov.scot/binaries/content/documents/govscot/publications/research-and-analysis/2018/06/ drug-related-deaths-women-increasing-scotland/documents/00537476-pdf/00537476-pdf/govscot%3Adocument/00537476.pdf (Accessed 01.03.2024)

Stengel, C. (2014). The risk of being "too honest": Drug use, stigma and pregnancy. *Health, Risk and Society*, 16(1), 36–50. https://doi.org/10.1080/13698575.2013.868408

Terplan, M., Kennedy-Hendricks, A., & Chisolm, M. S. (2015). Prenatal substance use: Exploring assumptions of maternal unfitness. *Substance Abuse: Research and Treatment*, 9, 1–4. https://doi.org/10.4137/SART.S23328

Thomson, S., Khalil, A., Hafford, S., & Waterstone, M. (2021). Opioid misuse in pregnancy. *The Obstetrician & Gynaecologist*, 1–8. https://doi.org/10.1111/tog.12779

United Nations Office on Drugs and Crime. (n.d.). World drug report 2015. (Accessed 01.09.2023)

Williams, L., Rycroft-Malone, J., & Burton, C. R. (2017). Bringing critical realism to nursing practice: Roy Bhaskar's contribution . In *Nursing philosophy* (Vol. 18, Issue 2, p. n/a-n/a). Wiley Subscription Services, Inc . https://doi.org/10.1111/nup.12130

12 Appendices

12.1.1 Appendix A:..Journal Author Guidelines for Qualitative Health Research (SAGE)

1.1 Aims & scope

QHR provides an international, interdisciplinary forum to enhance health and health care and further the development and understanding of qualitative health research. The journal is an invaluable resource for researchers and academics, administrators and others in the health and social service professions, and graduates, who seek examples of studies in which the authors used qualitative methodologies. Each issue of *QHR* provides readers with a wealth of information on conceptual, theoretical, methodological, and ethical issues pertaining to qualitative inquiry.

Rather than send query letters to the Editor regarding article fit, *QHR* asks authors to make their own decision regarding the suitability of their manuscript for *QHR* by asking: Does your proposed submission make a meaningful and strong contribution to qualitative health research literature? Is it useful to readers and/or practitioners?

1.2 Article types

The following manuscript types are considered for publication.

Original Research Studies: These are fully developed qualitative research studies. This may include mixed method studies in which the major focus/portion of the study is qualitative research. Please read Maintaining the Integrity of Qualitatively Driven Mixed Methods: Avoiding the "*This Work is Part of a Larger Study"* Syndrome.

Pearls, Piths, and Provocations: These manuscripts should foster discussion and debate about significant issues, enhance communication of methodological advances, promote and discuss issues related to the teaching of qualitative approaches in health contexts, and/or encourage the discussion of new and/or provocative ideas. They should also make clear what the manuscript adds to the existing body of knowledge in the area.

Editorials: These are generally invited articles written by editors/editorial board members associated with *QHR.*

Please note, *QHR* does NOT publish pilot studies. We do not normally publish literature reviews unless they focus on qualitative research studies elaborating methodological issues and developments. Review articles should be submitted to the Pearls, Piths, and Provocations section. They are reviewed according to criteria in 2.2.

Back to top

2. Review criteria

2.1 Original research

Reviewers are asked to consider the following areas and questions when making recommendations about research manuscripts:

Importance of submission: Does the manuscript make a significant contribution to qualitative health research literature? Is it original? Relevant? In depth? Insightful? Is it useful to the reader and/or practitioner?

Methodological considerations: Is the overall study design clearly explained including why this design was an appropriate one? Are the methodology/methods/approaches used in keeping with that design? Are they appropriate given the research question and/or aims? Are they logically articulated? Clarity in design and presentation? Data adequacy and appropriateness? Evidence of rigor?

Ethical Concerns: Are relevant ethical concerns discussed and acknowledged? Is enough detail given to enable the reader to understand how ethical issues were navigated? Has formal IRB approval (when needed) and consent from participants been obtained?

Data analysis, findings, discussion: Does the analysis of data reflect depth and coherence? In-depth descriptive but also interpretive dimensions? Creative and insightful analysis? Are results linked to existing literature and theory, as appropriate? Is the contribution of the research clear including its relevance to health disciplines and their practice?

Manuscript style and format: Is the manuscript organized in a clear and concise manner? Has sufficient attention been paid to word choice, spelling, grammar, and so forth? Did the author adhere to APA guidelines? Do diagrams/illustrations comply with guidelines? Is the overall manuscript aligned with *QHR* guidelines in relation to formatting?

Scope: Does the article fit with *QHR*'s publication mandate? Has the author cited the major work in the area, including those published in *QHR*?

2.2 Pearls, Piths, and Provocations

The purpose of papers in this section is to raise and discuss issues pertinent to the development and advancement of qualitative research in health-related arenas. As the name Pearls, Piths, and Provocations suggests, we are looking for manuscripts that make a significant contribution to areas of dialogue, development, experience sharing and debate relevant to the scope of *QHR* in this section of the journal. Reviewers are asked to consider the following questions when making recommendations about articles in the Pearls, Piths, and Provocations section.

Significance: Does the paper highlight issues that have the potential to advance, develop, and/or challenge thinking in qualitative health related research?

Clarity: Are the arguments clearly presented and well supported?

Rigor: Is there the explicit use of/interaction with methodology and/or theory and/or empirical studies (depending on the focus of the paper) that grounds the work and is coherently carried throughout the arguments and/or analysis in the manuscript? Put another way, is there evidence of a rigorously constructed argument?

Engagement: Does the paper have the potential to engage the reader to 'think differently' by raising questions, suggesting innovative directions for qualitative health research, and/or stimulating critical reflection? Are the implications of the paper for the practice of either qualitative research and/or health clear?

Quality of the writing: Is the main argument of the paper clearly articulated and presented with few grammatical or typographical issues? Are terms and concepts key to the scholarship communicated clearly and in sufficient detail?

2.3 Common reasons for rejection

QHR most commonly turns away manuscripts that fall outside the journal's scope, do not make a novel contribution to the literature, lack substantive and/or interpretative depth, require extensive revisions, and/or do not adequately address ethical issues that are fundamental to qualitative inquiry. Submissions of the supplementary component of mixed methods studies often are rejected as the findings are difficult to interpret without the findings of the primary study. For additional information on this policy, please read Maintaining the Integrity of Qualitatively Driven Mixed Methods: Avoiding the "*This Work is Part of a Larger Study"* Syndrome.

Back to top

3. Preparing your manuscript for submission

We strongly encourage all authors to review previously published articles in *QHR* for style prior to submission.

QHR journal practices include double anonymization. All identifying information MUST be removed completely from the Abstract, Manuscript, Acknowledgements, Tables, and Figure files prior to submission. ONLY the Title Page and Cover Letter may contain identifying information. See Sage's general submission guidelines for additional guidance on making an anonymous submission.

Preferred formats for the text and tables of your manuscript are Word DOC or PDF. The text must be double-spaced throughout with standard 1-inch margins (APA formatting). Text should be standard font (i.e., Times New Roman) 12-point.

3.1 Title page

The title page should be uploaded as a separate document containing the following information: Author names; Affiliations; Author contact information; Contribution list; Acknowledgements; Ethical statement; Funding Statement; Conflict of Interest Statements; and, Grant Number. Please know that the Title Page is NOT included in the materials sent out for Peer Review.

Ethical statement: An ethical statement must include the following: the full name of the ethical board that approved your study; the approval number given by the ethical board; and, confirmation that all your participants gave informed consent. Authors are also required to state in the methods section whether participants provided informed consent, whether the consent was written or verbal, and how it was obtained and by whom. For example: "Our study was approved by The Mercy Health Research Ethics Committee (approval no. XYZ123). All participants provided written informed consent prior to enrolment in the study." If your study did not need ethical approval (often manuscripts in the Pearls, Piths, and Provocations may not), we still need a statement that states that your study did not need approval and an explanation as to why. For example: "Ethical Statement: Our study did not require an ethical board approval because it did not directly involve humans or animals."

3.2 Abstract and Keywords

The Abstract should be unstructured, written in narrative form. Maximum of 250 words. This should be on its own page, appearing as the first page of the Main Manuscript file.

The keywords should be included beneath the abstract on the Main Manuscript file.

3.3 Manuscript

Length: 8,000 words or less excluding the abstract, list of references, and acknowledgements. This applies to both Original Research and Pearls, Piths, and Provocations. Please note that text from Tables and Figures is included in the word count limits. On-line supplementary materials are not included in the word limit.

Structure: While many authors will choose to use headings of Background, Methods, Results, and Discussion to organize their manuscript, it is up to authors to choose the most appropriate terms and structure for their submission. It is the expectation that manuscripts contain detailed reflections on methodological considerations.

Ethics: In studies where data collection or other methods present ethical challenges, the authors should explicate how such issues were navigated including how consent was gained and by whom. An anonymized version of the ethical statement should be included in the manuscript (in addition to appearing on the title page).

Participant identification: Generally, demographics should be described in narrative form or otherwise reported as a group. Quotations may be linked to particular participants and/or demographic features provided measures are taken to ensure anonymity of participants (e.g., use of pseudonyms).

Use of checklists: Authors should not include qualitative research checklists, such as COREQ (COnsolidated criteria for REporting Qualitative research). Generally, authors should use a narrative approach to describe the processes used to enhance the rigor of their study. For additional information on this policy, please read Why the *Qualitative Health Research* (QHR) Review Process Does Not Use Checklists

References: APA format. While there is no limit to the number of references, authors are recommended to use pertinent references only, including literature previously published in *QHR*. References should be on a separate page. *QHR* adheres to the APA 7 reference style. View the APA guidelines to ensure your manuscript conforms to this reference style. Please ensure you check carefully that both your in-text references and list of references are in the correct format.

Authors are required to disclose the use of generative Artificial Intelligence (such as ChatGPT) and other technologies (such as NVivo, ATLAS. Ti, Quirkos, etc.), whether used to conceive ideas, develop study design, generate data, assist in analysis, present study findings, or other activities formative of qualitative research. We suggest authors provide both a description of the technology, when it was accessed, and how it was used (see https://uk.sagepub.com/en-gb/eur/chatgpt-and-generative-ai).

Manuscripts that receive favorable reviews will not be accepted until any formatting and copy-editing required has been done.

3.4 Tables, Figures, Artwork, and other graphics

Tables, Figures, Artwork, and other graphics should be submitted as separate files rather than incorporated into the main manuscript file. Within the manuscript, indicate where these items should appear (i.e. INSERT TABLE 1 HERE).

In general, identifying features should not be contained within images. For example, in photographs faces should generally be concealed using mosaic patches – unless permission has been given by the individual to use their identity. This permission must be included at the time of submission.

TIFF, JPED, or common picture formats accepted. The preferred format for graphs and line art is EPS.

Resolution: Rasterized based files (i.e. with .tiff or .jpeg extension) require a resolution of at least 300 dpi (dots per inch). Line art should be supplied with a minimum resolution of 800 dpi.

Dimension: Check that the artworks supplied match or exceed the dimensions of the journal. Images cannot be scaled up after origination.

Figures supplied in color will appear in color online regardless of whether or not these illustrations are reproduced in color in the printed version. For specifically requested color reproduction in print, you will receive information regarding the costs from Sage after receipt of your accepted article.

3.5 Supplemental material

Core elements of the manuscript should not be included as supplementary material.

QHR is able to host additional materials online (e.g., datasets, podcasts, videos, images etc.) alongside the full text of the article. For more information please refer to Sage's general guidelines on submitting supplemental files.

Back to top

4. Submitting your manuscript

QHR is hosted on Sage Track, a web based online submission and peer review system powered by ScholarOne™ Manuscripts. Visit https://mc.manuscriptcentral.com/QHR to login and submit your article online.

IMPORTANT: Please check whether you already have an account in the system before trying to create a new one. If you have reviewed or authored for the Journal in the past year it is likely that you will have had an account created. For further guidance on submitting your manuscript online please visit ScholarOne Online Help.

Back to top

5. Editorial policies

5.1 Peer review policy

QHR adheres to a rigorous double-anonymized reviewing policy in which the identities of both the reviewer and author are always concealed from both parties.

Sage does not permit the use of author-suggested (recommended) reviewers at any stage of the submission process, be that through the web-based submission system or other communication. Reviewers should be experts in their fields and should be able to provide an objective assessment of the manuscript. Our policy is that reviewers should not be assigned to a manuscript if:

- The reviewer is based at the same institution as any of the co-authors
- The reviewer is based at the funding body of the manuscript
- The author has recommended the reviewer

• The reviewer has provided a personal (e.g. Gmail/Yahoo/Hotmail) email account and an institutional email account cannot be found after performing a basic Google search (name, department and institution).

Qualitative Health Research is committed to delivering high quality, fast peer-review for your manuscript, and as such has partnered with Web of Science. Web of Science is a third-party service that seeks to track, verify and give credit for peer review. Reviewers for Qualitative Health Research can opt in to Web of Science in order to claim their reviews or have them automatically verified and added to their reviewer profile. Reviewers claiming credit for their review will be associated with the relevant journal, but the article name, reviewer's decision, and the content of their review is not published on the site. For more information visit the Web of Science website.

The Editor or members of the Editorial Team or Board may occasionally submit their own manuscripts for possible publication in the Journal. In these cases, the peer review process will be managed by alternative members of the Editorial Team or Board and the submitting Editor Team/Board member will have no involvement in the decision-making process.

5.2 Authorship

Manuscripts should only be submitted for consideration once consent is given by all contributing authors. Those submitting manuscripts should carefully check that all those whose work contributed to the manuscript are acknowledged as contributing authors. The list of authors should include all those who can legitimately claim authorship. This is all those who meet all of the following criteria:

(i) Made a substantial contribution to the design of the work or acquisition, analysis, interpretation, or presentation of data,
(ii) Drafted the article or revised it critically for important intellectual content,
(iii) Approved the version to be published,
(iv) Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship, although all contributors who do not meet the criteria for authorship should be listed in the Acknowledgments section. Please refer to the International Committee of Medical Journal Editors (ICMJE) authorship guidelines for more information on authorship.

Authors are required to disclose the use of generative Artificial Intelligence (such as ChatGPT) and other technologies (such as NVivo, ATLAS. Ti, Quirkos, etc.), whether used to conceive ideas, develop study design, generate data, assist in analysis, present study findings, or other activities formative of qualitative research. We suggest authors provide both a description of the technology, when it was accessed, and how it was used. This needs to be clearly identified within the text and acknowledged within your Acknowledgements section. Please note that AI bots such as ChatGPT should not be listed as an author. For more details on this policy, please visit ChatGPT and Generative AI.

5.3 Acknowledgements

All contributors who do not meet the criteria for authorship should be listed in an Acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, or a department chair who provided only general support.

Please supply any personal acknowledgements separately to the main text to facilitate anonymous peer review.

Per ICMJE recommendations, it is best practice to obtain consent from non-author contributors who you are acknowledging in your manuscript.

1.3.1 Writing assistance

Individuals who provided writing assistance, e.g., from a specialist communications company, do not qualify as authors and so should be included in the Acknowledgements section. Authors must disclose any writing assistance – including the individual's name, company and level of input – and identify the entity that paid for this assistance. It is not necessary to disclose use of language polishing services.

5.4 Funding

Qualitative Health Research requires all authors to acknowledge their funding in a consistent fashion under a separate heading. Please visit the Funding Acknowledgements page on the Sage Journal Author Gateway to confirm the format of the acknowledgment text in the event of funding, or state that: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

5.5 Declaration of conflicting interests

It is the policy of *Qualitative Health Research* to require a declaration of conflicting interests from all authors enabling a statement to be carried within the paginated pages of all published articles.

Please ensure that a 'Declaration of Conflicting Interests' statement is included at the end of your manuscript, after any acknowledgements and prior to the references. If no conflict exists, please state that 'The Author(s) declare(s) that there is no conflict of interest'. For guidance on conflict of interest statements, please see the ICMJE recommendations here.

5.6 Research ethics and participant consent

Research involving participants must be conducted according to the World Medical Association Declaration of Helsinki

Submitted manuscripts should conform to the ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals:

All manuscripts must state that the relevant Ethics Committee or Institutional Review Board provided (or waived) approval. Please ensure that you blind the name and institution of the review committee until such time as your article has been accepted. The Editor will request authors to replace the name and add the approval number once the article review has been completed. Please note that in itself, simply stating that Ethics Committee or Institutional Review was obtained is not sufficient. Authors are also required to state in the methods section whether participants provided informed consent, whether the consent was written or verbal, and how it was obtained and by whom.

Please do not submit the participant's informed consent documents with your article, as this in itself breaches the participant's confidentiality. The Journal requests that you confirm to us, in writing, that you have obtained informed consent recognizing the documentation of consent itself should be held by the authors/investigators themselves (for example, in a participant's hospital record or an author's institution's archives).

Please also refer to the ICMJE Recommendations for the Protection of Research Participants.

Back to top

6. Publishing Policies

6.1 Publication ethics

Sage is committed to upholding the integrity of the academic record. We encourage authors to refer to the Committee on Publication Ethics' International Standards for Authors and view the Publication Ethics page on the Sage Author Gateway.

6.1.1 Plagiarism

Qualitative Health Research and Sage take issues of copyright infringement, plagiarism or other breaches of best practice in publication very seriously. The Committee on Publication Ethics (COPE) defines plagiarism as: "When somebody presents the work of others (data, words or theories) as if they were his/her own and without proper acknowledgment." We seek to protect the rights of our authors, and we always investigate claims of plagiarism or misuse of published articles. Equally, we seek to protect the reputation of the journal against malpractice. Submitted articles may be checked with duplication-checking software. Where an article, for example, is found to have plagiarised other work or included third-party copyright material without permission or with insufficient acknowledgement, or where the authorship of the article is contested, we reserve the right to take action including, but not limited to: publishing an erratum or corrigendum (correction); retracting the article; taking up the matter with the head of department or dean of the author's institution and/or relevant academic bodies or societies; or taking appropriate legal action.

6.1.2 Prior publication

If material has been previously published it is not generally acceptable for publication in a Sage journal. However, there are certain circumstances where previously published material can be considered for publication. Please refer to the guidance on the Sage Author Gateway or if in doubt, contact the Editor at the address given below.

6.2 Contributor's publishing agreement

Before publication, Sage requires the author as the rights holder to sign a Journal Contributor's Publishing Agreement. Sage's Journal Contributor's Publishing Agreement is an exclusive licence agreement which means that the author retains copyright of the work but grants Sage the sole and exclusive right and licence to publish for the full legal term of copyright. Exceptions may exist where an assignment of copyright is required or preferred by a proprietor other than Sage. In this case copyright in the work will be assigned from the author to the society. For more information, please visit the Sage Author Gateway.

6.3 Open access and author archiving

Qualitative Health Research offers optional open access publishing via the Sage Choice programme and Open Access agreements, where authors can publish open access either discounted or free of charge depending on the agreement with Sage. Find out if your institution is participating by visiting Open Access Agreements at Sage. For more information on Open Access publishing options at Sage please visit Sage Open Access. For information on funding body compliance, and depositing your article in repositories, please visit Sage's Author Archiving and Re-Use Guidelines and Publishing Policies.

12.1.2 Appendix B : Data Management: Steps To Protect Participant Confidentiality

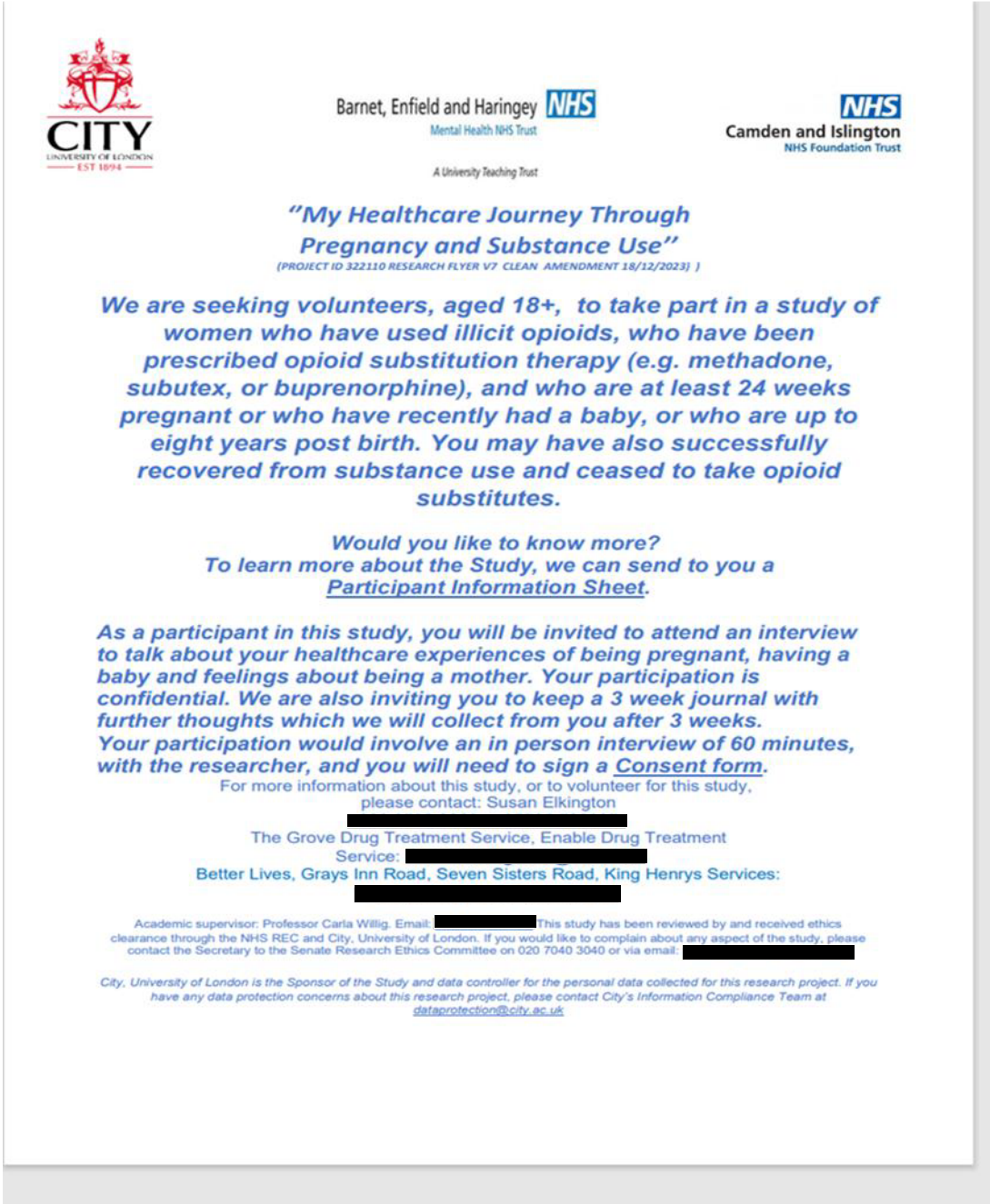
Recruitment	The researcher will solely use personal data such as name and contact details to make contact about the research study, as necessary.
The minimum data set	The minimum set of personal information will be used in the process of identifying potential participants.
Storage	The researcher will not store any personal information on any personal device at any time. An NHS Trust laptop is being provided for the purposes of recording and transferring data to the secure sponsor site.
Transfer of data from the NHS	The researcher will not use or transfer any personal information off NHS sites during the process of identifying participants.
Informing the participant of their personal records	The key step to inform participants of the potential use of their personal records is set out in the Patient Information Sheet (PIS) which will be provided early in the recruitment process.
Permission to retain personal records	The PIS will also explain that if the participant wishes to receive the results of the study, contact details will also be kept for this purpose.
Access to identifiable data	The only person who will have access to identifiable information will be the researcher.
Storage of personal data	The identifiable personal data of any potential participant who does not wish to participate, or who becomes ineligible will not be retained.
The use of a study ID De-identifying research materials	All participants will be assigned a study ID, and this will be kept in a separate file which cannot be linked to any personal data. Interview recordings and transcripts and journals will be de-identified, and labelled with this Study ID.
Transfer to sponsor	Research materials will be transferred electronically to secure University storage facilities, and password protected.

12.1.3 Appendix C : Participant Risk Management Procedures.

Summary of Risk, Adverse Events And Risk Management Plan

Risk or adverse event	**Risk or adverse event**	**Risk management plan**
Convenience and ease to participate	The participants are likely to have a busy schedule of perinatal/post-natal maternity care meetings. Participation in the research will require an additional commitment to an interview.	Interview times will be set to cause minimal inconvenience, with the option to coincide with other routine care appointments at substance abuse clinics or peri/post-natal appointments.
Physical discomfort	Women may find pregnancy physically uncomfortable, e.g., to sit for an hour. They may also require facilities for an infant.	Rooms will be comfortable and afford childcare facilities if required.
Access and physical discomfort	They may not be comfortable walking any distance within NHS sites to an interview room.	Interview rooms will be sourced and arranged with the participating Trusts to have easily accessible rooms.
Recall of difficult memories associated with pregnancy	It is possible that participants recall difficult memories associated with their experience e.g., childbirth pain either during or after the interview.	The researcher will allow time for any difficult memories to be empathetically supported, with the option for referral to therapeutic support given.
Adverse events	Adverse events may occur, and the participants require urgent perinatal clinical attention.	(e) The researcher will monitor the participant throughout all contact and inform the site Duty Manager, Keyworker or GP of any sign of distress emerges. (f) The researcher will ensure that the clinical care team e.g., GP, and Keyworker of each participant is informed and aware of the research participation and given the opportunity to highlight any risks unique to the participant they foresee. **e)** The Duty Manager will be informed of the date and time of the participant's interview in the event that any adverse events occur, care and risk plan can be enacted.
Recall e.g., of Intimate Partners Violence (IPV)	The participants in this population may have suffered from intimate partner violence (IPV) and trauma and the interview may prompt recall.	The researcher will monitor the participant throughout all contact and inform the site Duty Manager, Keyworker or GP of any sign of distress emerges.
Self-harm and risk	Disclosures of self-harm or risk during the interview	Any disclosure of self-harm or risk will be reported as risk to the Duty Manager and Clinical Care team.
Safeguarding	Safeguarding issues disclosed during interview	Any safeguarding issues concerning existing children or dependents of the participant will be raises with the Duty Manager and Clinical care team.
Post interview wellness		The researcher will call each participant within 24 hours of the interview to ensure participants are well and not experiencing any sense of being unwell. If the event of any sense of unwellness, the researcher will contact the Duty Manager.

12.1.4 Appendix D: Participant Recruitment Poster



CITY
UNIVERSITY OF LONDON
EST 1894

Barnet, Enfield and Haringey NHS
Mental Health NHS Trust
A University Teaching Trust

NHS
Camden and Islington
NHS Foundation Trust

"My Healthcare Journey Through Pregnancy and Substance Use"

(PROJECT ID 322110 RESEARCH FLYER V7 CLEAN AMENDMENT 18/12/2023))

We are seeking volunteers, aged 18+, to take part in a study of women who have used illicit opioids, who have been prescribed opioid substitution therapy (e.g. methadone, subutex, or buprenorphine), and who are at least 24 weeks pregnant or who have recently had a baby, or who are up to eight years post birth. You may have also successfully recovered from substance use and ceased to take opioid substitutes.

Would you like to know more?
To learn more about the Study, we can send to you a Participant Information Sheet.

As a participant in this study, you will be invited to attend an interview to talk about your healthcare experiences of being pregnant, having a baby and feelings about being a mother. Your participation is confidential. We are also inviting you to keep a 3 week journal with further thoughts which we will collect from you after 3 weeks. Your participation would involve an in person interview of 60 minutes, with the researcher, and you will need to sign a Consent form.

For more information about this study, or to volunteer for this study, please contact: Susan Elkington [redacted]
The Grove Drug Treatment Service, Enable Drug Treatment Service: [redacted]
Better Lives, Grays Inn Road, Seven Sisters Road, King Henrys Services: [redacted]

Academic supervisor: Professor Carla Willig. Email: [redacted] This study has been reviewed by and received ethics clearance through the NHS REC and City, University of London. If you would like to complain about any aspect of the study, please contact the Secretary to the Senate Research Ethics Committee on 020 7040 3040 or via email: [redacted]

City, University of London is the Sponsor of the Study and data controller for the personal data collected for this research project. If you have any data protection concerns about this research project, please contact City's Information Compliance Team at dataprotection@city.ac.uk

ii